ALLHAT *Forms Book*

Definitions

Acrostic – A six-character secondary identifier formed by the concatenation of the first three letters of the participants' last name, first two letters of the first name, and middle initial (if present). This has been blanked in the Limited Access Data Set (LADS).

Batch Date – Received date at the **ALLHAT** Clinical Trial Center; replaced in the LADS by two flag fields (see "Forms" for further details).

Blanked data – Confidentiality requirements of the LADS require blanking or deletion of confidential participant information such as the Social Security Number, Medicare Number, name, address, acrostic, and any other contact information. All initials and codes for study personnel have also been similarly blanked.

Closeout Date – Each patient is given a Closeout Date beyond which events are no longer used. If a patient had an AL22 (Closeout Form) on or beyond 10/01/2001, then that date is considered his/her Closeout Date. Otherwise, 3/31/2002 is considered his/her Closeout Date. For the Doxazosin comparison, 2/15/2000 is the Closeout Date (doxazosin and chlorthalidone patients).

CMS- Centers for Medicare and Medicare Research; previously known as HCFA (Health Care Finance Administration).

Confirmed/Known Death - Investigator report on an AL04, with or without a death certificate or summary, NDI report (with a match to one of 17 different patterns) + death certificate with matching ID information, or Social Security report of death + death certificate with matching ID information. (Yearly queries to the Social Security Agency returned information on vital status at the end of the last calendar year; death certificates were requested from the states for participants reported as deceased.)

Date Last Known Alive – Based on any of the following study forms: Antihypertensive or lipid-lowering trial randomization (AL80 or AL81), Follow-up visit form (AL03), Nonfatal event form (AL04), Unblinding form (AL06), Lost/refusal report form (AL07), Nonfatal adverse event report form (AL13), Doxazosin closeout form (AL20), Study closeout form (AL22), Closeout postcard (AL24), ECG (AL31 or AL32), Laboratory report (AL30), Outside report of hospitalization (CMS or VA), (AL41), Date last known alive according to Social Security Administration (must otherwise be determined from the Summary Record due to sensitivity of the source record).

Fatal endpoint date - The date of death. If death did not occur, then the Last Follow-up Date is used.

Flag - Any field marked as a flag is a 0/1 field with 0=no and 1=yes. This usually indicates handwritten text, most commonly the presence of an investigator signature.

ID – The original ALLHAT identification number was a nine digit composite of the Treatment Center Number ("Current Center"), Participant Number, and Randomization Center Number ("Original Center"). This was replaced for the LADS by a randomly generated number; see separate key file for conversion.

Known Alive - Based on the date last known alive, a participant is known alive for the study if the date is on or after October 1, 2001. For the Doxazosin comparison, defined as not missing two or more visits in the Visit Windows preceding the Closeout Date.

Known Dead – see **Confirmed Dead**

LADS - Limited Access Data Set

Last Visit Date - The date of the latest form using the AL03, AL20, AL22 or AL24 (only use visit versions of AL20 and AL22).

Last Follow-up Date - The date of the latest form using the AL03, AL04, AL06, AL07, AL13, AL20, AL22, AL24, AL30, AL31, AL81 or AL84 (only use the visit version of AL20 and AL22; do not use fatal AL13 or AL04).

LDL (Blood level of LDL Cholesterol) - Use the lab's calculated LDL cholesterol level unless triglycerides are greater than 350, then use the lab's Beta Quant value.

Lost - For any participant whose date last known alive is before October 1, 2001, and not known dead, and not known alive during the closeout period, but last follow-up is study form for lost to follow-up.

NDI - National Death Index.

Non-fatal endpoint date - The date of the endpoint. If no endpoint occurred, then the Last Visit Date is used.

Other unknown - For any participant whose date last known alive is before October 1, 2001, and not known dead, known alive, or lost or refused.

Pending - Participants who are classified as lost, refused, or other unknown may have had death records from CMS, VA, SSA, or NDI which remained unverified at the time of the final paper. These were classified as deaths pending confirmation.

Refused - For any participant whose date last known alive is before October 1, 2001, and not known dead, known alive, or lost, but last form is study form for refusal.

RZ - Randomization date

Silent MI - unreported MI. Follow-up Serial ECGs were checked for indications of MI (any of F32160-F32172 = 1). If indication was found for MI, then a date was calculated as the difference between that Serial ECG and the previous as the date of the event. Only ECGs with visit codes of 0, 2, 4, 6 and 8 are used. ECGs more than a year before randomization or after the patients' Closeout Date are excluded.

SSA – Social Security Administration.

SSN – Social Security number

VA – Veteran's Administration.

Visit Windows – See page following equations for detailed definitions.

Equations

Exponentiation - Is denoted by "**" (i.e. x squared would be x**2).

Range or group - When declaring ranges or groups, "(" or ")" indicates do not include the endpoint. "[" or "]" indicates include the endpoint. E.G. (10, 20] means greater than 10 and less than or equal to 20.

BMI (Body mass index in kg/m^2) – "In-house" analyses used Height (inches) in range [36, 95], Weight (pounds) in range [50, 500]. LADS recoding used Height (inches) in range [55, 80]; [< 45 reset to missing, 99 reset to missing, > 80 top-coded at 80], Weight (pounds) in range [90, 500]; [<90 reset to missing, =999 reset to missing]. Then

BMI = (704.5 * WGTLBS) / (HGTINS**2)

If Height or Weight missing, calculated BMI in analysis files is set to missing.

GFR (Glomerular filtration rate) - ALLHAT uses an estimated glomerular filtration rate: the simplified 4-variable Modified diet in Renal disease (MDRD) formula.

CREAT = Blood creatinine level

BLKFCT (Black Factor) = 1.212 if Black or 1.0 if Non-black

FEMFCT (Female Factor) = 0.742 if Female or 1.0 if Male

GFR = 186.3 * CREAT**(-1.154) * AGEYRS**(-0.203) * BLKFCT * FEMFCT

Visit Windows

Annual Blood Pressures or Annual Treatment Status - Start at the annual visit target date, subtract 6 calendar months plus one day for the lower extended window, and add six calendar months for the upper extended window. If a visit is in the **Standard Visit Window** (as defined below), it has precedence over a visit in the extended window. Choose the closest to the target date first in the Standard Window. If none, choose the closest to the target date in the Extended Window.

Baseline ECG – On or before Antihypertensive RZ date, but not more than one year prior. If more than one ECG available use the ECG closest to the RZ date.

Baseline labs - The earliest lab value less than or equal to 92 days after Randomization was considered the Baseline lab. Individual values (e.g. potassium or total cholesterol) may have been on different dates, but the earliest of each was used.

For Final Antihypertensive and Doxazosin Summaries, lab and ECG windows used a Standard Window. For the Update Summaries, Expanded/Extended Windows are used, as most writing groups have, in practice, found the Expanded Windows more practical.

Follow-up labs - For analysis, labs at years 1, 2, 4 and 6 were most often studied. As with the baseline labs, the individual values (e.g. potassium or total cholesterol) may have been on different dates. Also, first choice was given to a lab value in the Standard window, but the "earliest" value in the Standard window was selected. If no value was found in the Standard Window, then a value closest to the Lower Standard Window was selected in an Extended Window.

Standard Visit Windows (after the one year visit, visits were every four months):

Visit	Target	Low Window	High Window
1 month	RZ + 1 calendar month	- 14 days	+ 14 days
3 month	RZ + 3 calendar months	High Window of 1 mo + 1 day	+ 42 days
6 month	RZ + 6 calendar months	High Window of 3 mo + 1 day	+ 42 days
9 month	RZ + 9 calendar months	High Window of 6 mo + 1 day	+ 2 months
1 year	RZ + 12 calendar months	High Window of 9 mo + 1 day	+ 2 months
1 yr, 4 mo	RZ + 16 calendar months	High Window of 1 yr + 1 day	+ 2 months
1 yr, 8 mo	RZ + 20 calendar months	High Window of 16 mo+ 1 day	+ 2 months
2 year	RZ + 24 calendar months	High Window of 20 mo+ 1 day	+ 2 months
(etc.)			

Expanded/Extended windows:

Visit	Extended Lower Window	Extended Upper Window
1 year	Standard target - 6 months + 1 day	Standard target + 6 months
2 years	Standard target - 6 months + 1 day	Standard target + 12 months
4 years	Standard target - 12 months + 1 day	Standard target + 12 months
6 years	Standard target - 12 months + 1 day	Standard target + 12 months

Algorithms

Algorithm for Data Capture During Closeout (Final Papers)

The algorithm used for the final papers classified participants in the following order:

1. Determine **Date Last Known Alive** using a form described previously
2. Based on the **Date Last Known Alive** in #1, a participant is **Known Alive** for the study if the date is on or after October 1, 2001.
3. For any participant whose **Date Last Known Alive** is before October 1, 2001, classify as:
    a. **Known Dead** – study report of death OR confirmed through NDI (based upon a CTC-validated algorithm – see NDI Matching Patterns) OR SSA OR HCFA/VA confirmed by the study center on or before March 31, 2002.
        i. *This algorithm should have selected NDI records based on 17 different matching patterns, but two matching patterns were not included.*
    b. **Lost** – Not known dead, but last follow-up is study form for lost to follow-up.
    c. **Refused** – Not known dead or lost, but last form is study form for refusal.
    d. **Other Unknown** – Not known dead or lost or refused.
4. Participants who are classified as **Lost**, **Refused**, or **Other Unknown** may have had death records from CMS, VA, SSA, or NDI which remained unverified at the time of the final paper. These were classified as deaths **Pending** confirmation.

Algorithm for Data Capture in This Update (Antihypertensive/Lipid-Lowering Arms)

1. **Known Dead** – as defined above, with the two matching patterns inadvertently left out of the NDI matching criteria now included, and excluding HCFA/VA-identified deaths (study centers closed - no longer able to review and confirm/exclude events).
2. **Known Alive** – as defined above, with a modification to capture dates on the closeout form that may have been entered into the wrong data field (previously resulting in an invalid closeout date).
3. **Lost** – as defined above
4. **Refused** – as defined above
5. **Other Unknown** – as defined above
6. **Pending** - as defined above, with unconfirmed deaths suspected from the CMS and VA records removed, because a high proportion of those queried of the centers during the active part of the trial were reported by the sites as incorrect (52% of CMS reports and 73% of VA reports), and because of the relative accuracy of the NDI and SSA databases.

This updated algorithm was checked thoroughly by reviewing a variety of listings against original data files. Also, a reverse check was done by identifying all participants suspected as deceased at any time from any information source (confirmed or not), running them through the algorithm, and reviewing those who were <u>not</u> identified as deceased (as of the final paper cutoff) by the algorithm.

Algorithm for Data Capture in This Update (Doxazosin Arm)

1. **Known Dead**
2. Using the opening date of the 2nd <u>complete</u> visit window up to and including 2/15/2000:
    a. **Known alive** – **Date Last Known Alive** on or after the date above
    b. **Lost** – lost prior to 2/15/2000
    c. **Refused** – refused prior to 2/15/2000
    d. **Other Unknown** – otherwise has **Date Last Known Alive** prior to 2/15/2000

NDI Matching Patterns

As of the time of the writing of the **ALLHAT** final papers, 19,109 possible **NDI** matches had been retrieved from the **NDI** for **ALLHAT** participants. As it would not be a wise use of person-time or money to request that many death certificates from the states in order to verify which ones actually belonged to **ALLHAT** participants, an algorithm was sought to identify those which were most likely to match **ALLHAT** participants. The following matching algorithm was used, and, as of the time of the final papers, it identified 2176 of the 19,109 death certificates to request from the states.

SSN:
- 1 = all digits match
- 2 = 8 of 9 match
- 3 = 7 of 9 match
- 9 = other

First and last name:
- 1 = exact match
- 2 = *soundex* match (phonetic criteria, according to **NDI** matching) = first name *soundex* match, last name exact; first name exact, last name *soundex*; first and last are *soundex* matches
- 3 = known aliases used - last name *soundex* match, or alias used; only first initial matches, or alias used
- 9 = other

Date of birth:
- 1 = exact match on month, day and year
- 2 = exact match on month and day, but year can be off by ±1-5 years
- 9 = other

NDI Matching Pattern	SSN score	Name score	Date of birth score	NDI Matching Pattern	SSN score	Name score	Date of birth score
Death Certificates **Requested:**				Death Certificates **Not** Requested			
1	1	1	1	18	3	1	9
2	1	1	2	19	3	2	1
3	1	1	9	20	3	9	1
4	1	2	1	21	9	1	1
5	1	2	2	22	9	1	2
6	1	2	9	23	9	1	9
7	1	3	1	24	9	2	1
8	1	3	9	25	9	2	2
9	1	9	1	26	9	2	9
10	1	9	2	27	9	3	1
11	1	9	9	28	9	3	2
12	2	1	1	29	9	3	9
13	2	1	2	30	9	9	1
14	2	1	9	31	9	9	2
15	2	2	1	32	9	9	9
16	2	9	1				
17	3	1	1				

The patterns are not a strict hierarchy, although a lower matching score is generally indicative of a possible better match. The patterns were validated against **Known Deaths** submitted in the first **NDI** search.

Using the matching algorithm, death certificates were requested for the following:

- Any 2 scores = 1 (perfect matches), except 9-1-1 (bad match on **SSN**)

- Exact match on **SSN**, except 1-3-2 (multiple matches were provided from **NDI** for the same certificate – one for each reported alias and one for the legal name, so this matching pattern essentially duplicates 1-1-2 or 1-2-2)
- **SSN** score = 2 (8 of 9 numbers match) and score=1 on either name or date of birth, except 2-3-1

Forms

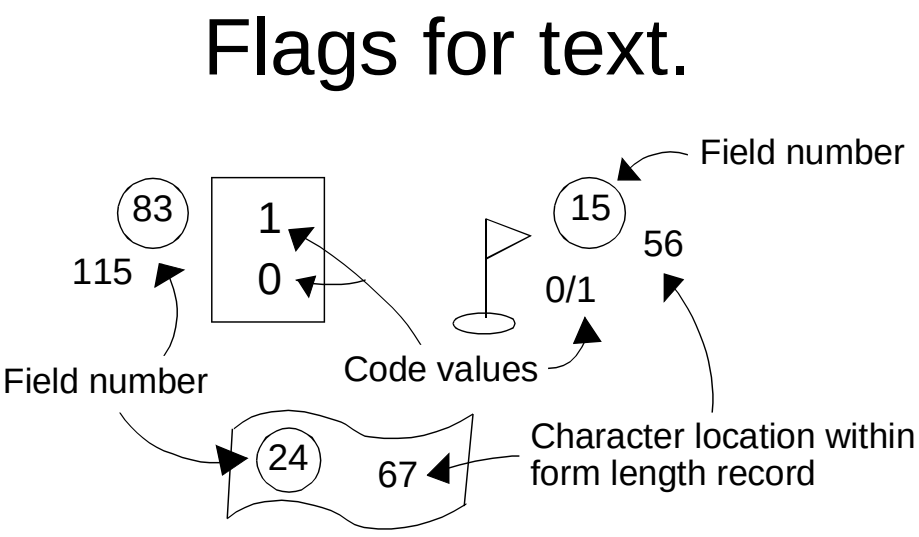
A thorough understanding of the **ALLHAT *Manual of Operations*** is required to correctly utilize form data.

A blank copy of each form precedes the field-marked version of the form, except for computer-only forms.

Batch dates have been replaced in the LADS by a flag indicating presence of the form on the **ALLHAT *Master File*** at the time of the specified cut-off:

Flag 1 – Doxazosin flag:	0=No, 1=Yes
Flag 2 – Antihypertensive/LLT flag:	0=No, 1=Yes

Fields are marked on the "field-marked" version of the forms. Flag fields, indicating the presence of a written comment, are identified by 0/1 coding and are marked on the forms as follows:



Note well: The summaries will, in a few instances, be the only means of reproducing the exact state of the **ALLHAT *Master File*** at the time of the final papers, particularly for the Doxazosin arm of the trial, as records continued to be added and edited.

Modified fields on **ALLHAT *Master File*** common to all forms:

Field Number	Item type*	Columns Used	Label	Remark
001	I	1 - 2	F#KPCOD	for internal CTC use only; blanked
002	IDR	3 - 8	F#BATDAT	recoded from date to flag to indicate form available at time of Doxazosin (Dox) and/or Antihypertensive (AHT)/Lipid-Lowering manuscript preparation: 00 = neither Dox nor AHT 01 = Dox No / AHT Yes 11 = Dox Yes / AHT yes Right-justified, blank-filled.
003	A	9 - 10	F#VERF	for internal CTC use only; blanked
004	I	11 - 16	F#DATMOD	for internal CTC use only; blanked
005	I	17 - 20	F#TIMMOD	for internal CTC use only; blanked
006	I	21 - 21	F#TYPMOD	for internal CTC use only; blanked
007 [008-009]	I	22 - 30	F#ID	Random ID generated to replace original ID assigned at RZ; from range of 1-200 000, zero-filled, right-justified (replaces F#TCN, F#PNO, F#RCN; see key)
Form #	I	31 - 33		Form # present but not assigned a field number; used with version number
011	I	34 - 34	F#VSN	combined with form number (no field number)
010	IDR	35 - 42	F#DATE8	converted to number of days since RZ (supersedes fields 012 and 013)
015	A	44 - 44	F#SITE	for internal CTC use only; blanked
016	A	45 - 50	F#ACROS	for internal CTC use only; blanked
017	I	51 - 52	F#EDIT	for internal CTC use only; blanked

*I=integer; A=alpha; D=date (mmddyy or ddmmyy); R=reverse (yymmdd)

ALLHAT Bounds File Format

Bounds File for Each Form Follows the Field-Marked Version of the Form

Columns Used	Length (char.)	Item type	Item Description	Value Labels or Remarks
1- 2	2	A	Study code	
3- 5	3	I	Form number	
6- 6	1		*blank (for easier reading)*	
7- 7	1	I	Version number of form	
8- 8	1		*blank*	*for easier reading*
9-11	3	I	Field number	
12-12	1	A	Type of data in field	I=integer A=alpha F=fixed-point format
13-14	2	A	Type of field	D=date DR=reverse date
15-17	3	I	Starting column of data on form-length record	
18-18	1		*Dash*	*punctuation for easier reading*
19-21	3	I	Ending column of data on form-length record	
22-22	1		*blank*	*for easier reading*
23-30	8	A	Name of Field	
31-31	1		*blank*	*for easier reading*
32-40	9	I	Lower range of field	may be blank filled for legibility
41-41	1		*blank*	*for easier reading*
42-50	9	I	Upper range of field	may be blank-filled for legibility
51-51	1		*blank*	*for easier reading*
52-52	1	I	Type of variable	0=alpha, or n/a 1=continuous 2=discrete
53-59	7		*blank*	*reserved columns, unused*
60-61	2	A	Restriction of changes to field	Y$=change restricted blank=change not restricted

Form Demographics

Form Number	ALLHAT Form Name	Number of Characters	Repeatable	Number of Records
AL001 – Version 1	Antihypertensive Trial Eligibility Worksheet Form	234		465
AL001 – Version 2		231		5751
AL001 – Version 3		234		36202
AL002 – Version 1	Lipid-Lowering Trial Eligibility and Randomization Form	98		92
AL002 – Version 2		95		10263
AL003 – Version 1	Follow-up Visit Form	264	R	474
AL003 – Version 2		244	R	39138
AL003 – Version 3		209	R	242750
AL003 – Version 4		187	R	246827
AL004 – Version 1	Event Reporting Form	113	R	12
AL004 – Version 2		126	R	6002
AL004 – Version 3		139	R	13456
AL006 – Version 1	Report of Study Drug Disclosure Form	75	R	2
AL006 – Version 2		76	R	111
AL006 – Version 3		131	R	2464
AL007 – Version 1	Report of Refusal or Loss to Follow-up Form	77	R	4280
AL007 – Version 2		77	R	3313
AL007 – Version 3		77	R	149
AL011 – Version 1	Receipt of Endpoint Documentation Form	166	R	19470
AL012 – Version 1	Endpoint Quality Control Selection and Documentation Form	230	R	498
AL013 – Version 2	Adverse Experience Form	290	R	363
AL020 – Version 1	Transition Form - Only for Participants Assigned to Doxazosin	129		8406
AL022 – Version 1	Closeout Form	206		29877
AL023 – Version 1	CHF Quality Control Form	566	R	3033
AL024 – Version 1	Closeout Postcard Form	79		338
AL025 – Version 1	Blood Pressure Medication at Study Entry Form	75		1446
AL030 – Version 1	Lab Record	626	R	184391
AL031 – Version 1	ECG Record	112	R	99203
AL032 – Version 1	Serial Change ECG Record	310	R	58366
AL040 – Version 1	Supplemental Death Record	95	R	2461
AL041 – Version 1	Supplemental Event Record	195	R	44369
AL080 – Version 1	Antihypertensive Randomization Screen	162		390
AL080 – Version 2		164		5809
AL080 – Version 3		165		36219
AL081 – Version 1	Lipid-lowering Randomization Screen	78		94
AL081 – Version 2		78		6525
AL081 – Version 3		87		3736
AL084 – Version 1	ECG Inventory Log Form	61	R	52639

Batch Flag Tabulation

Form Number	ALLHAT Form Name	Flag 1		Flag 2	
		No	Yes	No	Yes
AL001 – Version 1	Antihypertensive Trial Eligibility Worksheet Form	0	465	0	465
AL001 – Version 2		0	5751	0	5751
AL001 – Version 3		0	36202	0	36202
AL002 – Version 1	Lipid-Lowering Trial Eligibility and Randomization Form	0	92	0	92
AL002 – Version 2		0	10289	0	10263
AL003 – Version 1	Follow-up Visit Form	0	474	0	474
AL003 – Version 2		0	32138	0	39138
AL003 – Version 3		4	242746	0	242750
AL003 – Version 4		120809	126018	0	246827
AL004 – Version 1	Event Reporting Form	0	12	0	12
AL004 – Version 2		0	6002	0	6002
AL004 – Version 3		5810	7646	0	13456
AL006 – Version 1	Report of Study Drug Disclosure Form	0	2	0	2
AL006 – Version 2		0	111	0	111
AL006 – Version 3		819	1645	0	2464
AL007 – Version 1	Report of Refusal or Loss to Follow-up Form	3	4277	0	4280
AL007 – Version 2		1761	1552	0	3313
AL007 – Version 3		146	3	0	149
AL011 – Version 1	Receipt of Endpoint Documentation Form	5810	13660	0	19470
AL012 – Version 1	Endpoint Quality Control Selection and Documentation Form	132	366	0	498
AL013 – Version 2	Adverse Experience Form	27	336	0	363
AL020 – Version 1	Transition Form - Only for Participants Assigned to Doxazosin	7484	922	0	8406
AL022 – Version 1	Closeout Form	29875	2	0	29877
AL023 – Version 1	CHF Quality Control Form	1009	2024	0	3033
AL024 – Version 1	Closeout Postcard Form	338	0	0	338
AL025 – Version 1	Blood Pressure Medication at Study Entry Form	0	1446	0	1446
AL030 – Version 1	Lab Record	25198	159193	0	184391
AL031 – Version 1	ECG Record	22270	76933	0	99203
AL032 – Version 1	Serial Change ECG Record	22184	36182	0	58366
AL040 – Version 1	Supplemental Death Record	1918	543	1279	1182
AL041 – Version 1	Supplemental Event Record	19160	25209	0	44369
AL080 – Version 1	Antihypertensive Randomization Screen	0	390	0	390
AL080 – Version 2		0	5809	0	5809
AL080 – Version 3		0	36219	0	36219
AL081 – Version 1	Lipid-lowering Randomization Screen	0	94	0	94
AL081 – Version 2		0	6525	0	6525
AL081 – Version 3		0	3736	0	3736
AL084 – Version 1	ECG Inventory Log Form	22782	29857	0	52639

AL001 - ALLHAT Antihypertensive Trial Eligibility Worksheet Form

The AL001 is the hard-copy version of the information captured on the AL080 form during the Antihypertensive Randomization phone call. The AL001 was subject to editing for consistency and logic. The AL080 was never modified, even if there were discrepancies between the AL001 and the AL080. The AL080 was used for obtaining baseline characteristics until the AL001 was received at the CTC, and then the AL001 took precedence in analyses.

Versions:
Version 1 – 01/94
Unique fields to version 1: F01021, F01046, F01065, and F01080.

Version 2 – 06/94

Version 3 – 05/95
Unique fields to version 3: F01099, F01100, and F01101

Fields unique to version 2 and version 3: F01089 to F01098.

Modified Fields for LADS Master File:
Blanked:
F01018 (versions 1,2,3)
F01019 (versions 1,2,3)
F01020 (versions 1,2,3)
F01045 (versions 1,2,3)
F01047 (versions 1,2,3)
F01059 (versions 1,2,3)
F01066 (versions 1,2,3)
F01067 (versions 1,2,3)
F01068 (versions 1,2,3)
F01069 (versions 1,2,3)
F01070 (versions 1,2,3)
F01071 (versions 1,2,3)
F01072 (versions 1,2,3)
F01083 (versions 1,2,3)

Changed date (mmddyy) to days since randomization:
F01037 (versions 1,2,3)
F01049 (versions 1,2,3)
F01050 (versions 1,2,3)
F01063 (versions 1,2,3)
F01096 (versions 2,3)

Coding details:

F01050: reset to a top value of a maximum value of (equivalent of as now days from randomization) 90 years
F01060: reset range (upper and lower values) for BMI equation (see **Equations**)
F01061: reset range for BMI equation (see **Equations**)
F01078: Years of education, starting with first grade (code 99 if not known); reset to top value of 25 for LADS.

F01082: 'If you were to rate your current health on a scale of 0 to 100, with 100 being perfect health and 0 being death, what number would you rate yourself today?' (999=Unknown)

Blood pressure (F01039, F01040, F01041, F01042, F01043, F01044, F01053 F01054, F01055, F01056, F01057, F01058), heart rate (F01052), weight (F01060), height (F01061) were coded as "999" for missing/invalid values. Weight and height 999 recoded to missing to prevent misuse in LADS BMI calculations.

AL001 Version 1

ALLHAT ANTIHYPERTENSIVE TRIAL ELIGIBILITY WORKSHEET
Information from Chart Review and Visit 1

1. Full name: _____ _____ _____ _____
First MI Last

2. a. Date randomized (mm-dd-yy): __ __ - __ __ - __ __

b. Randomization number (given by CTC at Visit 2, if randomized): ___ - ___ - ___

c. Site code: __ d. Acrostic (given by CTC at Visit 2, if randomized): ___ ___ ___

3. Is this patient age 60 or older? ..... Yes ☐ 1
STOP, patient is not eligible ☞ No ☐ 2

Information from Chart Review or Local Determinations

Compliance exclusion:	**Yes**	**No**
4. Factors suggesting a low likelihood of compliance with protocol (e.g., dementia, history of alcohol or drug abuse within past six months, plans to move or travel extensively, or history of unreliability in keeping appointments or taking prescribed drugs)	☐ 1	☐ 2
Medical exclusion criteria for antihypertensive trial (*patient cannot meet any of the following criteria*):		
5. Symptomatic myocardial infarction or stroke within past six months	☐ 1	☐ 2
6. Symptomatic congestive heart failure and/or ejection fraction < 35%, if known	☐ 1	☐ 2
7. Angina pectoris within past 6 months	☐ 1	☐ 2
8. Known renal insufficiency (serum creatinine ≥ 2 mg/dl)	☐ 1	☐ 2
9. Requires thiazide-like diuretics, calcium antagonists, ACE inhibitors, or alpha adrenergic blockers for reasons other than treatment of hypertension (e.g, CHF, angina)	☐ 1	☐ 2
10. Requires three or more antihypertensive drugs to achieve satisfactory blood pressure control (SBP ≤ 160 mm Hg and DBP ≤ 90 mm Hg)	☐ 1	☐ 2
11. Sensitivity or contraindication to any of the first-line study medications	☐ 1	☐ 2
12. Disease, such as non-curable malignancy, likely to lead to non-cardiovascular death over the course of the study	☐ 1	☐ 2

If *ANY* of items 4 through 12 are answered "*Yes*" then STOP - patient is ineligible.

Eligibility criteria for antihypertensive trial (*patient must have one or more of the following*):	**Yes**	**No**
13. Old (>6 months) or age-indeterminate myocardial infarction or stroke	☐ 1	☐ 2
14. History of CABG or coronary angioplasty or other revascularization procedure	☐ 1	☐ 2
15. Other documented atherosclerotic cardiovascular disease not requiring surgery	☐ 1	☐ 2
16. Type II diabetes mellitus [plasma glucose > 140 mg/dl (fasting) or > 200 mg/dl (non-fasting) and/or on insulin or oral hypoglycemic agents]	☐ 1	☐ 2
17. HDL-cholesterol <35 mg/dl (on 2 or more determinations within past 5 years)	☐ 1	☐ 2
18. Left ventricular hypertrophy (LVH) by ECG	☐ 1	☐ 2

If *NONE* of items 13 through 18 are answered "*Yes*" then STOP - patient is ineligible.

Visit 1 Information

19. Visit 1 date (mm-dd-yy) . . . . . __ __ - __ __ - __ __

20. a. Blood pressure cuff size (arm circumference limits in parentheses) . . . Pediatric (16.0 - 22.5 cm) ☐ 1
Regular adult (22.6 - 30.0 cm) ☐ 2
Large arm (30.1 - 37.5 cm) ☐ 3
Thigh (37.6 - 43.7 cm) ☐ 4

b. Visit 1 seated blood pressure readings (mm Hg) . . . . . __ __ __ / __ __ __

__ __ __ / __ __ __

Average: __ __ __ / __ __ __

c. Initials of person performing blood pressure measurements . . . . . __ __ __

21. Antihypertensive medication status . . . . . On 1-2 drugs ≥ 3 years ☐ 1
On 1-2 drugs ≥ 2 months but < 3 years ☐ 2
On drugs < 2 months ☐ 3
Currently untreated ☐ 4

22. Initials of person completing form . . . . . __ __ __

23. Signature of person completing form . . . . . _____

☛ Perform physical examination, ECG, local laboratory analyses, etc., as necessary for eligibility determination.

☛ Schedule Visit 2 at least 1 week and not later than 8 weeks from Visit 1, depending on antihypertensive drug tapering requirements. Advise patient of need to fast prior to Visit 2.

***Note**: Patients requiring tapering of current antihypertensive medications between Visit 1 and Visit 2, whose blood pressure exceeds 180 mmHg SBP or 110 mmHg DBP at a step-down visit should return within a few days for a repeat blood pressure measurement. If the blood pressure is still above 180/110 mmHg, the patient should not be randomized into the antihypertensive trial.*

Place ID label here

Patient name: _____

ALLHAT ANTIHYPERTENSIVE TRIAL RANDOMIZATION VISIT
(Visit 2)

Full name: _____ _____ _____
First MI Last

Randomization number (given by CTC at Visit 2, if randomized): ___ - ___ - ___

Site code: __ Acrostic (given by CTC at Visit 2, if randomized): ___ ___ ___ ___ ___ ___

24. Visit 2 date: __ __ - __ __ - __ __ (mm dd yy)

25. Birthdate: __ __ - __ __ - __ __ __ __ (mm dd yyyy)

26. a. Blood pressure cuff size . . . . . Pediatric (16.0 - 22.5 cm) ☐ 1
Regular adult (22.6 - 30.0 cm) ☐ 2
Large arm (30.1 - 37.5 cm) ☐ 3
Thigh (37.6 - 43.7 cm) ☐ 4

b. Heart rate (beats/min = 30-second count x 2) . . . . . ___

c. Visit 2 seated blood pressure readings (mm Hg) . . . . . ___ / ___

___ / ___

Average: ___ / ___

d. Initials of person performing blood pressure measurements . . . . . ___

27. Weight (lbs) . . . . . ___

28. Height (inches) . . . . . ___

29. Consent for antihypertensive trial randomization signed? . . . . . Yes ☐ 1
STOP, patient is not eligible ☚ No, refused ☐ 2

To randomize into antihypertensive trial: Call 1-800-690-7870 between 7:00 a.m and 7:00 p.m. Central time.

30. Date randomized (mm-dd-yy) . . . . . __ __ - __ __ - __ __

31. Antihypertensive drug bottle number . . . . . ___

32. Is patient eligible and willing thus far for the lipid-lowering trial? . . . . . Yes ☐ 1
No ☐ 2

Note: Final eligibility for the lipid-lowering trial will be determined using results of today's blood draw.

33. Social Security Number: ___ ___ ___ - ___ ___ - ___ ___ ___ ___

34. Medicare Number (leave blank if unknown): ___ ___ ___ - ___ ___ - ___ ___ ___ ___ - ___

35. a. Race:
- ☐ 1 White
- ☐ 2 Black
- ☐ 3 Amer Indian/Alaskan native
- ☐ 4 Asian/Pacific Islander
- ☐ 5 Other, specify _____

b. Is the patient of Hispanic origin?
- ☐ 1 Yes
- ☐ 2 No
- ☐ 3 DK

36. Sex:
- ☐ 1 Male
- ☐ 2 Female

37. Cigarette smoking:
- ☐ 1 Current smoker
- ☐ 2 Past smoker
- ☐ 3 Never smoked

38. Years of education, starting with first grade (code 99 if not known) . . . . . ___ ___

39. Is patient currently taking *aspirin* regularly? . . . . . Yes ☐ 1 / No ☐ 2 / DK ☐ 3

40. If female, is patient currently taking oral estrogen? . . . . . Yes ☐ 1 / No ☐ 2 / DK ☐ 3

The following two questions should be asked of the participant at the time of Visit 2:

41. In general, would you say your health is: . . . . . Excellent ☐ 1 / Very good ☐ 2 / Good ☐ 3 / Fair ☐ 4 / Poor ☐ 5 / No answer/unknown ☐ 6

42. If you were to rate your current health on a scale of 0 to 100, with 100 being perfect health and 0 being death, what number would you rate yourself today? (Use example from manual; code 999 if no answer or unknown) . . . . . ___ ___ ___

43. Initials of person completing this form: . . . . . ___ ___ ___

Signature of person completing this form . . . . . _____

Other evaluations at this visit:

- ☛ Electrocardiogram (with routing slip AL05A) - if an ECG has been done within the past month, it may be submitted as the baseline ECG
- ☛ Central laboratory evaluations - baseline profile (serum potassium, creatinine, glucose, lipid profile, ALT)
- ☛ Lifestyle advice for blood pressure reduction

Please attach ***ALLHAT*** Antihypertensive Trial Eligibility Worksheet to the front of this form prior to sending to the Clinical Trial Center.

Place ID label here

Patient name: _____

Fields-Marked Version

(1001) DE (1002) Batch (1003) VERIFIER (1004) MOD DATE (1005) MOD TIME (1006) MOD FLAG

ALLHAT ANTIHYPERTENSIVE TRIAL ELIGIBILITY WORKSHEET

(1010) FORM (1011) VSN

Information from Chart Review and Visit 1

(1012) CENTURY (1014) SEQ

1. Full name: _____ (First) _____ (MI) _____ (Last)

(1017) EDIT FLAG

2. a. Date randomized (mm-dd-yy): __-__-__ (1013)

   b. Randomization number (given by CTC at Visit 2, if randomized): ___ (1007) - ___ (1008) - ____ (1009)

   c. Site code: __ (1015) d. Acrostic (given by CTC at Visit 2, if randomized): _____ (1016)

3. Is this patient age 60 or older? ..... Yes ☐ 1 (1021)
   STOP, patient is not eligible ☚ No ☐ 2

Information from Chart Review or Local Determinations

Compliance exclusion:	Yes	No	
4. Factors suggesting a low likelihood of compliance with protocol (e.g., dementia, history of alcohol or drug abuse within past six months, plans to move or travel extensively, or history of unreliability in keeping appointments or taking prescribed drugs)	☐ 1	☐ 2	(1022)
Medical exclusion criteria for antihypertensive trial (*patient cannot meet any of the following criteria*):			
5. Symptomatic myocardial infarction or stroke within past six months	☐ 1	☐ 2	(1023)
6. Symptomatic congestive heart failure and/or ejection fraction < 35%, if known	☐ 1	☐ 2	→ (1024)
7. Angina pectoris within past 6 months	☐ 1	☐ 2	(1025)
8. Known renal insufficiency (serum creatinine ≥ 2 mg/dl)	☐ 1	☐ 2	→ (1026)
9. Requires thiazide-like diuretics, calcium antagonists, ACE inhibitors, or alpha adrenergic blockers for reasons other than treatment of hypertension (e.g, CHF, angina)	☐ 1	☐ 2	(1027)
10. Requires three or more antihypertensive drugs to achieve satisfactory blood pressure control (SBP ≤ 160 mm Hg and DBP ≤ 90 mm Hg)	☐ 1	☐ 2	(1028)
11. Sensitivity or contraindication to any of the first-line study medications	☐ 1	☐ 2	→ (1029)
12. Disease, such as non-curable malignancy, likely to lead to non-cardiovascular death over the course of the study	☐ 1	☐ 2	(1030)

If *ANY* of items 4 through 12 are answered "*Yes*" then STOP - patient is ineligible.

Eligibility criteria for antihypertensive trial (*patient must have one or more of the following*):	Yes	No	
13. Old (>6 months) or age-indeterminate myocardial infarction or stroke	☐ 1	☐ 2	(1031)
14. History of CABG or coronary angioplasty or other revascularization procedure	☐ 1	☐ 2	(1032)
15. Other documented atherosclerotic cardiovascular disease not requiring surgery	☐ 1	☐ 2	(1033)
16. Type II diabetes mellitus [plasma glucose > 140 mg/dl (fasting) or > 200 mg/dl (non-fasting) and/or on insulin or oral hypoglycemic agents]	☐ 1	☐ 2	(1034)
17. HDL-cholesterol <35 mg/dl (on 2 or more determinations within past 5 years)	☐ 1	☐ 2	→ (1035)
18. Left ventricular hypertrophy (LVH) by ECG	☐ 1	☐ 2	(1036)

If *NONE* of items 13 through 18 are answered "*Yes*" then STOP - patient is ineligible.

Visit 1 Information

19. Visit 1 date (mm-dd-yy) ..... __-__-__ (1037)

20. a. Blood pressure cuff size (arm circumference limits in parentheses) ... Pediatric (16.0 - 22.5 cm) ☐ 1
Regular adult (22.6 - 30.0 cm) ☐ 2 (1038)
Large arm (30.1 - 37.5 cm) ☐ 3
Thigh (37.6 - 43.7 cm) ☐ 4

b. Visit 1 seated blood pressure readings (mm Hg) ..... (1039)(1040) __/__
(1041)(1042) __/__
Average: (1043)(1044) __/__

c. Initials of person performing blood pressure measurements ..... __ __ __ (1045)

21. Antihypertensive medication status ..... On 1-2 drugs ≥ 3 years ☐ 1
On 1-2 drugs ≥ 2 months but < 3 years ☐ 2 (1046)
On drugs < 2 months ☐ 3
Currently untreated ☐ 4

22. Initials of person completing form ..... __ __ __ (1047)

23. Signature of person completing form ..... (1048)

- Perform physical examination, ECG, local laboratory analyses, etc., as necessary for eligibility determination.
- Schedule Visit 2 at least 1 week and not later than 8 weeks from Visit 1, depending on antihypertensive drug tapering requirements. Advise patient of need to fast prior to Visit 2.

***Note**: Patients requiring tapering of current antihypertensive medications between Visit 1 and Visit 2, whose blood pressure exceeds 180 mmHg SBP or 110 mmHg DBP at a step-down visit should return within a few days for a repeat blood pressure measurement. If the blood pressure is still above 180/110 mmHg, the patient should not be randomized into the antihypertensive trial.*

Place ID label here

Patient name: _____

ALLHAT ANTIHYPERTENSIVE TRIAL RANDOMIZATION VISIT
(Visit 2)

Full name: _____ __ _____
First MI Last

Randomization number (given by CTC at Visit 2, if randomized): ___ - ___ - ___

Site code: __ Acrostic (given by CTC at Visit 2, if randomized): _____

24. Visit 2 date: (1049) __ - __ - __ (mm dd yy) 25. Birthdate: __ - __ - ____ (1050) (mm dd yyyy)

26. a. Blood pressure cuff size ..... Pediatric (16.0 - 22.5 cm) ☐ 1
Regular adult (22.6 - 30.0 cm) ☐ 2 (1051)
Large arm (30.1 - 37.5 cm) ☐ 3
Thigh (37.6 - 43.7 cm) ☐ 4

b. Heart rate (beats/min = 30-second count x 2) ..... (1052) ___

c. Visit 2 seated blood pressure readings (mm Hg) ..... (1053) ___ / (1054) ___
(1055) ___ / (1056) ___
Average: (1057) ___ / (1058) ___

d. Initials of person performing blood pressure measurements ..... (1059) ___

27. Weight (lbs) ..... (1060) ___

28. Height (inches) ..... (1061) ___

29. Consent for antihypertensive trial randomization signed? ..... Yes ☐ 1 (1062)
STOP, patient is not eligible ☚ No, refused ☐ 2

<u>To randomize into antihypertensive trial:</u> Call 1-800-690-7870 between 7:00 a.m and 7:00 p.m. Central time.

30. Date randomized (mm-dd-yy) ..... (1063) __ - __ - __

31. Antihypertensive drug bottle number ..... (1064) __

32. Is patient eligible and willing thus far for the lipid-lowering trial? ..... Yes ☐ 1 (1065)
No ☐ 2

Note: Final eligibility for the lipid-lowering trial will be determined using results of today's blood draw.

33. Social Security Number: 1066 ___ - 1067 ___ - 1068 ____

34. Medicare Number (leave blank if unknown): 1069 ___ - 1070 ___ - 1071 ____ - 1072 ___

35. a. Race: 1073
☐ 1 White
☐ 2 Black
☐ 3 Amer Indian/Alaskan native
☐ 4 Asian/Pacific Islander
☐ 5 Other, specify 1074 _____ P

b. Is the patient of Hispanic origin? 1075
☐ 1 Yes
☐ 2 No
☐ 3 DK

36. Sex: 1076
☐ 1 Male
☐ 2 Female

37. Cigarette smoking: 1077
☐ 1 Current smoker
☐ 2 Past smoker
☐ 3 Never smoked

38. Years of education, starting with first grade (code 99 if not known) ..... 1078 ___

39. Is patient currently taking *aspirin* regularly? ..... Yes ☐ 1 / No ☐ 2 / DK ☐ 3 — 1079

40. If female, is patient currently taking oral estrogen? ..... Yes ☐ 1 / No ☐ 2 / DK ☐ 3 — 1080

The following two questions should be asked of the participant at the time of Visit 2:

41. In general, would you say your health is: ..... Excellent ☐ 1 / Very good ☐ 2 / Good ☐ 3 / Fair ☐ 4 / Poor ☐ 5 / No answer/unknown ☐ 6 — 1081

42. If you were to rate your current health on a scale of 0 to 100, with 100 being perfect health and 0 being death, what number would you rate yourself today? (Use example from manual; code 999 if no answer or unknown) ..... 1082 ___

43. Initials of person completing this form: ..... 1083 ___

Signature of person completing this form ..... P 1084 _____

Other evaluations at this visit:

- Electrocardiogram (with routing slip AL05A) - if an ECG has been done within the past month, it may be submitted as the baseline ECG
- Central laboratory evaluations - baseline profile (serum potassium, creatinine, glucose, lipid profile, ALT)
- Lifestyle advice for blood pressure reduction

Please attach ***ALLHAT*** Antihypertensive Trial Eligibility Worksheet to the front of this form prior to sending to the Clinical Trial Center.

Place ID label here

Patient name: _____

```
ID000 1 001IV 022-024 TCENTER          1       750 1
ID000 1 002IC 025-027 PPTNUM           1       700 1
ID000 1 003IC 028-030 OCENTER          1       750 1
FM000 1 001I  031-034 FORMVSN          1       999 1
AL001 1 001I    1-  2 F1KPCD           1         9 2
AL001 1 002IDR  3-  8 F1BATDT          1    999999 1
AL001 1 003A    9- 10 F1VFCD           1         9 0
AL001 1 004IDR 11- 16 F1DATMOD         1    999999 1
AL001 1 005I   17- 20 F1TIMMOD         1      9999 1
AL001 1 006I   21- 21 F1TYPMOD         1         9 2
AL001 1 007I   22- 24 F1TCN            1       662 1       Y$
AL001 1 008I   25- 27 F1PNO            1       700 1       Y$
AL001 1 009I   28- 30 F1RCN            1       662 1       Y$
AL001 1 010I   35- 42 F1DATE8          1  99999999 1       Y$
AL001 1 011I   34- 34 F1VS             1         3 2       Y$
AL001 1 012I   35- 36 F1CENT          19        20 2       Y$
AL001 1 013IDR 37- 42 F01KEYDT         1    999999 1       Y$
AL001 1 014I   43- 43 F1SEQ            1         9 2       Y$
AL001 1 015A   44- 44 F1SITE           1         9 0       Y$
AL001 1 016A   45- 50 F1ACROS          1         9 0       Y$
AL001 1 017I   51- 52 F1EDIT           0         3 2       Y$
AL001 1 018A   53- 63 F1RINO           1         9 0       Y$
AL001 1 019I   64- 66 F1PAYCN          1       999 1       Y$
AL001 1 020A   70- 80 F1CKNUM          1         9 0       Y$
AL001 1 021I   81- 81 F01FD021         1         2 2
AL001 1 022I   82- 82 F01FD022         1         2 2
AL001 1 023I   83- 83 F01FD023         1         2 2
AL001 1 024I   84- 84 F01FD024         1         2 2
AL001 1 025I   85- 85 F01FD025         1         2 2
AL001 1 026I   86- 86 F01FD026         1         2 2
AL001 1 027I   87- 87 F01FD027         1         2 2
AL001 1 028I   88- 88 F01FD028         1         2 2
AL001 1 029I   89- 89 F01FD029         1         2 2
AL001 1 030I   90- 90 F01FD030         1         2 2
AL001 1 031I   91- 91 F01FD031         1         2 2
AL001 1 032I   92- 92 F01FD032         1         2 2
AL001 1 033I   93- 93 F01FD033         1         2 2
AL001 1 034I   94- 94 F01FD034         1         2 2
AL001 1 035I   95- 95 F01FD035         1         2 2
AL001 1 036I   96- 96 F01FD036         1         2 2
AL001 1 037ID  97-102 F01FD037         1        99 1
AL001 1 038I  103-103 F01FD038         1         4 2
AL001 1 039I  104-106 F01FD039        60       300 1
AL001 1 040I  107-109 F01FD040         0       200 1
AL001 1 041I  110-112 F01FD041        60       300 1
AL001 1 042I  113-115 F01FD042         0       200 1
AL001 1 043I  116-118 F01FD043        60       300 1
AL001 1 044I  119-121 F01FD044         0       200 1
AL001 1 045A  122-124 F01FD045         1        99 0
AL001 1 046I  125-125 F01FD046         1         4 2
AL001 1 047A  126-128 F01FD047         1        99 0
AL001 1 048I  129-129 F01FD048         0         1 2
AL001 1 049ID 130-135 F01FD049         1        99 1
AL001 1 050ID 136-143 F01FD050         1  99999999 1
AL001 1 051I  144-144 F01FD051         1         4 2
AL001 1 052I  145-147 F01FD052        10       200 1
AL001 1 053I  148-150 F01FD053        60       300 1
AL001 1 054I  151-153 F01FD054         0       200 1
AL001 1 055I  154-156 F01FD055        60       300 1
AL001 1 056I  157-159 F01FD056         0       200 1
AL001 1 057I  160-162 F01FD057        60       300 1
AL001 1 058I  163-165 F01FD058         0       200 1
AL001 1 059A  166-168 F01FD059         1        99 0
AL001 1 060I  169-171 F01FD060        20       500 1
```

```
AL001 1 061I  172-173 F01FD061        20       100 1
AL001 1 062I  174-174 F01FD062         1         2 2
AL001 1 063ID 175-180 F01FD063         1    999999 1
AL001 1 064I  181-182 F01FD064        10        56 1
AL001 1 065I  183-183 F01FD065         1         2 2
AL001 1 066A  184-186 F01FD066         1         9 2
AL001 1 067A  187-188 F01FD067         1         9 2
AL001 1 068A  189-192 F01FD068         1         9 2
AL001 1 069A  193-195 F01FD069         1         9 2
AL001 1 070A  196-197 F01FD070         1         9 2
AL001 1 071A  198-201 F01FD071         1         9 2
AL001 1 072A  202-203 F01FD072         1         9 0
AL001 1 073I  204-204 F01FD073         1         9 2
AL001 1 074I  205-205 F01FD074         0         1 2
AL001 1 075I  206-206 F01FD075         1         3 2
AL001 1 076I  207-207 F01FD076         1         9 2
AL001 1 077I  208-208 F01FD077         1         3 2
AL001 1 078I  209-210 F01FD078         0        99 1
AL001 1 079I  211-211 F01FD079         1         3 2
AL001 1 080I  212-212 F01FD080         0         3 2
AL001 1 081I  213-213 F01FD081         1         6 2
AL001 1 082I  214-216 F01FD082         0       100 1
AL001 1 083A  217-219 F01FD083         1         9 0
AL001 1 084I  220-220 F01FD084         0         1 2
AL001 1 085I  221-226 F01FD085         0    999999 1
AL001 1 086I  227-227 F01FD086         0         9 1
AL001 1 087I  228-233 F01FD087         0    999999 1
AL001 1 088I  234-234 F01FD088         0         9 1
```

AL001 Version 2

ALLHAT ANTIHYPERTENSIVE TRIAL ELIGIBILITY WORKSHEET
Information from Chart Review and Visit 1

Name: _____

1.a. ID #: __ __ __ - __ __ __ - __ __ __

b. Site code: __ c. Acrostic: __ __ __ __ __ __

Place ID label here after randomization.

1.d. Date randomized (mm-dd-yy):

__ __ - __ __ - __ __

Warning: Patients must be at least 60 years of age at the time of randomization!

Information from Chart Review or Local Determinations

Exclusion criteria for the antihypertensive trial (patient cannot have any of the following):	**Yes**	**No**
2. Factors suggesting a low likelihood of compliance with protocol (e.g., dementia, history of alcohol or drug abuse within past six months, plans to move or travel extensively, or history of unreliability in keeping appointments or taking prescribed drugs)	☐ 1	☐ 2
3. Symptomatic myocardial infarction or stroke within past six months	☐ 1	☐ 2
4. Symptomatic congestive heart failure and/or ejection fraction < 35%, if known	☐ 1	☐ 2
5. Angina pectoris (chest pain) within past 6 months - patient may still be eligible if their chest pain is controlled on medications (see Item #7)	☐ 1	☐ 2
6. Known renal insufficiency (serum creatinine ≥ 2 mg/dl)	☐ 1	☐ 2
7. ***Requires*** thiazide-like diuretics, calcium antagonists, ACE inhibitors, or alpha adrenergic blockers for reasons other than treatment of hypertension (e.g, CHF, angina)	☐ 1	☐ 2
8. Requires therapeutic doses of three or more antihypertensive drugs to achieve satisfactory blood pressure control (SBP ≤ 160 mm Hg and DBP ≤ 90 mm Hg)	☐ 1	☐ 2
9. Sensitivity or contraindication to any of the first-line study medications	☐ 1	☐ 2
10. Disease, such as non-curable malignancy, likely to lead to non-cardiovascular death over the course of the study	☐ 1	☐ 2

If *ANY* of Items 2 through 10 are answered "*Yes*" then STOP - patient is ineligible.

Eligibility criteria for antihypertensive trial (*patient must have one or more of the following*):	**Yes**	**No**
11. Old (>6 months) or age-indeterminate myocardial infarction or stroke	☐ 1	☐ 2
12. History of CABG or coronary angioplasty or other revascularization procedure	☐ 1	☐ 2
13. Major ST segment depression or T wave inversion on any ECG in the past two years	☐ 1	☐ 2
14. Other documented atherosclerotic cardiovascular disease	☐ 1	☐ 2
15. Type II diabetes mellitus [plasma glucose > 140 mg/dl (fasting) or > 200 mg/dl (non-fasting) and/or on insulin or oral hypoglycemic agents in the past two years]	☐ 1	☐ 2
16. HDL-cholesterol <35 mg/dl (on any 2 determinations within past 5 years)	☐ 1	☐ 2
17. Left ventricular hypertrophy (LVH) on any ECG in the past two years	☐ 1	☐ 2
18. Combined wall thickness of ≥ 25 mm on any echocardiogram in the past two years	☐ 1	☐ 2

If *NONE* of Items 11 through 18 are answered "*Yes*" then STOP - patient is ineligible.

Visit 1 Information

19. Visit 1 date (mm-dd-yy) . . . . . __ __ - __ __ - __ __

20. a. Blood pressure cuff size (arm circumference limits in parentheses) . . . . . Pediatric (16.0 - 22.5 cm) ☐ 1
Regular adult (22.6 - 30.0 cm) ☐ 2
Large arm (30.1 - 37.5 cm) ☐ 3
Thigh (37.6 - 43.7 cm) ☐ 4

b. Visit 1 seated blood pressure readings (mm Hg) . . . . . __ __ __ / __ __ __

Patient should be seated for at least five minutes without smoking, feet flat on the floor, in an erect but comfortable position.

__ __ __ / __ __ __

Average: __ __ __ / __ __ __

c. Initials of person performing blood pressure measurements . . . . . __ __ __

21. Antihypertensive medication status . . . . . On 1-2 drugs ≥ 2 months ☐ 1
On drugs < 2 months ☐ 2
Currently untreated ☐ 3

On 1-2 drugs ≥ 2 months:

SBP ≤ 160 ☐ Yes ☐ No

DBP ≤ 100 ☐ Yes ☐ No

Both must be "Yes" for patient to be eligible.

On drugs < 2 months or currently untreated:

SBP ≥ 140 ☐ Yes ☐ No

DBP ≥ 90 ☐ Yes ☐ No

One of these . . .

SBP ≤ 180 ☐ Yes ☐ No

DBP ≤ 110 ☐ Yes ☐ No

. . . and both of these must be "Yes" for patient to be eligible.

22. Initials of person completing form . . . . . __ __ __

23. Signature of person completing form . . . . . _____

☛ Perform physical examination, ECG, local laboratory analyses, etc., as necessary for eligibility determination.

☛ Schedule Visit 2 at least 1 day and not later than 8 weeks from Visit 1, depending on antihypertensive drug tapering requirements. Advise patient of need to fast prior to Visit 2, and that diuretics and potassium supplements should not be taken on the day of Visit 2.

***Note**: Patients requiring tapering of current antihypertensive medications between Visit 1 and Visit 2, whose blood pressure exceeds 180 mmHg SBP or 110 mmHg DBP at a step-down visit should return within a few days for a repeat blood pressure measurement. If the blood pressure is still above 180/110 mmHg, the patient should not be randomized into the antihypertensive trial.*

Place ID label here

Patient name: _____

ALLHAT ANTIHYPERTENSIVE TRIAL RANDOMIZATION VISIT
(Visit 2)

Name: _____

ID #: __ __ __ - __ __ __ - __ __ __

Site code: __ Acrostic: __ __ __ __ __ __

Place ID label here after randomization.

24. Visit 2 date (mm-dd-yy) __ __ - __ __ - __ __

25. Birthdate (mm-dd-yyyy) __ __ - __ __ - __ __ __ __

26. a. Blood pressure cuff size ..... Pediatric (16.0 - 22.5 cm) ☐ 1
Regular adult (22.6 - 30.0 cm) ☐ 2
Large arm (30.1 - 37.5 cm) ☐ 3
Thigh (37.6 - 43.7 cm) ☐ 4

b. Heart rate (beats/min = 30-second count x 2) ..... __ __ __

c. Visit 2 seated blood pressure readings (mm Hg) ..... __ __ __ / __ __ __

Patient should be seated for at least five minutes without smoking, feet flat on the floor, in an erect but comfortable position.

__ __ __ / __ __ __

Average: __ __ __ / __ __ __

On 1-2 drugs ≥ 2 months at Visit 1:

SBP ≤ 180 ☐ Yes ☐ No

DBP ≤ 110 ☐ Yes ☐ No

Both must be "Yes" for patient to be eligible.

On drugs < 2 months or untreated at Visit 1:

SBP ≥ 140 ☐ Yes ☐ No

DBP ≥ 90 ☐ Yes ☐ No

One of these . . .

SBP ≤ 180 ☐ Yes ☐ No

DBP ≤ 110 ☐ Yes ☐ No

. . . and both of these must be "Yes" for patient to be eligible.

d. Initials of person performing blood pressure measurements ..... __ __ __

27. Weight (lbs) ..... __ __ __

28. Height (inches) ..... __ __

29. Consent for antihypertensive trial randomization signed? ..... Yes ☐ 1
STOP, patient is not eligible ☚ No, refused ☐ 2

To randomize into antihypertensive trial: Call 1-800-690-7870 between 7:00 a.m and 7:00 p.m. Central time Monday through Friday.

30. Date randomized (mm-dd-yy) ..... __ __ - __ __ - __ __

31. Antihypertensive drug bottle number ..... __ __

32. Social Security number: ..... __ __ __ - __ __ - __ __ __ __

33. Medicare number (***required*** for patients ≥ 65 years of age): ..... __ __ __ - __ __ - __ __ __ __ - __

34. a. Race: ☐ 1 White
☐ 2 Black
☐ 3 Amer Indian/Alaskan native
☐ 4 Asian/Pacific Islander
☐ 5 Other, specify _____

b. Is the patient of Hispanic origin? ***(must be answered!)*** ☐ 1 Yes ☐ 2 No ☐ 3 DK

35. Sex: ☐ 1 Male ☐ 2 Female

36. ***Cigarette*** smoking: ☐ 1 Current smoker ☐ 2 Past smoker ☐ 3 Never smoked

37. Years of education, starting with first grade (code 99 if not known) . . . . . ___

38. Is patient currently taking *aspirin* regularly? . . . . . Yes ☐ 1
No ☐ 2
DK ☐ 3

39. ***For women only:*** Is patient currently prescribed an estrogen supplement? . . . . . Oral ☐ 1
Patch ☐ 2
No ☐ 3
DK ☐ 4

		Yes	No
40.	Does patient have evidence of CHD (known prior MI, angina, primary cardiac arrest, coronary stenosis > 50%, reversible perfusion defect, prior coronary revascularization procedure)?	☐ 1	☐ 2
Exclusions for lipid-lowering trial (*patient cannot meet any of the following criteria*):			
41.	Current use of prescribed lipid-lowering agents or ≥ 500 mg/day of non-prescription niacin, or use of probucol within the past year	☐ 1	☐ 2
42.	Contraindications to HMG CoA reductase inhibitors (significant hepatic or renal disease, previous organ transplantation requiring immunosuppressive therapy, or known allergy or intolerance)	☐ 1	☐ 2
43.	Known untreated secondary cause of hypercholesterolemia, such as nephrotic syndrome or untreated hypothyroidism	☐ 1	☐ 2

44. Is the patient willing to enroll in the cholesterol-lowering component? . . . . . Yes ☐ 1
No ☐ 2
Not sure ☐ 3
Not eligible ☐ 4

45. In general, would you say your health is: . . . . . Excellent ☐ 1
Very good ☐ 2
Good ☐ 3
Fair ☐ 4
Poor ☐ 5
No answer/unknown ☐ 6

46. If you were to rate your current health on a scale of 0 to 100, with 100 being perfect health and 0 being death, what number would you rate yourself today? (Use example from manual; code 999 if no answer or unknown) . . . . . ___

47. Date of next visit (mm-dd-yy) . . . . . ___-___-___

48. Initials of person completing this form: . . . . . ___

49. Signature of person completing this form . . . . . _____

Other evaluations at this visit:

☛ Electrocardiogram (with routing slip AL05A) - if an ECG has been done within the past year, it may be submitted as the baseline ECG. Be sure to use the latest ECG available. Use the preprinted baseline ECG label provided by the Clinical Trials Center.

☛ Central laboratory evaluations - baseline profile (check profile ***ALL01*** on the laboratory request slip)

☛ Lifestyle advice for blood pressure reduction

☛ Remind patients eligible for the cholesterol-lowering trial to fast prior to Visit 3.

Please attach ***ALLHAT*** Antihypertensive Trial Eligibility Worksheet to the front of this form prior to sending to the Clinical Trial Center.

Fields-Marked Version

ALLHAT ANTIHYPERTENSIVE TRIAL ELIGIBILITY WORKSHEET
Information from Chart Review and Visit 1

Name: _____ (1007) (1008) (1009)

a. ID #: ___-___-____

b. Site code: __ (1015) c. Acrostic: _____ (1016)

Place ID label here after randomization.

1.d. Date randomized (mm-dd-yy): __-__-__ (1013)

DE: (1001) Batch: (1002) VF: (1003)

Date mod: (1004) Time Mod: (1005) Mod Flag: (1006)

Fmno: (1010) Vsn: (1011) Cent: (1012) Seq: (1014)

Warning: Patients must be at least 60 years of age at the time of randomization! Eflag: (1017)

Information from Chart Review or Local Determinations

Exclusion criteria for the antihypertensive trial (patient cannot have any of the following):	**Yes**	**No**	
2. Factors suggesting a low likelihood of compliance with protocol (e.g., dementia, history of alcohol or drug abuse within past six months, plans to move or travel extensively, or history of unreliability in keeping appointments or taking prescribed drugs)	☐ 1	☐ 2	(1022)
3. Symptomatic myocardial infarction or stroke within past six month	☐ 1	☐ 2	(1023)
4. Symptomatic congestive heart failure and/or ejection fraction < 35%, if known	☐ 1	☐ 2	(1024)
5. Angina pectoris (chest pain) within past 6 months - patient may still be eligible if their chest pain is controlled on medications (see Item #7)	☐ 1	☐ 2	(1025)
6. Known renal insufficiency (serum creatinine ≥ 2 mg/dl)	☐ 1	☐ 2	(1026)
Requires thiazide-like diuretics, calcium antagonists, ACE inhibitors, or alpha adrenergic blockers for reasons other than treatment of hypertension (e.g, CHF, angina)	☐ 1	☐ 2	(1027)
8. Requires therapeutic doses of three or more antihypertensive drugs to achieve satisfactory blood pressure control (SBP ≤ 160 mm Hg and DBP ≤ 90 mm Hg)	☐ 1	☐ 2	(1028)
9. Sensitivity or contraindication to any of the first-line study medications	☐ 1	☐ 2	(1029)
10. Disease, such as non-curable malignancy, likely to lead to non-cardiovascular death over the course of the study	☐ 1	☐ 2	(1030)

If *ANY* of items 2 through 10 are answered "Yes" then STOP - patient is ineligible.

Eligibility criteria for antihypertensive trial (*patient must have one or more of the following*):	**Yes**	**No**	
11. Old (>6 months) or age-indeterminate myocardial infarction or stroke	☐ 1	☐ 2	(1031)
12. History of CABG or coronary angioplasty or other revascularization procedure	☐ 1	☐ 2	(1032)
13. Major ST segment depression or T wave inversion on any ECG in the past two years V2 V3 only	☐ 1	☐ 2	(1089)
14. Other documented atherosclerotic cardiovascular disease	☐ 1	☐ 2	(1033)
15. Type II diabetes mellitus [plasma glucose > 140 mg/dl (fasting) or > 200 mg/dl (non-fasting) and/or on insulin or oral hypoglycemic agents in the past two years]	☐ 1	☐ 2	(1034)
16. HDL-cholesterol <35 mg/dl (on any 2 determinations within past 5 years)	☐ 1	☐ 2	(1035)
17. Left ventricular hypertrophy (LVH) on any ECG in the past two years	☐ 1	☐ 2	(1036)
Combined wall thickness of ≥ 25 mm on any echocardiogram in the past two years V2 V3 only	☐ 1	☐ 2	(1090)

If *NONE* of items 11 through 18 are answered "Yes" then STOP - patient is ineligible.

Visit 1 Information

Visit 1 date (mm-dd-yy) ..... ___-___-___ 1037

20. a. Blood pressure cuff size (arm circumference limits in parentheses) .....Pediatric (16.0 - 22.5 cm) ☐ 1 1038
Regular adult (22.6 - 30.0 cm) ☐ 2
Large arm (30.1 - 37.5 cm) ☐ 3
Thigh (37.6 - 43.7 cm) ☐ 4

b. Visit 1 seated blood pressure readings (mm Hg) ..... 1039 ___/___ 1040

Patient should be seated for at least five minutes without smoking, feet flat on the floor, in an erect but comfortable position.

1041 ___/___ 1042

Average: 1043 ___/___ 1044

c. Initials of person performing blood pressure measurements ..... ___ 1045

21. Antihypertensive medication status ..... On 1-2 drugs ≥ 2 months ☐ 1 1097
On drugs < 2 months ☐ 2
Currently untreated ☐ 3

On 1-2 drugs ≥ 2 months:		*On drugs < 2 months or currently untreated:*			
SBP ≤ 160	☐ Yes ☐ No	SBP ≥ 140	☐ Yes ☐ No	SBP ≤ 180	☐ Yes ☐ No
DBP ≤ 100	☐ Yes ☐ No	DBP ≥ 90	☐ Yes ☐ No	DBP ≤ 110	☐ Yes ☐ No
[illegible] must be "Yes" for patient to be eligible.		One of these . . .		. . . and both of these must be "Yes" for patient to be eligible.	

22. Initials of person completing form ..... ___ 1047

23. Signature of person completing form ..... _____ 1048

☞ Perform physical examination, ECG, local laboratory analyses, etc., as necessary for eligibility determination.

☞ Schedule Visit 2 at least 1 day and not later than 8 weeks from Visit 1, depending on antihypertensive drug tapering requirements. Advise patient of need to fast prior to Visit 2, and that diuretics and potassium supplements should not be taken on the day of Visit 2.

Note: *Patients requiring <u>tapering</u> of current antihypertensive medications between Visit 1 and Visit 2, whose blood pressure exceeds 180 mmHg SBP or 110 mmHg DBP at a step-down visit should return within a few days for a repeat blood pressure measurement. If the blood pressure is still above 180/110 mmHg, the patient should not be randomized into the antihypertensive trial.*

Place ID label here

Patient name: _____

ALLHAT ANTIHYPERTENSIVE TRIAL RANDOMIZATION VISIT
(Visit 2)

Name: _____

ID #: ___-____-____

Site code: __ Acrostic: _____

Place ID label here after randomization.

24. Visit 2 date (mm-dd-yy) ___-___-___ 1049

25. Birthdate (mm-dd-yyyy) ___-___-_____ 1050

26. a. Blood pressure cuff size ..... Pediatric (16.0 - 22.5 cm) ☐ 1 1051
Regular adult (22.6 - 30.0 cm) ☐ 2
Large arm (30.1 - 37.5 cm) ☐ 3
Thigh (37.6 - 43.7 cm) ☐ 4

b. Heart rate (beats/min = 30-second count x 2) ..... ___ 1052

c. Visit 2 seated blood pressure readings (mm Hg) ..... 1053 ___/___ 1054

1055 ___/___ 1056

1057 Average: ___/___ 1058

Patient should be seated for at least five minutes without smoking, feet flat

On drugs < 2 months or untreated at Visit 1:

SBP ≤ 180	☐ Yes— ☐ No	SBP ≥ 140	☐ Yes— ☐ No	SBP ≤ 180	☐ Yes— ☐ No
DBP ≤ 110	☐ Yes— ☐ No	DBP ≥ 90	☐ Yes— ☐ No	DBP ≤ 110	☐ Yes— ☐ No
Both must be "Yes" for patient to be eligible.		One of these . . .		. . . and both of these must be "Yes" for patient to be eligible.	

d. Initials of person performing blood pressure measurements ..... ____ 1059

27. Weight (lbs) ..... ___ 1060

28. Height (inches) ..... __ 1061

29. Consent for antihypertensive trial randomization signed? ..... Yes ☐ 1
STOP, patient is not eligible ☜ No, refused ☐ 2 1062

To randomize into antihypertensive trial: Call 1-800-690-7870 between 7:00 a.m and 7:00 p.m. Central time Monday through Friday.

30. Date randomized (mm-dd-yy) ..... ___-___-___ 1063

31. Antihypertensive drug bottle number ..... ___ 1064

32. Social Security number: ..... 1066 1067 ___-___-____ 1068

33. Medicare number (***required*** for patients ≥ 65 years of age): ..... 1069 1070 1071 ___-___-_____-__ 1072

34. a. Race: ☐ 1 White 1073
☐ 2 Black
☐ 3 Amer Indian/Alaskan native
☐ 4 Asian/Pacific Islander
☐ 5 Other, specify _____ 1074

b. Is the patient of Hispanic origin? ***(must be answered!)*** ☐ 1 Yes 1075
☐ 2 No
☐ 3 DK

35. Sex: ☐ 1 Male 1076
☐ 2 Female

36. ***Cigarette*** smoking: ☐ 1 Current smoker
☐ 2 Past Smoker 1077
☐ 3 Never Smoked

37. Years of education, starting with first grade (code 99 if not known) ..... __ __ 1078

38. Is patient currently taking *aspirin* regularly? ..... Yes ☐ 1 1079
No ☐ 2
DK ☐ 3

39. ***For women only:*** Is patient currently prescribed an estrogen supplement? ..... Oral ☐ 1 1098
Patch ☐ 2
No ☐ 3
DK ☐ 4

		Yes	No	
40.	Does patient have evidence of CHD (known prior MI, angina, primary cardiac arrest, coronary stenosis > 50%, reversible perfusion defect, prior coronary revascularization procedure)?	☐ 1	☐ 2	1091

Exclusions for lipid-lowering trial (*patient cannot meet any of the following criteria*):

41.	Current use of prescribed lipid-lowering agents or ≥ 500 mg/day of non-prescription niacin, or use of probucol within the past year	☐ 1	☐ 2	1092
42.	Contraindications to HMG CoA reductase inhibitors (significant hepatic or renal disease, previous organ transplantation requiring immunosuppressive therapy, or known allergy or intolerance)	☐ 1	☐ 2	1093
43.	Known untreated secondary cause of hypercholesterolemia, such as nephrotic syndrome or untreated hypothyroidism	☐1	☐ 2	1094

44. Is the patient willing to enroll in the cholesterol-lowering component? ..... Yes ☐ 1 1095
No ☐ 2
Not sure ☐ 3
Not eligible ☐ 4

45. In general, would you say your health is: ..... Excellent ☐ 1 1081
Very good ☐ 2
Good ☐ 3
Fair ☐ 4
Poor ☐ 5
No answer/unknown ☐ 6

46. If you were to rate your current health on a scale of 0 to 100, with 100 being perfect health and 0 being death, what number would you rate yourself today? (Use example from manual; code 999 if no answer or unknown) ..... __ __ __ 1082

47. Date of next visit (mm-dd-yy) ..... __ __ - __ __ - __ __ 1096

48. Initials of person completing this form: ..... __ __ __ 1083

49. Signature of person completing this form ..... _____ 1084

Other evaluations at this visit:

☞ Electrocardiogram (with routing slip AL05A) - if an ECG has been done within the past year, it may be submitted as the baseline ECG. Be sure to use the latest ECG available. Use the preprinted baseline ECG label provided by the Clinical Trials Center.

☞ Central laboratory evaluations - baseline profile (check profile ***ALL01*** on the laboratory request slip)

☞ Lifestyle advice for blood pressure reduction

☞ Remind patients eligible for the cholesterol-lowering trial to fast prior to Visit 3.

Please attach ***ALLHAT*** Antihypertensive Trial Eligibility Worksheet to the front of this form prior to sending to the Clinical Trial Center.

```
AL001 2 001I    1-  2 F1KPCD          1        99 1
AL001 2 002IDR  3-  8 F1BATDT         1    999999 1
AL001 2 003A    9- 10 F1VFCD          1         9 0
AL001 2 004IDR 11- 16 F1DATMOD        1    999999 1
AL001 2 005I   17- 20 F1TIMMOD        1      9999 1
AL001 2 006I   21- 21 F1TYPMOD        1         9 2
AL001 2 007I   22- 24 F1TCN           1       662 1       Y$
AL001 2 008I   25- 27 F1PNO           1       700 1       Y$
AL001 2 009I   28- 30 F1RCN           1       662 1       Y$
AL001 2 010I   35- 42 F1DATE8         1  99999999 2       Y$
AL001 2 011I   34- 34 F1VS            1         3 2       Y$
AL001 2 012I   35- 36 F1CENT         19        19 1       Y$
AL001 2 013IDR 37- 42 F01KEYDT        1    999999 1       Y$
AL001 2 014I   43- 43 F1SEQ           1         9 2       Y$
AL001 2 015A   44- 44 F1SITE          1         9 0       Y$
AL001 2 016A   45- 50 F1ACROS         1         9 0       Y$
AL001 2 017I   51- 52 F1EDIT          0         3 2       Y$
AL001 2 018A   53- 63 F1RINO          1         9 0       Y$
AL001 2 019I   64- 66 F1PAYCN         1       999 1       Y$
AL001 2 020A   70- 80 F1CKNUM         1         9 0       Y$
AL001 2 022I   81- 81 F01FD022        1         2 2
AL001 2 023I   82- 82 F01FD023        1         2 2
AL001 2 024I   83- 83 F01FD024        1         2 2
AL001 2 025I   84- 84 F01FD025        1         2 2
AL001 2 026I   85- 85 F01FD026        1         2 2
AL001 2 027I   86- 86 F01FD027        1         2 2
AL001 2 028I   87- 87 F01FD028        1         2 2
AL001 2 029I   88- 88 F01FD029        1         2 2
AL001 2 030I   89- 89 F01FD030        1         2 2
AL001 2 031I   90- 90 F01FD031        1         2 2
AL001 2 032I   91- 91 F01FD032        1         2 2
AL001 2 089I   92- 92 F01FD089        1         2 2
AL001 2 033I   93- 93 F01FD033        1         2 2
AL001 2 034I   94- 94 F01FD034        1         2 2
AL001 2 035I   95- 95 F01FD035        1         2 2
AL001 2 036I   96- 96 F01FD036        1         2 2
AL001 2 090I   97- 97 F01FD090        1         2 2
AL001 2 037ID  98-103 F01FD037        1    999999 1
AL001 2 038I  104-104 F01FD038        1         4 2
AL001 2 039I  105-107 F01FD039       60       300 1
AL001 2 040I  108-110 F01FD040        0       200 1
AL001 2 041I  111-113 F01FD041       60       300 1
AL001 2 042I  114-116 F01FD042        0       200 1
AL001 2 043I  117-119 F01FD043       60       300 1
AL001 2 044I  120-122 F01FD044        0       200 1
AL001 2 045A  123-125 F01FD045        1        99 0
AL001 2 097I  126-126 F01FD097        1         3 2
AL001 2 047A  127-129 F01FD047        1        99 0
AL001 2 048I  130-130 F01FD048        0         1 2
AL001 2 049ID 131-136 F01FD049        1    999999 1
AL001 2 050ID 137-144 F01FD050        1  99999999 1
AL001 2 051I  145-145 F01FD051        1         4 2
AL001 2 052I  146-148 F01FD052       10       200 1
AL001 2 053I  149-151 F01FD053       60       300 1
AL001 2 054I  152-154 F01FD054        0       200 1
AL001 2 055I  155-157 F01FD055       60       300 1
AL001 2 056I  158-160 F01FD056        0       200 1
AL001 2 057I  161-163 F01FD057       60       300 1
AL001 2 058I  164-166 F01FD058        0       200 1
AL001 2 059A  167-169 F01FD059        1        99 0
AL001 2 060I  170-172 F01FD060       20       500 1
AL001 2 061I  173-174 F01FD061       20       100 1
AL001 2 062I  175-175 F01FD062        1         2 2
```

```
AL001 2 063ID 176-181 F01FD063         1    999999 1
AL001 2 064I  182-183 F01FD064        10        56 1
AL001 2 066A  184-186 F01FD066         1       999 1
AL001 2 067A  187-188 F01FD067         1        99 1
AL001 2 068A  189-192 F01FD068         1      9999 1
AL001 2 069A  193-195 F01FD069         1       999 1
AL001 2 070A  196-197 F01FD070         1        99 1
AL001 2 071A  198-201 F01FD071         1      9999 1
AL001 2 072A  202-203 F01FD072         1         9 0
AL001 2 073I  204-204 F01FD073         1         5 2
AL001 2 074I  205-205 F01FD074         0         1 2
AL001 2 075I  206-206 F01FD075         1         3 2
AL001 2 076I  207-207 F01FD076         1         2 2
AL001 2 077I  208-208 F01FD077         1         3 2
AL001 2 078I  209-210 F01FD078         0        99 1
AL001 2 079I  211-211 F01FD079         1         3 2
AL001 2 098I  212-212 F01FD098         0         4 1
AL001 2 091I  213-213 F01FD091         1         2 2
AL001 2 092I  214-214 F01FD092         1         2 2
AL001 2 093I  215-215 F01FD093         1         2 2
AL001 2 094I  216-216 F01FD094         1         2 2
AL001 2 095I  217-217 F01FD095         1         4 2
AL001 2 081I  218-218 F01FD081         1         6 2
AL001 2 082I  219-221 F01FD082         0       100 1
AL001 2 096ID 222-227 F01FD096         1    999999 1
AL001 2 083A  228-230 F01FD083         1         9 0
AL001 2 084I  231-231 F01FD084         0         1 2
```

AL001 Version 3

ALLHAT ANTIHYPERTENSIVE TRIAL ELIGIBILITY WORKSHEET- VERSION 3
Information from Chart Review and Visit 1

Name: _____

1.a. ID #: ___-___-___-____

b. Site code: __ c. Acrostic: _____

Place ID label here after randomization.

1.d. Date randomized (mm-dd-yy):

__-__-__

Warning: Patients must be at least 55 years of age at the time of randomization!

Information from Chart Review or Local Determinations

Exclusion criteria for the antihypertensive trial (patient cannot have any of the following):	**Yes**	**No**
2. Factors suggesting a low likelihood of compliance with protocol (e.g., dementia, history of alcohol or drug abuse within past six months, plans to move or travel extensively, or history of unreliability in keeping appointments or taking prescribed drugs)	☐ 1	☐ 2
3. Symptomatic myocardial infarction or stroke within past six months	☐ 1	☐ 2
4. Symptomatic congestive heart failure and/or ejection fraction < 35%, if known	☐ 1	☐ 2
5. Angina pectoris (chest pain) within past 6 months	☐ 1	☐ 2
6. Known renal insufficiency (serum creatinine ≥ 2 mg/dl)	☐ 1	☐ 2
7. ***Requires*** diuretics, calcium antagonists, ACE inhibitors, or alpha adrenergic blockers for reasons other than treatment of hypertension (e.g, CHF, angina)	☐ 1	☐ 2
8. Requires therapeutic doses of three or more antihypertensive drugs to achieve satisfactory blood pressure control (SBP ≤ 160 mm Hg and DBP ≤ 90 mm Hg)	☐ 1	☐ 2
9. Sensitivity or contraindication to any of the first-line study medications	☐ 1	☐ 2
10. Disease, such as non-curable malignancy, likely to lead to non-cardiovascular death over the course of the study	☐ 1	☐ 2
11. Participation in another clinical trial (observational studies are allowed)	☐ 1	☐ 2

If *ANY* of items 2 through 11 are answered "*Yes*" then STOP - patient is ineligible.

Eligibility criteria for antihypertensive trial (*patient must have one or more of the following*):	**Yes**	**No**
12. Old (>6 months) or age-indeterminate myocardial infarction or stroke	☐ 1	☐ 2
13. History of CABG or coronary angioplasty or other revascularization procedure	☐ 1	☐ 2
14. Major ST segment depression or T wave inversion on any ECG in the past two years	☐ 1	☐ 2
15. Other documented atherosclerotic cardiovascular disease	☐ 1	☐ 2
16. Type II diabetes mellitus [plasma glucose > 140 mg/dl (fasting) or > 200 mg/dl (non-fasting) and/or on insulin or oral hypoglycemic agents in the past two years]	☐ 1	☐ 2
17. HDL-cholesterol <35 mg/dl (on any 2 determinations within past 5 years)	☐ 1	☐ 2
18. Left ventricular hypertrophy (LVH) on any ECG in the past two years	☐ 1	☐ 2
19. Combined wall thickness of ≥ 25 mm on any echocardiogram in the past two years	☐ 1	☐ 2
20. Current cigarette smoker	☐ 1	☐ 2

If *NONE* of items 12 through 20 are answered "*Yes*" then STOP - patient is ineligible.

Visit 1 Information

21. Visit 1 date (mm-dd-yy) ..... __-__-__

22. a. Blood pressure cuff size (arm circumference limits in parentheses) ..... Pediatric (16.0 - 22.5 cm) ☐ 1
Regular adult (22.6 - 30.0 cm) ☐ 2
Large arm (30.1 - 37.5 cm) ☐ 3
Thigh (37.6 - 43.7 cm) ☐ 4

b. Visit 1 seated blood pressure readings (mm Hg) ..... ___/___

Patient should be seated for at least five minutes without smoking, feet flat on the floor, in an erect but comfortable position.

___/___

Average: ___/___

c. Initials of person performing blood pressure measurements ..... ___

23. Antihypertensive medication status ..... On 1-2 drugs ≥ 2 months ☐ 1
On drugs < 2 months ☐ 2
Currently untreated ☐ 3

On 1-2 drugs ≥ 2 months:

SBP ≤ 160 ☐ Yes ☐ No

DBP ≤ 100 ☐ Yes ☐ No

Both must be "Yes" for patient to be eligible.

On drugs < 2 months or currently untreated:

SBP ≥ 140 ☐ Yes ☐ No

DBP ≥ 90 ☐ Yes ☐ No

One of these . . .

SBP ≤ 180 ☐ Yes ☐ No

DBP ≤ 110 ☐ Yes ☐ No

. . . and both of these must be "Yes" for patient to be eligible.

24. Initials of person completing form ..... ___

25. Signature of person completing form ..... _____

☞ Perform physical examination, ECG, local laboratory analyses, etc., as necessary for eligibility determination.

☞ Schedule Visit 2 at least 1 day and not later than 12 weeks from Visit 1, depending on antihypertensive drug tapering requirements. Advise patient of need to fast prior to Visit 2, and that diuretics and potassium supplements should not be taken on the day of Visit 2.

***Note**: Patients requiring tapering of current antihypertensive medications between Visit 1 and Visit 2, whose blood pressure exceeds 180 mmHg SBP or 110 mmHg DBP at a step-down visit should return within a few days for a repeat blood pressure measurement. If the blood pressure is still above 180/110 mmHg, the patient should not be randomized into the antihypertensive trial.*

Place ID label here

Patient name: _____

ALLHAT ANTIHYPERTENSIVE TRIAL RANDOMIZATION VISIT (VISIT 2) - VERSION 3

Name: _____

ID #: ___-___-____

Site code: __ Acrostic: _____

Place ID label here after randomization.

26. Visit 2 date (mm-dd-yy) ___-___-___

27. Birthdate (mm-dd-yyyy) ___-___-_____

28. a. Blood pressure cuff size ..... Pediatric (16.0 - 22.5 cm) ☐ 1
Regular adult (22.6 - 30.0 cm) ☐ 2
Large arm (30.1 - 37.5 cm) ☐ 3
Thigh (37.6 - 43.7 cm) ☐ 4

b. Heart rate (beats/min = 30-second count x 2) ..... ___

c. Visit 2 seated blood pressure readings (mm Hg) ..... ___/___
___/___
Average: ___/___

Patient should be seated for at least five minutes without smoking, feet flat on the floor, in an erect but comfortable position.

On 1-2 drugs ≥ 2 months at Visit 1:

SBP ≤ 180 ☐ Yes ☐ No

DBP ≤ 110 ☐ Yes ☐ No

Both must be "Yes" for patient to be eligible.

On drugs < 2 months or untreated at Visit 1:

SBP ≥ 140 ☐ Yes ☐ No

DBP ≥ 90 ☐ Yes ☐ No

One of these . . .

SBP ≤ 180 ☐ Yes ☐ No

DBP ≤ 110 ☐ Yes ☐ No

. . . and both of these must be "Yes" for patient to be eligible.

d. Initials of person performing blood pressure measurements ..... ___

29. Weight (lbs) ..... ___

30. Height (inches) ..... ___

31. Consent for antihypertensive trial randomization signed? ..... Yes ☐ 1
STOP, patient is not eligible ☎ No, refused ☐ 2

Antihypertensive trial randomization: Call 1-800-690-7870 from 7:00 a.m. to 5:00 p.m. Central time Monday – Friday.

32. Date randomized (mm-dd-yy) ..... ___-___-___

33. Antihypertensive drug bottle number ..... ___

34. Social Security number: ..... ___-___-____

35. Medicare number (***required*** for patients ≥ 65 years of age): ..... ___-___-_____-__

36. a. Race: ☐ 1 White
☐ 2 Black
☐ 3 Amer Indian/Alaskan native
☐ 4 Asian/Pacific Islander
☐ 5 Other, specify _____

b. Is the patient of Hispanic origin? ***(must be answered!)*** ☐ 1 Yes ☐ 2 No ☐ 3 DK

37. Sex: ☐ 1 Male ☐ 2 Female

38. ***Cigarette*** smoking: ☐ 1 Current smoker ☐ 2 Past smoker ☐ 3 Never smoked

39. Years of education, starting with first grade (code 99 if not known) ..... ___

40. Is patient currently taking *aspirin* regularly? ..... Yes ☐ 1
No ☐ 2
DK ☐ 3

41. ***For women only:*** Is patient currently prescribed an estrogen supplement? ..... Oral ☐ 1
Patch ☐ 2
No ☐ 3
DK ☐ 4

		Yes	No
42.	Does patient have evidence of CHD (known prior MI, angina, primary cardiac arrest, coronary stenosis > 50%, reversible perfusion defect, prior coronary revascularization procedure)?	☐ 1	☐ 2

Exclusions for lipid-lowering trial (*patient cannot meet any of the following criteria*):

43.	Current use of prescribed lipid-lowering agents or ≥ 500 mg/day of non-prescription niacin, or use of probucol within the past year	☐ 1	☐ 2
44.	Contraindications to HMG CoA reductase inhibitors (significant hepatic or renal disease, previous organ transplantation requiring immunosuppressive therapy, or known allergy or intolerance)	☐ 1	☐ 2
45.	Known untreated secondary cause of hypercholesterolemia, such as nephrotic syndrome or untreated hypothyroidism	☐ 1	☐ 2

46. Is the patient willing to enroll in the cholesterol-lowering component? ..... Yes ☐ 1
No ☐ 2
Not sure ☐ 3
Not eligible ☐ 4

47. In general, would you say your health is: ..... Excellent ☐ 1
Very good ☐ 2
Good ☐ 3
Fair ☐ 4
Poor ☐ 5
No answer/unknown ☐ 6

48. If you were to rate your current health on a scale of 0 to 100, with 100 being perfect health and 0 being death, what number would you rate yourself today? (Unknown=999) ..... ___ ___ ___

49. Has the patient signed the consent allowing DNA analysis of the baseline blood? ..... Yes ☐ 1
No ☐ 2

50. Date of next visit (mm-dd-yy) ..... ___ ___ - ___ ___ - ___ ___

51. Initials of person completing this form: ..... ___ ___ ___

52. Signature of person completing this form ..... _____

Other evaluations at this visit:

☞ Electrocardiogram (with routing slip AL05A) - if an ECG has been done within the past year, it may be submitted as the baseline ECG. Be sure to use the latest ECG available. Use the preprinted baseline ECG label provided by the Clinical Trials Center.

☞ Central laboratory evaluations - baseline profile (check profile ***ALL01*** on the laboratory request slip)

☞ Lifestyle advice for blood pressure reduction

☞ Remind patients eligible for the cholesterol-lowering trial to fast prior to Visit 3.

☞ Dispense one bottle of Dose 0 and one bottle of Dose 1 of assigned bottle number.

☞ Please staple all 4 pages of the AL01 together prior to sending this form to the Clinical Trials Center.

Place patient label here

Patient name: _____

Fields-Marked Version

ALLHAT ANTIHYPERTENSIVE TRIAL ELIGIBILITY WORKSHEET
Information from Chart Review and Visit 1

Name: _____ (1007) (1008) (1009)
1.a. ID #: ___-___-____
b. Site code: __ (1015) c. Acrostic: _____ (1016)

Place ID label here after randomization.

1.d. Date randomized (mm-dd-yy): ___-___-___ (1013)
DE: (1001) Batch: (1002) VF: (1003)
Date mod: (1004) Time Mod: (1005) Mod Flag: (1006)
Fmno: (1010) Vsn: (1011) Cent: (1012) Seq: (1014)

Warning: Patients must be at least 55 years of age at the time of randomization! Eflag: (1017)

Information from Chart Review or Local Determinations

Exclusion criteria for the antihypertensive trial (patient cannot have any of the following):	**Yes**	**No**	
2. Factors suggesting a low likelihood of compliance with protocol (e.g., dementia, history of alcohol or drug abuse within past six months, plans to move or travel extensively, or history of unreliability in keeping appointments or taking prescribed drugs)	☐ 1	☐ 2	(1022)
3. Symptomatic myocardial infarction or stroke within past six months	☐ 1	☐ 2	(1023)
4. Symptomatic congestive heart failure and/or ejection fraction < 35%, if known	☐ 1	☐ 2	(1024)
5. Angina pectoris (chest pain) within past 6 months	☐ 1	☐ 2	(1025)
6. Known renal insufficiency (serum creatinine ≥ 2 mg/dl)	☐ 1	☐ 2	(1026)
7. ***Requires*** diuretics, calcium antagonists, ACE inhibitors, or alpha adrenergic blockers for reasons other than treatment of hypertension (e.g, CHF, angina)	☐ 1	☐ 2	(1027)
8. Requires therapeutic doses of three or more antihypertensive drugs to achieve satisfactory blood pressure control (SBP ≤ 160 mm Hg and DBP ≤ 90 mm Hg)	☐ 1	☐ 2	(1028)
9. Sensitivity or contraindication to any of the first-line study medications	☐ 1	☐ 2	(1029)
10. Disease, such as non-curable malignancy, likely to lead to non-cardiovascular death over the course of the study	☐ 1	☐ 2	(1030)
11. Participation in another clinical trial (observational studies are allowed) V3 only	☐ 1	☐ 2	(1099)

If *ANY* of items 2 through 11 are answered "*Yes*" then STOP - patient is ineligible.

Eligibility criteria for antihypertensive trial (*patient must have one or more of the following*):	**Yes**	**No**	
12. Old (>6 months) or age-indeterminate myocardial infarction or stroke	☐ 1	☐ 2	(1031)
13. History of CABG or coronary angioplasty or other revascularization procedure	☐ 1	☐ 2	(1032)
14. Major ST segment depression or T wave inversion on any ECG in the past two years	☐ 1	☐ 2	(1089) V2
15 Other documented atherosclerotic cardiovascular disease	☐ 1	☐ 2	(1033)
16. Type II diabetes mellitus [plasma glucose > 140 mg/dl (fasting) or > 200 mg/dl (non-fasting) and/or on insulin or oral hypoglycemic agents in the past two years]	☐ 1	☐ 2	(1034)
17. HDL-cholesterol <35 mg/dl (on any 2 determinations within past 5 years)	☐ 1	☐ 2	(1035)
18. Left ventricular hypertrophy (LVH) on any ECG in the past two years	☐ 1	☐ 2	(1036)
19. Combined wall thickness of ≥ 25 mm on any echocardiogram in the past two years	☐ 1	☐ 2	(1090) V2,3
20. Current cigarette smoker	☐ 1	☐ 2	(1100)

If *NONE* of items 12 through 20 are answered "*Yes*" then STOP - patient is ineligible.

Visit 1 Information

21. Visit 1 date (mm-dd-yy) ..... __ __ - __ __ - __ __ 1037

22. a. Blood pressure cuff size (arm circumference limits in parentheses) .....Pediatric (16.0 - 22.5 cm) ☐ 1 1038
Regular adult (22.6 - 30.0 cm) ☐ 2
Large arm (30.1 - 37.5 cm) ☐ 3
Thigh (37.6 - 43.7 cm) ☐ 4

b. Visit 1 seated blood pressure readings (mm Hg) ..... 1039 __ __ __ / __ __ __ 1040

Patient should be seated for at least five minutes without smoking, feet flat on the floor, in an erect but comfortable position.

1041 __ __ __ / __ __ __ 1042

Average: 1043 __ __ __ / __ __ __ 1044

c. Initials of person performing blood pressure measurements ..... __ __ __ 1045

23. Antihypertensive medication status ..... On 1-2 drugs ≥ 2 months ☐ 1 1097
On drugs < 2 months ☐ 2
Currently untreated ☐ 3

On 1-2 drugs ≥ 2 months:		***On drugs < 2 months or currently untreated:***			
SBP ≤ 160	☐ Yes— ☐ No	SBP ≥ 140	☐ Yes— ☐ No	SBP ≤ 180	☐ Yes— ☐ No
DBP ≤ 100	☐ Yes— ☐ No	DBP ≥ 90	☐ Yes— ☐ No	DBP ≤ 110	☐ Yes— ☐ No
Both must be "Yes" for patient to be eligible.		One of these . . .		. . . and both of these must be "Yes" for patient to be eligible.	

24. Initials of person completing form ..... __ __ __ 1047

25. Signature of person completing form ..... _____ 1048

☞ Perform physical examination, ECG, local laboratory analyses, etc., as necessary for eligibility determination.

☞ Schedule Visit 2 at least 1 day and not later than 12 weeks from Visit 1, depending on antihypertensive drug tapering requirements. Advise patient of need to fast prior to Visit 2, and that diuretics and potassium supplements should not be taken on the day of Visit 2.

***Note**: Patients requiring tapering of current antihypertensive medications between Visit 1 and Visit 2, whose blood pressure exceeds 180 mmHg SBP or 110 mmHg DBP at a step-down visit should return within a few days for a repeat blood pressure measurement. If the blood pressure is still above 180/110 mmHg, the patient should not be randomized into the antihypertensive trial.*

Place ID label here

Patient name: _____

ALLHAT ANTIHYPERTENSIVE TRIAL RANDOMIZATION VISIT
(Visit 2)

Name: _____

ID #: ___-___-____

Site code: __ Acrostic: _____

Place ID label here after randomization.

26. Visit 2 date (mm-dd-yy) __-__-__ 1049

27. Birthdate (mm-dd-yyyy) __-__-____ 1050

28. a. Blood pressure cuff size ..... Pediatric (16.0 - 22.5 cm) ☐ 1 1051
Regular adult (22.6 - 30.0 cm) ☐ 2
Large arm (30.1 - 37.5 cm) ☐ 3
Thigh (37.6 - 43.7 cm) ☐ 4

b. Heart rate (beats/min = 30-second count x 2) ..... ___ 1052

c. Visit 2 seated blood pressure readings (mm Hg) ..... 1053 ___/___ 1054

1055 ___/___ 1056

Patient should be seated for at least five minutes without smoking, feet flat on the floor, in an erect but comfortable position.

1057 Average: ___/___ 1058

On 1-2 drugs ≥ 2 months at Visit 1:

SBP ≤ 180 ☐ Yes— ☐ No

DBP ≤ 110 ☐ Yes— ☐ No

Both must be "Yes" for patient to be eligible.

On drugs < 2 months or untreated at Visit 1:

SBP ≥ 140 ☐ Yes— ☐ No

DBP ≥ 90 ☐ Yes— ☐ No

One of these . . .

SBP ≤ 180 ☐ Yes— ☐ No

DBP ≤ 110 ☐ Yes— ☐ No

. . . and both of these must be "Yes" for patient to be eligible.

d. Initials of person performing blood pressure measurements ..... ___ 1059

29. Weight (lbs) ..... ___ 1060

30. Height (inches) ..... ___ 1061

31. Consent for antihypertensive trial randomization signed? ..... Yes ☐ 1
STOP, patient is not eligible ☜ No, refused ☐ 2 1062

Antihypertensive trial randomization: Call 1-800-690-7870 from 7:00 a.m to 6:00 p.m. Central time Monday - Friday.

32. Date randomized (mm-dd-yy) ..... __-__-__ 1063

33. Antihypertensive drug bottle number ..... __ 1064

34. Social Security number: ..... 1066 1067 ___-___-____ 1068

35. Medicare number (***required*** for patients ≥ 65 years of age): 1071 ___-___-____-__
1069 1070 1071 1072

36. a. Race: ☐ 1 White (1073)
☐ 2 Black
☐ 3 Amer Indian/Alaskan native
☐ 4 Asian/Pacific Islander
☐ 5 Other, specify _____ (1074)

b. Is the patient of Hispanic origin? ***(must be answered!)*** ☐ 1 Yes (1075)
☐ 2 No
☐ 3 DK

37. Sex: ☐ 1 Male (1076)
☐ 2 Female

38. *Cigarette* smoking: ☐ 1 Current smoker
☐ 2 Past Smoker
☐ 3 Never Smoked (1077)

39. Years of education, starting with first grade (code 99 if not known) ..... __ __ (1078)

40. Is patient currently taking *aspirin* regularly? ..... Yes ☐ 1 (1079)
No ☐ 2
DK ☐ 3

41. ***For women only:*** Is patient currently prescribed an estrogen supplement? ..... Oral ☐ 1 (1098)
Patch ☐ 2
No ☐ 3
DK ☐ 4

		Yes	No	
42.	Does patient have evidence of CHD (known prior MI, angina, primary cardiac arrest, coronary stenosis > 50%, reversible perfusion defect, prior coronary revascularization procedure)?	☐ 1	☐ 2	(1091)

Exclusions for lipid-lowering trial (*patient cannot meet any of the following criteria*):

43.	Current use of prescribed lipid-lowering agents or ≥ 500 mg/day of non-prescription niacin, or use of probucol within the past year	☐ 1	☐ 2	(1092)
44.	Contraindications to HMG CoA reductase inhibitors (significant hepatic or renal disease, previous organ transplantation requiring immunosuppressive therapy, or known allergy or intolerance)	☐ 1	☐ 2	(1093)
45.	Known untreated secondary cause of hypercholesterolemia, such as nephrotic syndrome or untreated hypothyroidism	☐ 1	☐ 2	(1094)

46. Is the patient willing to enroll in the cholesterol-lowering component? ..... Yes ☐ 1 (1095)
No ☐ 2
Not sure ☐ 3
Not eligible ☐ 4

47. In general, would you say your health is: ..... Excellent ☐ 1 (1081)
Very good ☐ 2
Good ☐ 3
Fair ☐ 4
Poor ☐ 5
No answer/unknown ☐ 6

48. If you were to rate your current health on a scale of 0 to 100, with 100 being perfect health and 0 being death, what number would you rate yourself today? (Unknown = 999) ..... ___ (1082)

49. Has the patient signed the consent allowing DNA analysis of the baseline blood? ..... Yes ☐ 1 (1101)
No ☐ 2

50. Date of next visit (mm-dd-yy) ..... __ __ - __ __ - __ __ (1096)

51. Initials of person completing this form: ..... ___ 1083

52. Signature of person completing this form..... _____ 1084

Other evaluations at this visit:

- Electrocardiogram (with routing slip AL05A) - if an ECG has been done within the past year, it may be submitted as the baseline ECG. Be sure to use the latest ECG available. Use the preprinted baseline ECG label provided by the Clinical Trials Center.
- Central laboratory evaluations - baseline profile (check profile ***ALL01*** on the laboratory request slip)
- Lifestyle advice for blood pressure reduction
- Remind patients eligible for the cholesterol-lowering trial to fast prior to Visit 3.
- Dispense one bottle of Dose 0 and one bottle of Dose 1 of assigned bottle number.
- Please staple all 4 pages of the AL01 together prior to sending this form to the Clinical Trials Center

Place patient label here

Patient name: _____

```
AL001 3 001I    1-  2 F1KPCD          1        99 1
AL001 3 002IDR  3-  8 F1BATDT         1    999999 1
AL001 3 003A    9- 10 F1VFCD          1         9 0
AL001 3 004IDR 11- 16 F1DATMOD        1    999999 1
AL001 3 005I   17- 20 F1TIMMOD        1      9999 1
AL001 3 006I   21- 21 F1TYPMOD        1         9 2
AL001 3 007I   22- 24 F1TCN           1       662 1       Y$
AL001 3 008I   25- 27 F1PNO           1       700 1       Y$
AL001 3 009I   28- 30 F1RCN           1       662 1       Y$
AL001 3 010I   35- 42 F1DATE8         1  99999999 1       Y$
AL001 3 011I   34- 34 F1VS            1         9 2       Y$
AL001 3 012I   35- 36 F1CENT         19        19 1       Y$
AL001 3 013IDR 37- 42 F01KEYDT        1    999999 1       Y$
AL001 3 014I   43- 43 F1SEQ           1         9 2       Y$
AL001 3 015A   44- 44 F1SITE          1         9 0       Y$
AL001 3 016A   45- 50 F1ACROS         1         9 0       Y$
AL001 3 017I   51- 52 F1EDIT          0         3 2       Y$
AL001 3 018A   53- 63 F1RINO          1         9 0       Y$
AL001 3 019I   64- 66 F1PAYCN         1       999 1       Y$
AL001 3 020A   70- 80 F1CKNUM         1         9 0       Y$
AL001 3 022I   81- 81 F01FD022        1         2 2
AL001 3 023I   82- 82 F01FD023        1         2 2
AL001 3 024I   83- 83 F01FD024        1         2 2
AL001 3 025I   84- 84 F01FD025        1         2 2
AL001 3 026I   85- 85 F01FD026        1         2 2
AL001 3 027I   86- 86 F01FD027        1         2 2
AL001 3 028I   87- 87 F01FD028        1         2 2
AL001 3 029I   88- 88 F01FD029        1         2 2
AL001 3 030I   89- 89 F01FD030        1         2 2
AL001 3 031I   90- 90 F01FD031        1         2 2
AL001 3 032I   91- 91 F01FD032        1         2 2
AL001 3 089I   92- 92 F01FD089        1         2 2
AL001 3 033I   93- 93 F01FD033        1         2 2
AL001 3 034I   94- 94 F01FD034        1         2 2
AL001 3 035I   95- 95 F01FD035        1         2 2
AL001 3 036I   96- 96 F01FD036        1         2 2
AL001 3 090I   97- 97 F01FD090        1         2 2
AL001 3 037ID  98-103 F01FD037        1    999999 1
AL001 3 038I  104-104 F01FD038        1         4 2
AL001 3 039I  105-107 F01FD039       60       300 1
AL001 3 040I  108-110 F01FD040        0       200 1
AL001 3 041I  111-113 F01FD041       60       300 1
AL001 3 042I  114-116 F01FD042        0       200 1
AL001 3 043I  117-119 F01FD043       60       300 1
AL001 3 044I  120-122 F01FD044        0       200 1
AL001 3 045A  123-125 F01FD045        1        99 0
AL001 3 097I  126-126 F01FD097        1         3 2
AL001 3 047A  127-129 F01FD047        1        99 0
AL001 3 048I  130-130 F01FD048        0         1 2
AL001 3 049ID 131-136 F01FD049        1    999999 1
AL001 3 050ID 137-144 F01FD050        1  99999999 1
AL001 3 051I  145-145 F01FD051        1         4 2
AL001 3 052I  146-148 F01FD052       10       200 1
AL001 3 053I  149-151 F01FD053       60       300 1
AL001 3 054I  152-154 F01FD054        0       200 1
AL001 3 055I  155-157 F01FD055       60       300 1
AL001 3 056I  158-160 F01FD056        0       200 1
AL001 3 057I  161-163 F01FD057       60       300 1
AL001 3 058I  164-166 F01FD058        0       200 1
AL001 3 059A  167-169 F01FD059        1        99 0
AL001 3 060I  170-172 F01FD060       20       500 1
AL001 3 061I  173-174 F01FD061       20       100 1
AL001 3 062I  175-175 F01FD062        1         2 2
```

```
AL001 3 063ID 176-181 F01FD063         1    999999 0
AL001 3 064I  182-183 F01FD064        10        56 1
AL001 3 066A  184-186 F01FD066         1       999 1
AL001 3 067A  187-188 F01FD067         1        99 1
AL001 3 068A  189-192 F01FD068         1      9999 1
AL001 3 069A  193-195 F01FD069         1       999 1
AL001 3 070A  196-197 F01FD070         1        99 1
AL001 3 071A  198-201 F01FD071         1      9999 1
AL001 3 072A  202-203 F01FD072         1         9 0
AL001 3 073I  204-204 F01FD073         1         5 2
AL001 3 074I  205-205 F01FD074         0         1 2
AL001 3 075I  206-206 F01FD075         1         3 2
AL001 3 076I  207-207 F01FD076         1         2 2
AL001 3 077I  208-208 F01FD077         1         3 2
AL001 3 078I  209-210 F01FD078         0        99 1
AL001 3 079I  211-211 F01FD079         1         3 2
AL001 3 098I  212-212 F01FD098         1         4 2
AL001 3 091I  213-213 F01FD091         1         2 2
AL001 3 092I  214-214 F01FD092         1         2 2
AL001 3 093I  215-215 F01FD093         1         2 2
AL001 3 094I  216-216 F01FD094         1         2 2
AL001 3 095I  217-217 F01FD095         1         4 2
AL001 3 081I  218-218 F01FD081         1         6 2
AL001 3 082I  219-221 F01FD082         0       100 1
AL001 3 096ID 222-227 F01FD096         1    999999 1
AL001 3 083A  228-230 F01FD083         1         9 0
AL001 3 084I  231-231 F01FD084         0         1 2
AL001 3 099I  232-232 F01FD099         1         2 2
AL001 3 100I  233-233 F01FD100         1         2 2
AL001 3 101I  234-234 F01FD101         1         2 2
```

AL002 - ALLHAT Lipid-Lowering Trial Eligibility and Randomization Form

The AL002 is the hard-copy version of the information captured on the AL081 form during the Lipid-Lowering Randomization phone call. The AL002 was subject to editing for consistency and logic. The AL081 was never modified, even if there were discrepancies between the AL002 and the AL081. The AL081 was used for obtaining baseline characteristics until the AL002 was received at the CTC, and then the AL002 took precedence in analyses.

Versions:
Version 1 – 01/94
Unique fields to version 1: F02021, F02022, F02023, F02024, F02025 and F02028.

Version 2 – 03/95
Unique field to version 2: F02033.

Modified Fields for LADS Master File:
Blanked:
F02018 (versions 1,2)
F02019 (versions 1,2)
F02020 (versions 1,2)
F02029 (versions 1,2) may be blank (AL081 precedence)
F02031 (versions 1,2)

AL002 Version 1

ALLHAT LIPID-LOWERING TRIAL ELIGIBILITY AND RANDOMIZATION FORM

Place ID label here

Patient name: _____

1. Date randomized to lipid-lowering trial (mm-dd-yy): __ __ - __ __ - __ __

Information from Chart Review and Visit 1

***Warning**: Only patients **not on** any lipid-lowering medication or large doses of non-prescription niacin (≥ 500 mg/day) in the last two months are eligible for the lipid-lowering trial. Patients previously on probucol must be off that drug for at least one year.*

2. Is patient eligible for the antihypertensive trial? ..... Yes ☐ 1
   STOP - patient is not eligible for the lipid-lowering trial, either ☚ No ☐ 2

	Yes	No
3. Does patient have evidence of CHD (known prior MI, angina, primary cardiac arrest, coronary stenosis > 50%, reversible perfusion defect, prior coronary revascularization procedure)?	☐ 1	☐ 2

Exclusion criteria for the lipid-lowering trial (*patient cannot meet any of the following criteria*):

4. Current use of prescribed lipid-lowering agents or ≥ 500 mg/day of non-prescription niacin, or use of probucol within the past year	☐ 1	☐ 2
5. Contraindications to HMG CoA reductase inhibitors (significant hepatic or renal disease, previous organ transplantation requiring immunosuppressive therapy, or known allergy or intolerance)	☐ 1	☐ 2
6. Known untreated secondary cause of hypercholesterolemia, such as nephrotic syndrome or untreated hypothyroidism	☐ 1	☐ 2

If *ANY* of items 4 through 6 are answered "*Yes*" then STOP - patient is ineligible.

Information from Visit 2

7. LDL cholesterol at Visit 2, from central laboratory ..... __ __ __ mg/dl

Must be between 120-189 mg/dl (100-159 mg/dl for patients with known CHD).

8. Triglycerides at Visit 2, from central laboratory ..... __ __ __ mg/dl

Must be less than 350 mg/dl.

	Yes	No
9. ALT value from central laboratory *confirmed* as > 2 times upper limit of normal?	☐ 1	☐ 2

Patients with Visit 2 ALT > 2 times upper limit of normal should have blood redrawn for confirmation of ALT by the central laboratory. Patients with ALT *confirmed* as > 2 times upper limit of normal from the central laboratory are not eligible.

Information from Visit 3

To randomize into lipid-lowering trial: Call 1-800-690-7870 between 7:00 a.m. and 7:00 p.m. Central time.

10. Lipid-lowering trial informed consent signed? . . . . . Yes ☐ 1
STOP, patient is not eligible ☛ No, refused ☐ 2

11. Patient is assigned to . . . . . Pravastatin ☐ 1
Usual Care ☐ 2

12. Initials of person completing this form: . . . . . ___ ___ ___

13. Signature of person completing this form . . . . . _____

☛ ***Initiate NCEP Step 1 diet***

Place ID label here

Patient name: _____

Fields-Marked Version

ALLHAT LIPID-LOWERING TRIAL ELIGIBILITY AND RANDOMIZATION FORM

2007 TCENTER
2008 PNUMBER
2009 RCENTER
2010 FORM
2011 VSN
2014 SEQ
2015
2016

Place ID label here

Patient name: _____

1. Date randomized to lipid-lowering trial (mm-dd-yy): __ __ - __ __ - __ __ (2013)

Information from Chart Review and Visit 1

Warning: *Only patients **not on** any lipid-lowering medication or large doses of non-prescription niacin (≥ 500 mg/day) in the last two months are eligible for the lipid-lowering trial. Patients previously on probucol must be off that drug for at least one year.*

2. Is patient eligible for the antihypertensive trial? ..... Yes ☐ 1 (2021)
   STOP - patient is not eligible for the lipid-lowering trial, either ... No ☐ 2

	Yes	No	
3. Does patient have evidence of CHD (known prior MI, angina, primary cardiac arrest, coronary stenosis > 50%, reversible perfusion defect, prior coronary revascularization procedure)?	☐ 1	☐ 2	(2022)

Exclusion criteria for the lipid-lowering trial (*patient cannot meet any of the following criteria*):

4. Current use of prescribed lipid-lowering agents or ≥ 500 mg/day of non-prescription niacin, or use of probucol within the past year	☐ 1	☐ 2	(2023)
5. Contraindications to HMG CoA reductase inhibitors (significant hepatic or renal disease, previous organ transplantation requiring immunosuppressive therapy, or known allergy or intolerance)	☐ 1	☐ 2	(2024)
6. Known untreated secondary cause of hypercholesterolemia, such as nephrotic syndrome or untreated hypothyroidism	☐ 1	☐ 2	(2025)

If *ANY* of items 4 through 6 are answered "*Yes*" then STOP - patient is ineligible.

Information from Visit 2

7. LDL cholesterol at Visit 2, from central laboratory ..... (2026) ___ mg/dl

Must be between 120-189 mg/dl (100-159 mg/dl for patients with known CHD).

8. Triglycerides at Visit 2, from central laboratory ..... (2027) ___ mg/dl

Must be less than 350 mg/dl.

		Yes	No
9.	ALT value from central laboratory *confirmed* as > 2 times upper limit of normal? (2028)	☐ 1	☐ 2

Patients with Visit 2 ALT > 2 times upper limit of normal should have blood redrawn for confirmation of ALT by the central laboratory. Patients with ALT *confirmed* as > 2 times upper limit of normal from the central laboratory are not eligible.

Information from Visit 3

To randomize into lipid-lowering trial: Call 1-800-690-7870 between 7:00 a.m. and 7:00 p.m. Central time.

10. Lipid-lowering trial informed consent signed? ..... Yes ☐ 1 (2029)
    STOP, patient is not eligible ☞ No, refused ☐ 2

11. Patient is assigned to ..... Pravastatin ☐ 1 (2030)
    Usual Care ☐ 2

12. Initials of person completing this form: ..... (2031) ___

13. Signature of person completing this form ..... P (2032) _____

☞ ***Initiate NCEP Step 1 diet***

Place ID label here

Patient name: _____

```
AL002 1 001I    1-  2 F2KPCOD          1        99 1
AL002 1 002IDR  3-  8 F2BATDAT         1    999999 1
AL002 1 003A    9- 10 F2VFCOD          1         9 0
AL002 1 004IDR 11- 16 F2DATMOD         1    999999 1
AL002 1 005I   17- 20 F2TIMMOD         1      9999 1
AL002 1 006I   21- 21 F2MODFLG         1         9 2
AL002 1 007I   22- 24 F2TCN            1       662 1       Y$
AL002 1 008I   25- 27 F2PNO            1       700 1       Y$
AL002 1 009I   28- 30 F2RCN            1       662 1       Y$
AL002 1 010I   35- 42 F2DATE8          1  99999999 2       Y$
AL002 1 011I   34- 34 F2VS             1         3 2       Y$
AL002 1 012I   35- 36 F2CENT          19        19 2       Y$
AL002 1 013IDR 37- 42 F02KEYDT         1    999999 1       Y$
AL002 1 014I   43- 43 F2SEQ            1         9 2       Y$
AL002 1 015A   44- 44 F2SITE           1         9 0       Y$
AL002 1 016A   45- 50 F2ACR            1         9 0       Y$
AL002 1 017I   51- 52 F2EDIT           0         3 2       Y$
AL002 1 018A   53- 63 F2RINO           1         9 0       Y$
AL002 1 019I   64- 66 F2PAYCN          1       999 1       Y$
AL002 1 020A   70- 80 F2CKNO           1         9 0       Y$
AL002 1 021I   81- 81 F02FD021         1         2 2
AL002 1 022I   82- 82 F02FD022         1         2 2
AL002 1 023I   83- 83 F02FD023         1         2 2
AL002 1 024I   84- 84 F02FD024         1         2 2
AL002 1 025I   85- 85 F02FD025         1         2 2
AL002 1 026I   86- 88 F02FD026         1         9 2
AL002 1 027I   89- 91 F02FD027         1         9 2
AL002 1 028I   92- 92 F02FD028         1         2 2
AL002 1 029I   93- 93 F02FD029         1         2 2
AL002 1 030I   94- 94 F02FD030         1         2 2
AL002 1 031A   95- 97 F02FD031         1         9 0
AL002 1 032I   98- 98 F02FD032         0         1 2
```

AL002 Version 2

ALLHAT LIPID-LOWERING TRIAL ELIGIBILITY AND RANDOMIZATION FORM

Place ID label here

Patient name: _____

1. Date randomized to lipid-lowering trial (mm-dd-yy): __ __ - __ __ - __ __

Review of Previous Information (see AL01 items #40-#43)

Only patients **not on** any lipid-lowering medication or large doses of non-prescription niacin (≥ 500 mg/day) in the last two months are eligible for the lipid-lowering trial. Patients previously on probucol must be off that drug for at least one year.

Patients with contraindication to HMG CoA reductase inhibitors (significant hepatic or renal disease, previous organ transplantation requiring immunosuppressive therapy, or known allergy or intolerance) are **not** eligible.

Patients with known untreated secondary cause of hypercholesterolemia, such as nephrotic syndrome or untreated hypothyroidism are **not** eligible.

Information from Visit 2

2. LDL cholesterol at Visit 2, from central laboratory . . . . . __ __ __ mg/dl

   LDL cholesterol must be between 120-189 mg/dl (100-129 mg/dl for patients with known CHD).

3. Triglycerides at Visit 2, from central laboratory . . . . . __ __ __ mg/dl

   Triglycerides must be less than 350 mg/dl.

4. Confirmed ALT value from central laboratory . . . . . __ __ __ IU/L

   Patients with Visit 2 ALT > 100 IU/L (2 times upper limit of normal) should have blood redrawn for confirmation of ALT by the central laboratory. Patients with ALT *confirmed* as > 100 from the central laboratory are not eligible.

To randomize into lipid-lowering trial: Call 1-800-690-7870 between 7:00 a.m. and 5:00 p.m. Central time Monday through Friday.

5. Lipid-lowering trial informed consent signed? . . . . . Yes ☐ 1
   STOP, patient is not eligible ☛ No, refused ☐ 2

6. Patient is assigned to . . . . . Pravastatin ☐ 1
   Usual Care ☐ 2

7. Initials of person completing this form: . . . . . __ __ __

8. Signature of person completing this form . . . . . _____

☛ ***Initiate NCEP Step 1 diet & draw blood for panel ALL02***

Fields-Marked Version

ALLHAT LIPID-LOWERING TRIAL ELIGIBILITY AND RANDOMIZATION FORM

Place ID label here

Patient name: _____

1. Date randomized to lipid-lowering trial (mm-dd-yy)__ __ - __ __ - __ __ (2013)

Review of Previous Information (see AL01 Items #40-#43)

Only patients **not on** any lipid-lowering medication or large doses of non-prescription niacin (≥ 500 mg/day) in the last two months are eligible for the lipid-lowering trial. Patients previously on probucol must be off that drug for at least one year.

Patients with contraindication to HMG CoA reductase inhibitors (significant hepatic or renal disease, previous organ transplantation requiring immunosuppressive therapy, or known allergy or intolerance) are **not** eligible.

Patients with known untreated secondary cause of hypercholesterolemia, such as nephrotic syndrome or untreated hypothyroidism are **not** eligible.

Information from Visit 2

2. Fasting LDL cholesterol at Visit 2, from central laboratory..... (2026) __ __ __ mg/dl

   Fasting LDL cholesterol must be between 120-189 mg/dl (100-159 mg/dl for patients with known CHD).

3. Fasting triglycerides at Visit 2, from central laboratory..... (2027) __ __ __ mg/dl

   Fasting triglycerides must be less than 350 mg/dl .

4. Confirmed ALT value from central laboratory ..... (2033) __ __ __ IU/L

   Patients with Visit 2 ALT > 100 IU/L (2 times upper limit of normal) should have blood redrawn for confirmation of ALT by the central laboratory. Patients with ALT *confirmed* as > 100 from the central laboratory are not eligible.

To randomize into lipid-lowering trial: Call 1-800-690-7870 between 7:00 a.m. and 7:00 p.m. Central time Monday through Friday.

5. Lipid-lowering trial informed consent signed?..... Yes ☐ 1 (2029)
   STOP, patient is not eligible ☜ No, refused ☐ 2

6. Patient is assigned to ..... Pravastatin ☐ 1 (2030)
   Usual Care ☐ 2

7. Initials of person completing this form: ..... (2031) __ __ __

8. Signature of person completing this form..... (2032) _____

☞ ***Initiate NCEP Step 1 diet***

```
AL002 2 001I    1-  2 F2KPCOD          1        99 1       Y$
AL002 2 002IDR  3-  8 F2BATDAT         1    999999 1       Y$
AL002 2 003A    9- 10 F2VFCOD          1         9 0       Y$
AL002 2 004IDR 11- 16 F2DATMOD         1    999999 1       Y$
AL002 2 005I   17- 20 F2TIMMOD         1      9999 1       Y$
AL002 2 006I   21- 21 F2MODFLG         1         9 2       Y$
AL002 2 007I   22- 24 F2TCN            1       662 1       Y$
AL002 2 008I   25- 27 F2PNO            1       700 1       Y$
AL002 2 009I   28- 30 F2RCN            1       662 1       Y$
AL002 2 010I   35- 42 F2DATE8          1  99999999 1       Y$
AL002 2 011I   34- 34 F2VS             1         9 2       Y$
AL002 2 012I   35- 36 F2CENT          19        99 1       Y$
AL002 2 013IDR 37- 42 F02KEYDT         1    999999 1       Y$
AL002 2 014I   43- 43 F2SEQ            1         9 2       Y$
AL002 2 015A   44- 44 F2SITE           1         9 0       Y$
AL002 2 016A   45- 50 F2ACR            1         9 0       Y$
AL002 2 017I   51- 52 F2EDIT           0         3 2       Y$
AL002 2 018A   53- 63 F2RINO           1         9 0       Y$
AL002 2 019I   64- 66 F2PAYCN          1       999 1       Y$
AL002 2 020A   70- 80 F2CKNO           1         9 0       Y$
AL002 2 026I   81- 83 F02FD026         0       999 1
AL002 2 027I   84- 86 F02FD027         0       999 1
AL002 2 033I   87- 89 F02FD033         0       999 1
AL002 2 029I   90- 90 F02FD029         1         2 2
AL002 2 030I   91- 91 F02FD030         1         2 2
AL002 2 031A   92- 94 F02FD031         1         9 0
AL002 2 032I   95- 95 F02FD032         0         1 2
```

AL003 - ALLHAT Follow-up Visit Form

See the **ALLHAT *Manual of Operations*** for completion schedule; some questions completed only at 2, 4, and 6 years. Also see the **ALLHAT *Manual of Operations*** for detailed instructions on blood pressure measurement; there are some valid diastolic blood pressure measures of 000.

Versions:

Version 1 – 01/94
Unique fields to version 1: F03082, F03099, F030100, F030101, F030102, F030103, F030106, F030107, F030108, F030109, F030110, F030111, F030112, F030113, F030114, F030115.

Version 2 – 06/94
Unique fields to version 2: F03119, F03120, F03121, F03122, F03123, F03124, F03125, F03126, F03127, F03128, F03129.

Version 3 – 02/96
Unique fields to version 3: F03131, F03140, F03141.

Version 4 – 07/98
Unique fields to version 4: F03143, F03144, F03145, F03146, F03147, F03148, F03149.

Fields unique to version 1 and 2 only: F03022, F03042, F03043, F03044, F03045, F03046, F03047, F03059, F03090, F03092, F03097, F03098.

Fields unique to versions 1, 2, and 3 only: F03039, F03040, F03048, F03067, F03068, F03070, F03091, F03093, F03094, F03095, F03096, F030.

Fields unique to version 2 and 3 only: F03117, F03118.

Fields unique to versions 2, 3, and 4 only: F03116.

Fields unique to versions 3 and 4: F03132, F03133, F03134, F03135, F03136, F03137, F03138, F03139.

Modified Fields for LADS Master File:

Blanked:

F03018 (versions 1,2,3,4)
F03019 (versions 1,2,3,4)
F03020 (versions 1,2,3,4)
F03029 (versions 1,2,3,4)
F03083 (versions 1,2,3,4)
F03084 (versions 1,2,3,4)
F03085 (versions 1,2,3,4)
F03086 (versions 1,2,3,4)
F03087 (versions 1,2,3,4)
F03088 (versions 1,2,3,4)
F03089 (versions 1,2,3,4)
F03104 (versions 1,2,3,4)
F03106 (version 1)
F03107 (version 1)
F03108 (version 1)
F03109 (version 1)
F03110 (version 1)
F03111 (version 1)
F03112 (version 1)
F03113 (version 1)
F03114 (version 1)
F03115 (version 1)

Changed date (mmddyy) to days since randomization:
F03090 (versions 1,2)

Coding details:

Blood pressure fields (F03023, F03024, F03025, F03026, F03027, F03028, and F03029) are coded as "999" for missing/invalid values.

Hospitalizations and clinic visits - F03030, F03031 are coded as "99" for invalid values.

Step 1 capsules returned (F03039, F03040) are coded as "999" if unable to determine measurement and "000" if empty bottles returned.

AL003 Version 1

ALLHAT FOLLOW-UP VISIT FORM

Place ID label here

Patient name: _____

1. a. Today's date: __ __ - __ __ - __ __ (mm-dd-yy)

   b. Visit #: __ __

2. a. Blood pressure cuff size . . . . . Pediatric (16.0 - 22.5 cm) ☐ 1
   Regular adult (22.6 - 30.0 cm) ☐ 2
   Large arm (30.1 - 37.5 cm) ☐ 3
   Thigh (37.6 - 43.7 cm) ☐ 4

   b. Seated blood pressure readings (mm Hg) . . . . . __ __ __ / __ __ __

   __ __ __ / __ __ __

   Average: __ __ __ / __ __ __

   Blood pressure goals are <90 mmHg diastolic and <140 mmHg systolic. Treatment should be intensified for patients with BP levels ≥160 mmHg systolic or ≥100 mmHg diastolic.

   c. Initials of person performing blood pressure measurements . . . . . __ __ __

Interval History:

3. Number of overnight hospitalizations since the patient's last ALLHAT visit (none = 00) . . . . . __ __

4. Number of visits to a doctor's office or clinic since the patient's last ALLHAT visit (none = 00) . . . . __ __

5. Since the last visit, has the participant experienced any of the following:

	Hospitalized or Procedure	Not Hospitalized But Treated	No
a. Myocardial infarction	☐ 1	☐ 2	☐ 3
b. Stroke	☐ 1	☐ 2	☐ 3
c. Congestive heart failure	☐ 1	☐ 2	☐ 3
d. Angina pectoris	☐ 1	☐ 2	☐ 3
e. Peripheral arterial disease	☐ 1	☐ 2	☐ 3
f. A new diagnosis of cancer	☐ 1	☐ 2	☐ 3

Please complete an Event Form (AL04) for all events in Items 5a-f involving a hospitalization or procedure, and for all non-hospitalized but treated myocardial infarctions and strokes.

6. a. Considering the Step 1 (blinded) ALLHAT antihypertensive medications, what proportion of ALLHAT antihypertensive medications does the patient report having taken since the last visit? . . . . . < 80% ☐ 1
   ≥ 80% ☐ 2
   Go to #7 ☛ Not on ALLHAT Step 1 medications ☐ 3
   Unable to determine ☐ 4

b. How many study capsules (Step 1 blinded) have been returned? (If unable to determine, use "999" for cylinder measurement.) . . . . . ___ ___ ___ mls (cylinder) or ___ ___ ___ capsules

Encourage patients reporting taking less than 80% of their medications to take their medications regularly as prescribed.

7. ALLHAT Step 1 antihypertensive medication prescription this visit . . . . . Dose 1 ☐ 1
Dose 2 ☐ 2
Dose 3 ☐ 3
None ☐ 4

8. Open-label ALLHAT medication prescription this visit . . . . . a. None (skip to #9) ☐ 1
b. Reserpine mg/day 0.___ ___
c. Clonidine mg/day 0.___
d. Atenolol mg/day ___ ___
e. Hydralazine mg/day ___ ___ ___
f. K supplement meq/day ___ ___

9. If any Step 1 antihypertensive study medications are decreased or stopped, or if the patient is not on Step 1 antihypertensive study drugs, please give reason (check all that apply) . . . . . a. Not applicable (go to #10) ☐ 1
b. Morbid event ☐ 1
c. Symptomatic adverse effect ☐ 1
d. Other adverse effect (e.g., laboratory) ☐ 1
e. Blood pressure too high ☐ 1
f. Blood pressure too low ☐ 1
g. Refusal ☐ 1
h. Other non-medical reason ☐ 1
i. Other (specify) _____ ☐ 1

10. Other current open-label antihypertensive or lipid-lowering medication use (check all that apply) . . . . . a. None (go to #11) ☐ 1
b. Diuretic ☐ 1
c. Calcium channel blocker ☐ 1
d. ACE inhibitor ☐ 1
e. Alpha blocker ☐ 1
f. Other antihypertensive medication ☐ 1
g. HMG CoA reductase inhibitor (including study pravastatin) ☐ 1
h. Other lipid-lowering medication (including niacin and resins) ☐ 1

At Visit 3, go to Item #21. At subsequent visits, for patients not assigned to pravastatin, skip items #11-13.

11. a. What proportion of ALLHAT pravastatin tablets does the patient report having taken since the last visit? . . . . . < 80%) ☐ 1
≥ 80% ☐ 2
Go to #12 ☚ Not on pravastatin ☐ 3
Unable to determine ☐ 4

Place ID label here

Patient name: _____

b. How many pravastatin tablets have been returned? . . . . . __ __ __ mls (cylinder) or __ __ __ tablets
(If unable to determine, use "999" for cylinder measurement.)

Encourage patients reporting taking less than 80% of their medications to take their medications regularly as prescribed.

12. Pravastatin prescription this visit . . . . . Once per day ☐ 1
Twice per day ☐ 2
None ☐ 3

13. If pravastatin has been decreased or stopped, or if the patient is not on pravastatin, please give reason (check all that apply) . a. Not applicable (go to next section) ☐ 1
b. Morbid event ☐ 1
c. Symptomatic adverse effect ☐ 1
d. Other adverse effect (e.g., laboratory) ☐ 1
e. Refusal ☐ 1
f. Non-medical reason ☐ 1
g. Other (specify) _____ ☐ 1

Ask the following questions of the participant at 2 years, 4 years and 6 years (refer to patient's visit schedule):

14. In general, would you say your health is: . . . . . Excellent ☐ 1
Very good ☐ 2
Good ☐ 3
Fair ☐ 4
Poor ☐ 5
No answer/unknown ☐ 6

15. If you were to rate your current health on a scale of 0 to 100, with 100 being perfect health and 0 being death, what number would you rate yourself today?
(Code 999 if no answer or unknown) . . . . . __ __ __

16. Cigarette smoking . . . . . Current smoker ☐ 1
Past smoker ☐ 2
Never smoked ☐ 3
Unknown ☐ 4

17. Is patient currently taking *aspirin* regularly? . . . . . Yes ☐ 1
No ☐ 2
Don't know ☐ 3

18. If female, is patient currently taking oral estrogen? . . . . . Yes ☐ 1
No ☐ 2
Don't know ☐ 3

19. Social Security number: __ __ __ - __ __ - __ __ __ __

20. Medicare number: __ __ __ - __ __ - __ __ __ __ - __

Place ID label here

Patient name: _____

21. Date of next visit (mm-dd-yy) . . . . . __ __ - __ __ - __ __

22. Are you re-dispensing returned medicine at this visit? . . . . . Yes ☐ 1
No ☐ 2
None returned ☐ 3

23. Number of *new* bottles dispensed this visit
(small = 30-day supply, large = 120-day supply) . . . . . a. Step 1 Dose 0: ___

b. Step 1 Dose 1: ___ small ___ large

c. Step 1 Dose 2: ___ small ___ large

d. Pravastatin: ___ small ___ large

e. Reserpine ___

f. Clonidine ___

g. Atenolol ___

h. Hydralazine ___

i. K Supplement ___

24. Initials of person completing this form: . . . . . __ __ __

25. Signature of person completing this form . . . . . _____

At Visit 3 (1 Month), if the participant is eligible and willing to participate in the lipid-lowering trial, perform lipid randomization.

Check patient's visit schedule to determine labwork and ECGs to be done at this visit. At Visit 3, patients randomized to the lipid-lowering trial should have blood drawn for a lipid profile.

Place ID label here

Patient name: _____

Fields-Marked Version

ALLHAT FOLLOW-UP VISIT FORM

3007 TCENTER 3010 FORM
3008 PNUMBER **Place ID label here** 3011 VSV
3009 RCENTER 3015 SITE 3014 SEC
Patient name: _____

3016 ACROSTIC

1. a. Today's date: __ __ - __ __ - __ __ (3013)
(mm-dd-yy)

b. Visit #: __ __ (3021)

2. a. Blood pressure cuff size ..... Pediatric (16.0 - 22.5 cm) ☐ 1
Regular adult (22.6 - 30.0 cm) ☐ 2 (3022)
Large arm (30.1 - 37.5 cm) ☐ 3
Thigh (37.6 - 43.7 cm) ☐ 4

b. Seated blood pressure readings (mm Hg) ..... (3023) __ __ __ / __ __ __ (3024)
(3025) __ __ __ / __ __ __ (3026)

Blood pressure goals are <90 mmHg diastolic and <140 mmHg systolic. Treatment should be intensified for patients with BP levels ≥160 mmHg systolic or ≥100 mmHg diastolic.

Average: (3027) __ __ __ / __ __ __ (3028)

c. Initials of person performing blood pressure measurements ..... (3029) __ __ __

Interval History:

3. Number of overnight hospitalizations since the patient's last ALLHAT visit (none = 00) ..... (3030) __ __

4. Number of visits to a doctor's office or clinic since the patient's last ALLHAT visit (none = 00) .... __ __ (3031)

5. Since the last visit, has the participant experienced any of the following:

	Hospitalized or Procedure	Not Hospitalized But Treated	No	
a. Myocardial infarction	☐ 1	☐ 2	☐ 3	(3032)
b. Stroke	☐ 1	☐ 2	☐ 3	→ (3033)
c. Congestive heart failure	☐ 1	☐ 2	☐ 3	(3034)
d. Angina pectoris	☐ 1	☐ 2	☐ 3	→ (3035)
e. Peripheral arterial disease	☐ 1	☐ 2	☐ 3	(3036)
f. A new diagnosis of cancer	☐ 1	☐ 2	☐ 3	→ (3037)

Please complete an Event Form (AL04) for all events in items 5a-f involving a hospitalization or procedure, and for all non-hospitalized but treated myocardial infarctions and strokes.

6. a. Considering the Step 1 (blinded) ALLHAT antihypertensive medications, what proportion of ALLHAT antihypertensive medications does the patient report having taken since the last visit? ..... < 80% ☐ 1
≥ 80% ☐ 2 (3038)
Go to #7 ☜ Not on ALLHAT Step 1 medications ☐ 3
Unable to determine ☐ 4

b. How many study capsules (Step 1 blinded) have been returned? (If unable to determine, use "999" for cylinder measurement.) ..... 3039 ___ mls (cylinder) or 3040 ___ capsules

Encourage patients reporting taking less than 80% of their medications to take their medications regularly as prescribed.

7. ALLHAT Step 1 antihypertensive medication prescription this visit ..... Dose 1 ☐ 1
Dose 2 ☐ 2
Dose 3 ☐ 3
None ☐ 4 — 3041

8. Open-label ALLHAT medication prescription this visit ..... a. None (skip to #9) ☐ 1 — 3042
b. Reserpine mg/day 0.___ — 3043
c. Clonidine mg/day 0.___ — 3044
d. Atenolol mg/day ___ — 3045
e. Hydralazine mg/day ___ — 3046
f. K supplement meq/day ___ — 3047

9. If any Step 1 antihypertensive study medications are decreased or stopped, or if the patient is not on Step 1 antihypertensive study drugs, please give reason (check all that apply) ..... a. Not applicable (go to #10) ☐ 1 → 3048
b. Morbid event ☐ 1 — 3049
c. Symptomatic adverse effect ☐ 1 → 3050
3051 d. Other adverse effect (e.g., laboratory) ☐ 1
3052 → e. Blood pressure too high ☐ 1
f. Blood pressure too low ☐ 1 → 3053
3054 → g. Refusal ☐ 1
h. Other non-medical reason ☐ 1 — 3055
i. Other (specify) _____ ☐ 1 → 3056
3057

10. Other current open-label antihypertensive or lipid-lowering medication use (check all that apply) ..... 3058 a. None (go to #11) ☐ 1
b. Diuretic ☐ 1 → 3059
3060 c. Calcium channel blocker ☐ 1
d. ACE inhibitor ☐ 1 → 3061
3062 → e. Alpha blocker ☐ 1
3064 → f. Other antihypertensive medication ☐ 1 → 3063
g. HMG CoA reductase inhibitor (including study pravastatin) ☐ 1
h. Other lipid-lowering medication (including niacin and resins) ☐ 1 → 3065

At Visit 3, go to Item #21. At subsequent visits, for patients not assigned to pravastatin, skip items #11-13.

11. a. What proportion of ALLHAT pravastatin tablets does the patient report having taken since the last visit? ..... < 80%) ☐ 1
≥ 80% ☐ 2 — 3066
Go to #12 ← Not on pravastatin ☐ 3
Unable to determine ☐ 4

Place ID label here

Patient name: _____

b. How many pravastatin tablets have been returned? . . . . . 3067 ___ mls (cylinder) or 3068 ___ tablets
(If unable to determine, use "999" for cylinder measurement.)

Encourage patients reporting taking less than 80% of their medications to take their medications regularly as prescribed.

12. Pravastatin prescription this visit . . . . . Once per day ☐ 1
Twice per day ☐ 2
None ☐ 3 (3069)

13. If pravastatin has been decreased or stopped, or if the patient is not on pravastatin, please give reason (check all that apply)
a. Not applicable (go to next section) ☐ 1 (3070)
b. Morbid event ☐ 1 (3071)
c. Symptomatic adverse effect ☐ 1 (3072)
(3073) d. Other adverse effect (e.g., laboratory) ☐ 1
e. Refusal ☐ 1 (3074)
(3075) f. Non-medical reason ☐ 1
g. Other (specify) _____ ☐ 1 (3076)
(3077)

Ask the following questions of the participant at 2 years, 4 years and 6 years (refer to patient's visit schedule):

14. In general, would you say your health is: . . . . . Excellent ☐ 1
Very good ☐ 2
Good ☐ 3
Fair ☐ 4
Poor ☐ 5
No answer/unknown ☐ 6 (3078)

15. If you were to rate your current health on a scale of 0 to 100, with 100 being perfect health and 0 being death, what number would you rate yourself today? (Code 999 if no answer or unknown) . . . . . (3079) ___

16. Cigarette smoking . . . . . Current smoker ☐ 1
Past smoker ☐ 2
Never smoked ☐ 3
Unknown ☐ 4 (3080)

17. Is patient currently taking *aspirin* regularly? . . . . . Yes ☐ 1
No ☐ 2
Don't know ☐ 3 (3081)

18. If female, is patient currently taking oral estrogen? . . . . . Yes ☐ 1
No ☐ 2
Don't know ☐ 3 (3082)

19. Social Security number: (3083) ___ - (3084) ___ - (3085) ____

20. Medicare number: (3086) ___ - (3087) ___ - (3088) ____ - (3089) _

Place ID label here

Patient name: _____

21. Date of next visit (mm-dd-yy) ..... 3090 __ __ - __ __ - __ __

22. Are you re-dispensing returned medicine at this visit? ..... Yes ☐ 1 3091
No ☐ 2
None returned ☐ 3

23. Number of *new* bottles dispensed this visit
(small = 30-day supply, large = 120-day supply) .....

a. Step 1 Dose 0: ___ 3092

b. Step 1 Dose 1: 3093 ___ small 3094 ___ large

3095 c. Step 1 Dose 2: ___ small ___ large 3096

3097 d. Pravastatin: ___ small ___ large 3098

e. Reserpine ___ 3099

f. Clonidine ___ 3100

3101 g. Atenolol ___

h. Hydralazine ___ 3102

i. K Supplement ___ 3103

24. Initials of person completing this form: ..... 3104 ___

25. Signature of person completing this form ..... P 3105 _____

At Visit 3 (1 Month), if the participant is eligible and willing to participate in the lipid-lowering trial, perform lipid randomization.

Check patient's visit schedule to determine labwork and ECGs to be done at this visit. At Visit 3, patients randomized to the lipid-lowering trial should have blood drawn for a lipid profile.

Place ID label here

Patient name: _____

```
AL003 1 001I    1-  2 F3KPCOD          1        99 1       Y$
AL003 1 002IDR  3-  8 F3BATDAT         1    999999 1       Y$
AL003 1 003A    9- 10 F3VFCOD          1         9 0       Y$
AL003 1 004IDR 11- 16 F3DATMOD         1    999999 1       Y$
AL003 1 005I   17- 20 F3TIMMOD         1      9999 1       Y$
AL003 1 006I   21- 21 F3MODFLG         1         9 2       Y$
AL003 1 007I   22- 24 F3TCN            1       662 1       Y$
AL003 1 008I   25- 27 F3PNO            1       700 1       Y$
AL003 1 009I   28- 30 F3RCN            1       662 1       Y$
AL003 1 010I   35- 42 F3DATE8          1  99999999 1       Y$
AL003 1 011I   34- 34 F3VS             1         4 2       Y$
AL003 1 012I   35- 36 F3CENT          19        20 2       Y$
AL003 1 013IDR 37- 42 F03KEYDT         1    999999 1       Y$
AL003 1 014I   43- 43 F3SEQ            1         9 2       Y$
AL003 1 015A   44- 44 F3SITE           1         9 0       Y$
AL003 1 016A   45- 50 F3ACROS          1         9 0       Y$
AL003 1 017I   51- 52 F3EDIT           0         3 2       Y$
AL003 1 018A   53- 63 F3RINO           1         9 0       Y$
AL003 1 019I   64- 66 F3PAYCN          1       999 1       Y$
AL003 1 020A   70- 80 F3CKNO           1         9 0       Y$
AL003 1 021I   81- 82 F03FD021         0        99 1
AL003 1 022I   83- 83 F03FD022         1         4 2
AL003 1 023I   84- 86 F03FD023        60       300 1
AL003 1 024I   87- 89 F03FD024         0       200 1
AL003 1 025I   90- 92 F03FD025        60       300 1
AL003 1 026I   93- 95 F03FD026         0       200 1
AL003 1 027I   96- 98 F03FD027        60       300 1
AL003 1 028I   99-101 F03FD028         0       200 1
AL003 1 029A  102-104 F03FD029         1         9 0
AL003 1 030I  105-106 F03FD030         0        99 1
AL003 1 031I  107-108 F03FD031         0        99 1
AL003 1 032I  109-109 F03FD032         1         3 2
AL003 1 033I  110-110 F03FD033         1         3 2
AL003 1 034I  111-111 F03FD034         1         3 2
AL003 1 035I  112-112 F03FD035         1         3 2
AL003 1 036I  113-113 F03FD036         1         3 2
AL003 1 037I  114-114 F03FD037         1         3 2
AL003 1 038I  115-115 F03FD038         1         4 2
AL003 1 039I  116-118 F03FD039         1         9 2
AL003 1 040I  119-121 F03FD040         1         9 2
AL003 1 041I  122-122 F03FD041         1         4 2
AL003 1 042I  123-123 F03FD042         0         1 2
AL003 1 043I  124-125 F03FD043         0        99 1
AL003 1 044I  126-126 F03FD044         0         9 1
AL003 1 045I  127-128 F03FD045         0        99 1
AL003 1 046I  129-131 F03FD046         0       999 1
AL003 1 047I  132-133 F03FD047         0        99 1
AL003 1 048I  134-134 F03FD048         0         1 2
AL003 1 049I  135-135 F03FD049         0         1 2
AL003 1 050I  136-136 F03FD050         0         1 2
AL003 1 051I  137-137 F03FD051         0         1 2
AL003 1 052I  138-138 F03FD052         0         1 2
AL003 1 053I  139-139 F03FD053         0         1 2
AL003 1 054I  140-140 F03FD054         0         1 2
AL003 1 055I  141-141 F03FD055         0         1 2
AL003 1 056I  142-142 F03FD056         1         9 2
AL003 1 057I  143-143 F03FD057         0         1 2
AL003 1 058I  144-144 F03FD058         0         1 2
AL003 1 059I  145-145 F03FD059         0         1 2
AL003 1 060I  146-146 F03FD060         0         1 2
AL003 1 061I  147-147 F03FD061         0         1 2
AL003 1 062I  148-148 F03FD062         0         1 2
AL003 1 063I  149-149 F03FD063         0         1 2
```

```
AL003 1 064I  150-150 F03FD064         0         1 2
AL003 1 065I  151-151 F03FD065         0         1 2
AL003 1 066I  152-152 F03FD066         1         4 2
AL003 1 067I  153-155 F03FD067         1         9 2
AL003 1 068I  156-158 F03FD068         1         9 2
AL003 1 069I  159-159 F03FD069         1         3 2
AL003 1 070I  160-160 F03FD070         0         1 2
AL003 1 071I  161-161 F03FD071         0         1 2
AL003 1 072I  162-162 F03FD072         0         1 2
AL003 1 073I  163-163 F03FD073         0         1 2
AL003 1 074I  164-164 F03FD074         0         1 2
AL003 1 075I  165-165 F03FD075         0         1 2
AL003 1 076I  166-166 F03FD076         1         9 2
AL003 1 077I  167-167 F03FD077         1         9 2
AL003 1 078I  168-168 F03FD078         1         6 2
AL003 1 079I  169-171 F03FD079         0       100 1
AL003 1 080I  172-172 F03FD080         1         4 2
AL003 1 081I  173-173 F03FD081         1         3 2
AL003 1 082I  174-174 F03FD082         1         3 2
AL003 1 083A  175-177 F03FD083         1         9 2
AL003 1 084A  178-179 F03FD084         1         9 2
AL003 1 085A  180-183 F03FD085         1         9 2
AL003 1 086A  184-186 F03FD086         1         9 2
AL003 1 087A  187-188 F03FD087         1         9 2
AL003 1 088A  189-192 F03FD088         1         9 2
AL003 1 089A  193-194 F03FD089         1         9 2
AL003 1 090ID 195-200 F03FD090         1         9 2
AL003 1 091I  201-201 F03FD091         1         9 2
AL003 1 092I  202-203 F03FD092         1         9 2
AL003 1 093I  204-205 F03FD093         1         9 2
AL003 1 094I  206-207 F03FD094         1         9 2
AL003 1 095I  208-209 F03FD095         1         9 2
AL003 1 096I  210-211 F03FD096         1         9 2
AL003 1 097I  212-213 F03FD097         1         9 2
AL003 1 098I  214-215 F03FD098         1         9 2
AL003 1 099I  216-217 F03FD099         1         9 2
AL003 1 100I  218-219 F03FD100         1         9 2
AL003 1 101I  220-221 F03FD101         1         9 2
AL003 1 102I  222-223 F03FD102         1         9 2
AL003 1 103I  224-225 F03FD103         1         9 2
AL003 1 104A  226-228 F03FD104         1         9 0
AL003 1 105I  229-229 F03FD105         1         9 2
AL003 1 106I  230-235 F03FD106         0    999999 1
AL003 1 107I  236-236 F03FD107         0         9 1
AL003 1 108I  237-242 F03FD108         0    999999 1
AL003 1 109I  243-243 F03FD109         0         9 1
AL003 1 110I  244-249 F03FD110         0    999999 1
AL003 1 111I  250-250 F03FD111         0         9 1
AL003 1 112I  251-256 F03FD112         0    999999 1
AL003 1 113I  257-257 F03FD113         0         9 1
AL003 1 114I  258-263 F03FD114         0    999999 1
AL003 1 115I  264-264 F03FD115         0         9 1       Y$
```

AL003 Version 2

ALLHAT FOLLOW-UP VISIT FORM

Place ID label here

Patient name: _____

1. a. Today's date: __ __ - __ __ - __ __ (mm-dd-yy)

   b. Visit # (range 03 - 26): __ __

2. a. Blood pressure cuff size . . . . . Pediatric (16.0 - 22.5 cm) ☐ 1
   Regular adult (22.6 - 30.0 cm) ☐ 2
   Large arm (30.1 - 37.5 cm) ☐ 3
   Thigh (37.6 - 43.7 cm) ☐ 4

   b. Seated blood pressure readings (mm Hg) . . . . . __ __ __ / __ __ __

   __ __ __ / __ __ __

   Average: __ __ __ / __ __ __

   Patient should be seated for five minutes without smoking, feet flat on the floor, in an erect but comfortable position.

   Blood pressure goals are <90 mmHg diastolic and <140 mmHg systolic.

   c. Initials of person performing blood pressure measurements . . . . . __ __ __

Interval History:

3. Number of overnight hospitalizations since the patient's last ALLHAT visit (none = 00) . . . . . __ __

4. Number of visits to a doctor's office or clinic since the patient's last ALLHAT visit (none = 00) . . . . . __ __
   (Includes interim visits to ***ALLHAT*** clinic for BP checks.)

5. Since the last visit, has the participant experienced any of the following:
   (Please answer all Items #5a-g.)

	Hospitalized or Procedure	Not Hospitalized But Treated	No
a. Acute myocardial infarction	☐ 1	☐ 2	☐ 3
b. Stroke	☐ 1	☐ 2	☐ 3
c. Congestive heart failure	☐ 1	☐ 2	☐ 3
d. Angina pectoris	☐ 1	☐ 2	☐ 3
e. Peripheral arterial disease	☐ 1	☐ 2	☐ 3
f. A new diagnosis of cancer (not non-melanoma skin cancer)	☐ 1	☐ 2	☐ 3
g. Accident or attempted suicide	☐ 1	☐ 2	☐ 3

Please complete an Event Reporting Form (AL04) for all events in Items 5a-g involving a hospitalization or procedure, and for all non-hospitalized but treated myocardial infarctions and strokes.

6. a. Considering the Step 1 (blinded) ALLHAT antihypertensive medications, what proportion of ALLHAT antihypertensive medications does the patient report having taken since the last visit? . . . . . < 80% ☐ 1
   ≥ 80% ☐ 2
   Go to #7 ☚ Not on ALLHAT Step 1 medications ☐ 3
   Unable to determine ☐ 4

b. How many study capsules (Step 1 blinded) have been returned? (If unable to determine, use "999" for cylinder measurement.) . . . . . __ __ __ mls (cylinder) or __ __ __ capsules

Encourage patients reporting taking less than 80% of their medications to take their medications regularly as prescribed.

7. ALLHAT Step 1 antihypertensive medication prescription this visit . . . . . Dose 1 ☐ 1
Dose 2 ☐ 2
Dose 3 ☐ 3
None ☐ 4

8. If any Step 1 antihypertensive study medications are decreased or stopped, or if the patient is not on Step 1 antihypertensive study drugs, please give reason (*check all that apply*) . . . . . a. Not applicable (go to #9) ☐ 1
b. Morbid event ☐ 1
c. Symptomatic adverse effect ☐ 1
d. Other adverse effect (e.g., laboratory) ☐ 1
e. Blood pressure too high ☐ 1
f. Blood pressure too low ☐ 1
g. Refusal ☐ 1
h. Other non-medical reason ☐ 1
i. Other (specify) _____ ☐ 1

9. Open-label ALLHAT medication prescription this visit . . . . . a. None (skip to #9) ☐ 1
b. Reserpine mg/day 0.__ __
c. Clonidine mg/day 0.__
d. Atenolol mg/day __ __ __
e. Hydralazine mg/day __ __ __
f. K supplement meq/day __ __

10. Current open-label antihypertensive or lipid-lowering medication use (*check all that apply*) . . . . . a. None (go to #11) ☐ 1
b. Diuretic ☐ 1
c. Calcium channel blocker ☐ 1
d. ACE inhibitor ☐ 1
e. Alpha blocker ☐ 1
f. Other antihypertensive medication ☐ 1
g. HMG CoA reductase inhibitor (including study pravastatin) ☐ 1
h. Other lipid-lowering medication (including niacin, resins and probucol) ☐ 1

11. a. What proportion of ALLHAT pravastatin tablets does the patient report having taken since the last visit? . . . . . < 80%) ☐ 1
≥ 80% ☐ 2
Go to #12 ☎ Not on ALLHAT pravastatin ☐ 3
Unable to determine ☐ 4

b. How many pravastatin tablets have been returned? . . . . . __ __ __ mls (cylinder) or __ __ __ tablets
(If unable to determine, use "999" for cylinder measurement.)

Encourage patients reporting taking less than 80% of their medications to take their medications regularly as prescribed.

Place ID label here

Patient name: _____

12. ALLHAT pravastatin prescription this visit . . . . . 10 mg ☐ 1
20 mg ☐ 2
40 mg ☐ 3
None ☐ 4

13. If ALLHAT pravastatin has been decreased or stopped, or if the patient is not on ALLHAT pravastatin, please give reason (check all that apply) . . . . . a. Not applicable (go to next section) ☐ 1
b. Morbid event ☐ 1
c. Symptomatic adverse effect ☐ 1
d. Other adverse effect (e.g., laboratory) ☐ 1
e. Refusal ☐ 1
f. Non-medical reason ☐ 1
g. Other (specify) _____ ☐ 1

Ask the following questions of the participant at 2 years, 4 years and 6 years (refer to patient's visit schedule):

14. In general, would you say your health is: . . . . . Excellent ☐ 1
Very good ☐ 2
Good ☐ 3
Fair ☐ 4
Poor ☐ 5
No answer/unknown ☐ 6

15. If you were to rate your current health on a scale of 0 to 100, with 100 being perfect health and 0 being death, what number would you rate yourself today? (Code 999 if no answer or unknown) . . . . . ___ ___ ___

16. ***Cigarette*** smoking . . . . . Current smoker ☐ 1
Past smoker ☐ 2
Never smoked ☐ 3
Unknown ☐ 4

17. Is patient currently taking *aspirin* regularly? . . . . . Yes ☐ 1
No ☐ 2
Don't know ☐ 3

18. ***For women only:*** Is patient currently prescribed an estrogen supplement? . . . . . Oral ☐ 1
Patch ☐ 2
No ☐ 3
Don't know ☐ 4

19. Social Security number . . . . . ___ ___ ___ - ___ ___ - ___ ___ ___ ___

20. Medicare number (required for patients ≥ 65 years of age) . . . . . ___ ___ ___ - ___ ___ - ___ ___ ___ ___ - ___

Place ID label here

Patient name: _____

21. Date of next visit (mm-dd-yy) . . . . . __ __ - __ __ - __ __

22. Are you re-dispensing returned medicine at this visit? . . . . . Yes ☐ 1
No ☐ 2
None returned ☐ 3

23. ***Number*** of *new* bottles dispensed this visit
(small = 44-count, large = 134-count) . . . . . a. No ALLHAT medications dispensed ☐ 1

For Items #23b - #23j, do not use X or ✓, but indicate the ***number*** of new bottles dispensed. Take care to differentiate between small and large bottles.

b. Restart kit ___

c. Step 1 Dose 0: ___

c. Step 1 Dose 1	___ small	___ large
d. Step 1 Dose 2/3	___ small	___ large
e. Pravastatin	___ small	___ large
f. Reserpine	___ small	___ large
g. Clonidine	___ small	___ large
h. Atenolol	___ small	___ large
i. Hydralazine	___ small	___ large
j. K Supplement	___ small	___ large

24. Initials of person completing this form: . . . . . __ __ __

25. Signature of person completing this form . . . . . _____

At Visit 3 (1 Month), if the participant is eligible and willing to participate in the lipid-lowering trial, perform lipid randomization.

Check patient's visit schedule to determine labwork and ECGs to be done at this visit. At Visit 3, patients randomized to the lipid-lowering trial should have blood drawn for a lipid profile (panel ALL02 on the laboratory request slip).

Place ID label here

Patient name: _____

Fields-Marked Version

ALLHAT FOLLOW-UP VISIT FORM

Place ID label here

Patient name: _____

1. a. Today's date: __ __ - __ __ - __ __ (mm-dd-yy) 3013

   b. Visit # (range 03 - 26): __ __ 3021

2. a. Blood pressure cuff size ..... Pediatric (16.0 - 22.5 cm) ☐ 1 3022
   Regular adult (22.6 - 30.0 cm) ☐ 2
   Large arm (30.1 - 37.5 cm) ☐ 3
   Thigh (37.6 - 43.7 cm) ☐ 4

   b. Seated blood pressure readings (mm Hg) ..... 3023 __ __ __ / __ __ __ 3024

   Patient should be seated for five minutes without smoking, feet flat on the floor, in an erect but comfortable position.
   Blood pressure goals are <90 mmHg diastolic and <140 mmHg systolic.

   3025 __ __ __ / __ __ __ 3026

   3027 Average: __ __ __ / __ __ __ 3028

   c. Initials of person performing blood pressure measurements ..... __ __ __ 3029

Interval History:

3. Number of overnight hospitalizations since the patient's last ALLHAT visit (none = 00)..... __ __ 3030

4. Number of visits to a doctor's office or clinic since the patient's last ALLHAT visit (none = 00)..... __ __ 3031
   (Includes interim visits to ***ALLHAT*** clinic for BP checks.)

5. Since the last visit, has the participant experienced any of the following:
   (Please answer all Items #5a-g.)

		Hospitalized or Procedure	Not Hospitalized But Treated	No
a.	Acute myocardial infarction	3032 ☐ 1	☐ 2	☐ 3
b.	Stroke	3033 ☐ 1	☐ 2	☐ 3
c.	Congestive heart failure	3034 ☐ 1	☐ 2	☐ 3
d.	Angina pectoris	3035 ☐ 1	☐ 2	☐ 3
e.	Peripheral arterial disease	3036 ☐ 1	☐ 2	☐ 3
f.	A new diagnosis of cancer (not non-melanoma skin cancer)	3037 ☐ 1	☐ 2	☐ 3
g.	Accident or attempted suicide	3116 ☐ 1	☐ 2	☐ 3

Please complete an Event Reporting Form (AL04) for all events in Items 5a-g involving a hospitalization or procedure, and for all non-hospitalized but treated myocardial infarctions and strokes.

6. a. Considering the Step 1 (blinded) ALLHAT antihypertensive medications, what proportion of ALLHAT antihypertensive medications does the patient report having taken since the last visit? ..... < 80% ☐ 1 3038
   ≥ 80% ☐ 2
   Go to #7 ☜ Not on ALLHAT Step 1 medications ☐ 3
   Unable to determine ☐ 4

b. How many study capsules (Step 1 blinded) have been returned? (If unable to determine, use "999" for cylinder measurement.) ..... 3039 ___ mls (cylinder) or 3040 ___ capsules

Encourage patients reporting taking less than 80% of their medications to take their medications regularly as prescribed.

7. ALLHAT Step 1 antihypertensive medication prescription this visit ..... Dose 1 ☐ 1 3041
Dose 2 ☐ 2
Dose 3 ☐ 3
None ☐ 4

8. If any Step 1 antihypertensive study medications are decreased or stopped, or if the patient is not on Step 1 antihypertensive study drugs, please give reason (*check all that apply*) ..... a. Not applicable (go to #9) ☐ 1 3048
3049 b. Morbid event ☐ 1
c. Symptomatic adverse effect ☐ 1 3050
3051 d. Other adverse effect (e.g., laboratory) ☐ 1
e. Blood pressure too high ☐ 1 3052
3053 f. Blood pressure too low ☐ 1
g. Refusal ☐ 1 3054
3055 h. Other non-medical reason ☐ 1
i. Other (specify) _____ 3057 _____ ☐ 1 3056

9. Open-label ALLHAT medication prescription this visit ..... a. None (skip to #9) ☐ 1 3042
b. Reserpine mg/day 0.___ 3043
c. Clonidine mg/day 0.___ 3044
d. Atenolol mg/day ___ 3045
e. Hydralazine mg/day ___ 3046
f. K supplement meq/day ___ 3047

10. Current open-label antihypertensive or lipid-lowering medication use (*check all that apply*) ..... a. None (go to #11) ☐ 1 3058
3059 b. Diuretic ☐ 1
c. Calcium channel blocker ☐ 1 3060
3061 d. ACE inhibitor ☐ 1
e. Alpha blocker ☐ 1 3062
3063 f. Other antihypertensive medication ☐ 1
g. HMG CoA reductase inhibitor (including study pravastatin) ☐ 1 3064
h. Other lipid-lowering medication (including niacin, resins and probucol) ☐ 1 3065

11. a. What proportion of ALLHAT pravastatin tablets does the patient report having taken since the last visit? ..... < 80%) ☐ 1 3066
≥ 80% ☐ 2
Go to #12 ☜ Not on ALLHAT pravastatin ☐ 3
Unable to determine ☐ 4

b. How many pravastatin tablets have been returned? ..... 3067 ___ mls (cylinder) or ___ tablets 3068
(If unable to determine, use "999" for cylinder measurement.)

Encourage patients reporting taking less than 80% of their medications to take their medications regularly as prescribed.

Place ID label here

Patient name: _____

12. ALLHAT pravastatin prescription this visit ..... 10 mg ☐ 1 (3069)
20 mg ☐ 2
40 mg ☐ 3
None ☐ 4

13. If ALLHAT pravastatin has been decreased or stopped, or if the patient is not on ALLHAT pravastatin, please give reason (check all that apply) ..... a. Not applicable (go to next section) ☐ 1 (3070)
(3071) b. Morbid event ☐ 1
c. Symptomatic adverse effect ☐ 1 (3072)
(3073) d. Other adverse effect (e.g., laboratory) ☐ 1
e. Refusal ☐ 1 (3074)
(3075) f. Non-medical reason ☐ 1
g. Other (specify) _____ (3077) _____ ☐ 1 (3076)

Ask the following questions of the participant at 2 years, 4 years and 6 years (refer to patient's visit schedule):

14. In general, would you say your health is: ..... Excellent ☐ 1 (3078)
Very good ☐ 2
Good ☐ 3
Fair ☐ 4
Poor ☐ 5
No answer/unknown ☐ 6

15. If you were to rate your current health on a scale of 0 to 100, with 100 being perfect health and 0 being death, what number would you rate yourself today? (Code 999 if no answer or unknown) ..... ___ ___ ___ (3079)

16. ***Cigarette*** smoking ..... Current smoker ☐ 1 (3080)
Past smoker ☐ 2
Never smoked ☐ 3
Unknown ☐ 4

17. Is patient currently taking *aspirin* regularly? ..... Yes ☐ 1 (3081)
No ☐ 2
Don't know ☐ 3

18. ***For women only:*** Is patient currently prescribed an estrogen supplement? ..... Oral ☐ 1 (3117)
Patch ☐ 2
No ☐ 3
Don't know ☐ 4

19. Social Security number ..... (3083) (3084) ___ ___ ___ - ___ ___ - ___ ___ ___ ___ (3085)

20. Medicare number (required for patients ≥ 65 years of age) (3086) (3087) ___ ___ ___ - ___ ___ - ___ ___ (3088) ___ - ___ (3089)

Place ID label here

Patient name: _____

21. Date of next visit (mm-dd-yy)..... __ __ - __ __ - __ __ 3090

22. Are you re-dispensing returned medicine at this visit? ..... Yes ☐ 1 3091
No ☐ 2
None returned ☐ 3

23. ***Number*** of *new* bottles dispensed this visit
(small = 44-count, large = 134-count) .....a. No ALLHAT medications dispensed ☐ 1 3118

NOTE >>>Original form has d-k miss-labeled as c-j.

b. Restart kit ___ 3119

c. Step 1 Dose 0: ___ 3092

For Items #23b - #23j, do not use X or ✓, but indicate the ***number*** of new bottles dispensed. Take care to differentiate between small and large bottles

3093	*d. Step 1 Dose 1	___ small	___ large	3094
3095	e. Step 1 Dose 2/3	___ small	___ large	3096
3097	f. Pravastatin	___ small	___ large	3098
3120	g. Reserpine	___ small	___ large	3121
3122	h. Clonidine	___ small	___ large	3123
3124	i. Atenolol	___ small	___ large	3125
3126	j. Hydralazine	___ small	___ large	3127
3128	k. K Supplement	___ small	___ large	3129

24. Initials of person completing this form: ..... __ __ __ 3104

25. Signature of person completing this form..... _____ 3105

*** Note: On orignal forms used by clinic, items 23e-k were mislabeled as 23c-j.**

At Visit 3 (1 Month), if the participant is eligible and willing to participate in the lipid-lowering trial, perform lipid randomization.

Check patient's visit schedule to determine labwork and ECGs to be done at this visit. At Visit 3, patients randomized to the lipid-lowering trial should have blood drawn for a lipid profile (panel ALL 02 on the laboratory request slip).

Place ID label here

Patient name: _____

```
AL003 2 001I    1-  2 F3KPCOD          1        99 1       Y$
AL003 2 002IDR  3-  8 F3BATDAT         1    999999 1       Y$
AL003 2 003A    9- 10 F3VFCOD          1         9 0       Y$
AL003 2 004IDR 11- 16 F3DATMOD         1    999999 1       Y$
AL003 2 005I   17- 20 F3TIMMOD         1      9999 1       Y$
AL003 2 006I   21- 21 F3MODFLG         1         9 2       Y$
AL003 2 007I   22- 24 F3TCN            1       662 1       Y$
AL003 2 008I   25- 27 F3PNO            1       700 1       Y$
AL003 2 009I   28- 30 F3RCN            1       662 1       Y$
AL003 2 010I   35- 42 F3DATE8          1  99999999 1       Y$
AL003 2 011I   34- 34 F3VS             1         9 2       Y$
AL003 2 012I   35- 36 F3CENT          19        20 2       Y$
AL003 2 013IDR 37- 42 F03KEYDT         1    999999 1       Y$
AL003 2 014I   43- 43 F3SEQ            1         9 2       Y$
AL003 2 015A   44- 44 F3SITE           1         9 0       Y$
AL003 2 0161   45- 50 F3ACROS          1         3 1       Y$
AL003 2 017I   51- 52 F3EDIT           0         3 2       Y$
AL003 2 018A   53- 63 F3RINO           1         9 0       Y$
AL003 2 019I   64- 66 F3PAYCN          1       999 1       Y$
AL003 2 020A   70- 80 F3CKNO           1         9 0       Y$
AL003 2 021I   81- 82 F03FD021         0        99 1
AL003 2 022I   83- 83 F03FD022         1         4 2
AL003 2 023I   84- 86 F03FD023        60       300 1
AL003 2 024I   87- 89 F03FD024         0       200 1
AL003 2 025I   90- 92 F03FD025        60       300 1
AL003 2 026I   93- 95 F03FD026         0       200 1
AL003 2 027I   96- 98 F03FD027        60       300 1
AL003 2 028I   99-101 F03FD028         0       200 1
AL003 2 029A  102-104 F03FD029         1         9 0
AL003 2 030I  105-106 F03FD030         0        99 1
AL003 2 031I  107-108 F03FD031         0        99 1
AL003 2 032I  109-109 F03FD032         1         3 2
AL003 2 033I  110-110 F03FD033         1         3 2
AL003 2 034I  111-111 F03FD034         1         3 2
AL003 2 035I  112-112 F03FD035         1         3 2
AL003 2 036I  113-113 F03FD036         1         3 2
AL003 2 037I  114-114 F03FD037         1         3 2
AL003 2 116I  115-115 F03FD116         1         3 2
AL003 2 038I  116-116 F03FD038         1         4 2
AL003 2 039I  117-119 F03FD039         0       999 1
AL003 2 040I  120-122 F03FD040         0       999 1
AL003 2 041I  123-123 F03FD041         1         4 2
AL003 2 048I  124-124 F03FD048         0         1 2
AL003 2 049I  125-125 F03FD049         0         1 2
AL003 2 050I  126-126 F03FD050         0         1 2
AL003 2 051I  127-127 F03FD051         0         1 2
AL003 2 052I  128-128 F03FD052         0         1 2
AL003 2 053I  129-129 F03FD053         0         1 2
AL003 2 054I  130-130 F03FD054         0         1 2
AL003 2 055I  131-131 F03FD055         0         1 2
AL003 2 056I  132-132 F03FD056         0         1 2
AL003 2 057I  133-133 F03FD057         0         1 2
AL003 2 042I  134-134 F03FD042         0         1 2
AL003 2 043I  135-136 F03FD043         0        99 1
AL003 2 044I  137-137 F03FD044         0         9 1
AL003 2 045I  138-140 F03FD045         0       999 1
AL003 2 046I  141-143 F03FD046         0       999 1
AL003 2 047I  144-145 F03FD047         0        99 1
AL003 2 058I  146-146 F03FD058         0         1 2
AL003 2 059I  147-147 F03FD059         0         1 2
AL003 2 060I  148-148 F03FD060         0         1 2
AL003 2 061I  149-149 F03FD061         0         1 2
AL003 2 062I  150-150 F03FD062         0         1 2
```

```
AL003 2 063I  151-151 F03FD063         0         1 2
AL003 2 064I  152-152 F03FD064         0         1 2
AL003 2 065I  153-153 F03FD065         0         1 2
AL003 2 066I  154-154 F03FD066         0         4 2
AL003 2 067I  155-157 F03FD067         0       999 1
AL003 2 068I  158-160 F03FD068         0       999 1
AL003 2 069I  161-161 F03FD069         1         4 2
AL003 2 070I  162-162 F03FD070         0         1 2
AL003 2 071I  163-163 F03FD071         0         1 2
AL003 2 072I  164-164 F03FD072         0         1 2
AL003 2 073I  165-165 F03FD073         0         1 2
AL003 2 074I  166-166 F03FD074         0         1 2
AL003 2 075I  167-167 F03FD075         0         1 2
AL003 2 076I  168-168 F03FD076         0         1 2
AL003 2 077I  169-169 F03FD077         0         1 2
AL003 2 078I  170-170 F03FD078         0         6 2
AL003 2 079I  171-173 F03FD079         0       100 1
AL003 2 080I  174-174 F03FD080         0         4 2
AL003 2 081I  175-175 F03FD081         0         3 2
AL003 2 117I  176-176 F03FD117         0         4 2
AL003 2 083A  177-179 F03FD083         1       999 1
AL003 2 084A  180-181 F03FD084         1        99 1
AL003 2 085A  182-185 F03FD085         1      9999 1
AL003 2 086A  186-188 F03FD086         1       999 1
AL003 2 087A  189-190 F03FD087         1        99 1
AL003 2 088A  191-194 F03FD088         1      9999 1
AL003 2 089A  195-196 F03FD089         1        99 0
AL003 2 090AD 197-202 F03FD090         1    999999 1
AL003 2 091I  203-203 F03FD091         1         3 2
AL003 2 118I  204-204 F03FD118         0         1 2
AL003 2 119I  205-206 F03FD119         0        99 1
AL003 2 092I  207-208 F03FD092         0        99 1
AL003 2 093I  209-210 F03FD093         0        99 1
AL003 2 094I  211-212 F03FD094         0        99 1
AL003 2 095I  213-214 F03FD095         0        99 1
AL003 2 096I  215-216 F03FD096         0        99 1
AL003 2 097I  217-218 F03FD097         0        99 1
AL003 2 098I  219-220 F03FD098         0        99 1
AL003 2 120I  221-222 F03FD120         0        99 1
AL003 2 121I  223-224 F03FD121         0        99 1
AL003 2 122I  225-226 F03FD122         0        99 1
AL003 2 123I  227-228 F03FD123         0        99 1
AL003 2 124I  229-230 F03FD124         0        99 1
AL003 2 125I  231-232 F03FD125         0        99 1
AL003 2 126I  233-234 F03FD126         0        99 1
AL003 2 127I  235-236 F03FD127         0        99 1
AL003 2 128I  237-238 F03FD128         0        99 1
AL003 2 129I  239-240 F03FD129         0        99 1
AL003 2 104A  241-243 F03FD104         1         9 0
AL003 2 105I  244-244 F03FD105         0         1 2
```

AL003 Version 3

ALLHAT FOLLOW-UP VISIT FORM - VERSION 3

Place ID label here

Patient name: _____

1. a. Today's date (mm-dd-yy): __ __ - __ __ - __ __

   b. Visit # (range 03 - 26): __ __

   c. Type of visit (check one): Clinic visit ☐ 1
   Telephone visit ☐ 2
   Postcard information ☐ 3

2. a. Seated blood pressure readings (mmHg) (use 999 for telephone visits and postcard information)

   Patient should be seated for five minutes without smoking, feet flat on the floor, in an erect but comfortable position. Be sure to use the correct cuff size: pediatric (16.0-22.5 cm), regular arm (22.6 - 30.0 cm), large arm (30.1 - 37.5 cm), thigh (37.6 - 43.7 cm). See Manual of Operations, Appendix B, for further instructions.

   Blood pressure goals are <90 mmHg diastolic and <140 mmHg systolic.

   __ __ __ / __ __ __
   __ __ __ / __ __ __
   Average: __ __ __ / __ __ __

   b. Initials of person performing blood pressure measurements (use 999 for telephone visits and postcard information) ..... __ __ __

Interval History:

3. Number of overnight hospitalizations since the patient's last ALLHAT visit (none = 00, unknown = 99) ..... __ __

4. Number of visits to any doctor's office or clinic since the patient's last ALLHAT visit (none = 00, unknown = 99) .. __ __
   (Includes interim visits to ***ALLHAT*** clinic for blood pressure measurements and/or drug titration.)

5. Since the last visit, has the participant experienced any of the following:
   (Please answer all Items #5a-h.)

	Hospitalized or Procedure*	Not Hospitalized But Treated	No
a. Acute myocardial infarction	☐ 1	☐ 2	☐ 3
b. Stroke	☐ 1	☐ 2	☐ 3
c. Congestive heart failure	☐ 1	☐ 2	☐ 3
d. Angina pectoris	☐ 1	☐ 2	☐ 3
e. Peripheral arterial disease	☐ 1	☐ 2	☐ 3
f. Cancer (a new diagnosis; not non-melanoma skin cancer)	☐ 1	☐ 2	☐ 3
g. Accident or attempted suicide	☐ 1	☐ 2	☐ 3
h. Kidney transplant or start of chronic dialysis	☐ 1	☐ 2	☐ 3

Complete an Event Reporting Form (AL04) for all events in items 5a-h involving a hospitalization or procedure, and for all non-hospitalized but treated myocardial infarctions and strokes (boxed items). *Refer to MOO Chapter 5 for examples of procedures.

6. a. Considering the Step 1 (blinded) ALLHAT antihypertensive medication, what percent of ALLHAT antihypertensive medication does the patient report having taken since the last visit? ..... < 80% ☐ 1
   ≥ 80% ☐ 2
   Go to #7 ☜ Not on ALLHAT Step 1 (blinded) medication ☐ 3
   Unable to determine ☐ 4

   b. How many of the Step 1 (blinded) study capsules did the patient return today? (Empty bottles returned = "000"; if unable to determine, use "999".) ..... __ __ __ mls (cylinder) or __ __ __ capsules

Count pills whenever possible; encourage patients reporting taking less than 80% of their medications to take their medications regularly as prescribed.

7. What dose of the ALLHAT Step 1 (blinded) antihypertensive medication is the patient being advised to take until the next visit?
   - Dose 1 ☐ 1
   - Dose 2 ☐ 2
   - Dose 3 ☐ 3
   - None ☐ 4

8. If the Step 1 (blinded) antihypertensive study medication dosage is decreased or stopped at this visit, or if the patient will not be taking the Step 1 (blinded) antihypertensive study drug, please give reason (*check all that apply*).
   - a. Not applicable (go to #9) ☐ 1
   - b. Morbid event ☐ 1
   - c. Symptomatic adverse effect ☐ 1
   - d. Other adverse effect (e.g., abnormal blood test) ☐ 1
   - e. Blood pressure too high ☐ 1
   - f. Blood pressure too low ☐ 1
   - g. Refusal ☐ 1
   - h. Other non-medical reason ☐ 1
   - i. Other (specify) _____ ☐ 1

9. What open-label antihypertensive or lipid-lowering medication is the patient being advised to take until the next visit? (*check all that apply*)

   This refers to any open-label antihypertensive or lipid-lowering medication, including medications provided by ALLHAT or from another source.

   - a. None (go to #10) ☐ 1
   - b. Diuretic 1-2 times per week ☐ 1
   - c. Diuretic 3 or more times per week ☐ 1
   - d. Calcium channel blocker ☐ 1
   - e. ACE inhibitor ☐ 1
   - f. Alpha blocker ☐ 1
   - g. Atenolol ☐ 1
   - h. Clonidine ☐ 1
   - I. Reserpine ☐ 1
   - j. Hydralazine ☐ 1
   - k. Other antihypertensive medication (specify) _____ ☐ 1
   - l. HMG CoA reductase inhibitor (including ALLHAT pravastatin) ☐ 1
   - m. Other lipid-lowering medication (including niacin, resins and probucol) ☐ 1
   - n. Potassium chloride or other potassium supplement ☐ 1

If patient is not participating in the lipid-lowering part of ALLHAT, or is not assigned to study pravastatin, or if the study pravastatin was assigned today, go to item #13.

10. a. What percent of ALLHAT pravastatin tablets does the patient having taken since the last visit?
    - < 80%) ☐ 1
    - ≥ 80% ☐ 2
    - Go to #11 ☎ Not on ALLHAT pravastatin ☐ 3
    - Unable to determine ☐ 4

    b. How many pravastatin tablets did the patient return today? ____ mls (cylinder) or ____ tablets
    (Empty bottles returned = "000"; if unable to determine, use "999".)

    Count tablets whenever possible; encourage patients reporting taking less than 80% of their medications to take their medications regularly as prescribed.

11. What dose of the ALLHAT pravastatin is the patient being advised to take until the next visit?
    - 10 mg ☐ 1
    - 20 mg ☐ 2
    - 40 mg ☐ 3
    - None ☐ 4

12. If ALLHAT pravastatin dosage has been decreased or stopped at this visit, or if the patient will not be taking the ALLHAT pravastatin, give reason (check all that apply).
    - a. Not applicable (go to next section) ☐ 1
    - b. Morbid event ☐ 1
    - c. Symptomatic adverse effect ☐ 1
    - d. Other adverse effect (e.g., abnormal blood test) ☐ 1
    - e. Refusal ☐ 1
    - f. Non-medical reason ☐ 1
    - g. Other (specify) _____ ☐ 1

Place ID label here

Patient name: _____

Ask the following questions of the participant at 2 years, 4 years and 6 years (refer to patient's visit schedule):

13. In general, would you say your health is: ..... Excellent ☐ 1
Very good ☐ 2
Good ☐ 3
Fair ☐ 4
Poor ☐ 5
No answer/unknown ☐ 6

14. If you were to rate your current health on a scale of 0 to 100, with 100 being perfect health and 0 being death, what number would you rate yourself today? (Unknown = 999) ..... ___ ___ ___

15. Have you ever smoked ***cigarettes***? ..... Current smoker (past 30 days) ☐ 1
Past smoker (100+ cigarettes) ☐ 2
Never smoked ☐ 3
Unknown ☐ 4

16. Are you currently taking *aspirin* regularly? ..... Yes ☐ 1
(Including aspirin-containing products; see Manual of Operations Chapter 2 for a list) No ☐ 2
Don't know ☐ 3

17. ***For women only:*** Are you currently prescribed an estrogen supplement? ..... Oral ☐ 1
Patch ☐ 2
No ☐ 3
Don't know ☐ 4

From clinic records (complete with 9's if not available):

18. Social Security number ..... ___ ___ ___ - ___ ___ - ___ ___ ___ ___

19. Medicare number (required for patients ≥65 years of age) ..... ___ ___ ___ - ___ ___ - ___ ___ ___ ___ - ___

20. a. Are you re-dispensing Step 1 (blinded) medications that the patient returned at this visit? ..... Dose 1 ☐ 1
Dose 2/3 ☐ 2
No ☐ 3

b. Are you re-dispensing ALLHAT pravastatin that the patient returned at this visit? ..... Yes ☐ 1
No ☐ 2

21. Number of new bottles dispensed this visit ..... a. Step 1 (blinded) Dose 1 ___ small ___ large
(Small = 44-count, large = 134-count)

For items #21a-c, indicate the ***number*** of new bottles dispensed (do not use X or ✓). Differentiate between small and large bottles.

b. Step 1 (blinded) Dose 2/3 ___ small ___ large

c. Pravastatin ___

d. No new bottles dispensed ☐ 1

22. Initials of person completing this form: ..... ___ ___ ___

23. Signature of person completing this form ..... _____

Place ID label here

Patient name: _____

At Visit 3 or 4 (1 month or 3 months), if the participant is eligible and willing to participate in the lipid-lowering trial, perform lipid randomization. Patients randomized to the lipid-lowering trial at Visit 3 or 4 should have blood drawn for a lipid profile (panel ALL02 on the laboratory request slip).

Check patient's visit schedule to determine labwork and ECGs to be done at this visit.

Schedule the patient's next ALLHAT visit according to their individual visit

Fields-Marked Version

ALLHAT FOLLOW-UP VISIT FORM - VERSION 3

Place ID label here

Patient name: _____

1. a. Today's date (mm-dd-yy): __ __ - __ __ - __ __ (3013)

   b. Visit # (range 03 - 26): __ __ (3021)

   c. Type of visit (check one): (3130)
   Clinic visit ☐ 1
   Telephone visit ☐ 2
   Postcard information ☐ 3

2. a. Seated blood pressure readings (mmHg) (use 999 for telephone visits and postcard information

   (3023) (3024)
   (3025) __ / __ (3026)
   Average : (3027) __ / (3028)

   Patient should be seated for five minutes without smoking, feet flat on the floor, in an erect but comfortable position. Be sure to use the correct cuff size: pediatric (16.0-22.5 cm), regular arm (22.6 - 30.0 cm), large arm (30.1 - 37.5 cm), thigh (37.6 - 43.7 cm). See Manual of Operations, Appendix B, for further instructions.

   Blood pressure goals are <90 mmHg diastolic and <140 mmHg systolic.

   b. Initials of person performing blood pressure measurements (use 999 for telephone visits and postcard information) . . . . . __ __ __ (3029)

Interval History:

3. Number of overnight hospitalizations since the patient's last ALLHAT visit (none = 00, unknown = 99) ..... __ __ (3030)

4. Number of visits to any doctor's office or clinic since the patient's last ALLHAT visit (none = 00, unknown = 99) . __ (3031)
   (Includes interim visits to ***ALLHAT*** clinic for blood pressure measurements and/or drug titration.)

5. Since the last visit, has the participant experienced any of the following:
   (Please answer all Items #5a-h.)

	Hospitalized or Procedure*	Not Hospitalized But Treated	No
a. Acute myocardial infarction (3032)	☐ 1	☐ 2	☐ 3
b. Stroke (3033)	☐ 1	☐ 2	☐ 3
c. Congestive heart failure (3034)	☐ 1	☐ 2	☐ 3
d. Angina pectoris (3035)	☐ 1	☐ 2	☐ 3
e. Peripheral arterial disease (3036)	☐ 1	☐ 2	☐ 3
f. Cancer (a new diagnosis; not non-melanoma skin cancer) (3037)	☐ 1	☐ 2	☐ 3
g. Accident or attempted suicide (3116)	☐ 1	☐ 2	☐ 3
h. Kidney transplant or start of chronic dialysis (3131)	☐ 1	☐ 2	☐ 3

Complete an Event Reporting Form (AL04) for all events in Items 5a-h involving a hospitalization or procedure, and for all non-hospitalized but treated myocardial infarctions and strokes (boxed items). *Refer to MOO Chapter 5 for examples of procedures.

6. a. Considering the Step 1 (blinded) ALLHAT antihypertensive medication , what percent of ALLHAT antihypertensive medication does the patient report having taken since the last visit?

   (3038) ..... < 80% ☐ 1
   ≥ 80% ☐ 2
   Go to #7 ☜ Not on ALLHAT Step 1 (blinded) medication ☐ 3
   Unable to determine ☐ 4

   b. How many of the Step 1 (blinded) study capsules did the patient return today? (Empty bottles returned = "000"; if unable to determine, use "999".) ..... (3039) __ __ __ mls (cylinder) or (3040) __ __ __ capsules

Count pills whenever possible; encourage patients reporting taking less than 80% of their medications to take their medications regularly as prescribed.

7. What dose of the ALLHAT Step 1 (blinded) antihypertensive medication is the patient being advised to take until the next visit?

3041 .... Dose 1 ☐ 1
Dose 2 ☐ 2
Dose 3 ☐ 3
None ☐ 4

8. If the Step 1 (blinded) antihypertensive study medication dosage is decreased or stopped at this visit, or if the patient will not be taking the Step 1 (blinded) antihypertensive study drug, please give reason (*check all that apply*).

3048 ..... a. Not applicable (go to #9) ☐ 1
3049 b. Morbid event ☐ 1
3050 c. Symptomatic adverse effect ☐ 1
3051 d. Other adverse effect (e.g., abnormal blood test) ☐ 1
3052 e. Blood pressure too high ☐ 1
3053 f. Blood pressure too low ☐ 1
3054 g. Refusal ☐ 1
3055 h. Other non-medical reason ☐ 1
3056 i. Other (specify) _____ 3057 _____ ☐ 1

9. What open-label antihypertensive or lipid-lowering medication is the patient being advised to take until the next visit? (*check all that apply*) ☐

3058 .....a. None (go to #10) ☐ 1
3132 .... b. Diuretic 1-2 times per week
3133 c. Diuretic 3 or more times per week ☐ 1
3060 d. Calcium channel blocker ☐ 1
3061 e . ACE inhibitor ☐ 1
3062 f. Alpha blocker ☐ 1
3134 g. Atenolol ☐ 1
3135 h. Clonidine ☐ 1
3136 I. Reserpine ☐ 1
3137 j. Hydralazine ☐ 1
3063 k. Other antihypertensive medication (specify) 3138 _____ ☐ 1
3064 l. HMG CoA reductase inhibitor (including ALLHAT pravastatin) ☐ 1
3065 m. Other lipid-lowering medication (including niacin, resins and probucol) ☐ 1
3139 n. Potassium chloride or other potassium supplement ☐ 1

This refers to any open-label antihypertensive or lipid-lowering medication, including medications provided by ALLHAT or from another source

If patient is not participating in the lipid-lowering part of ALLHAT, or is not assigned to study pravastatin, or if the study pravastatin was assigned today, go to Item #13.

10. a. What percent of ALLHAT pravastatin tablets does the patient report having taken since the last visit?

3066 ... < 80%) ☐ 1
≥ 80% ☐ 2
Go to #11 ☜ Not on ALLHAT pravastatin ☐ 3
Unable to determine ☐ 4

b. How many pravastatin tablets did the patient return today? 3067 ___ mls (cylinder) or 3068 ___ tablets

(Empty bottles returned = "000"; if unable to determine, use "999".)

Count tablets whenever possible; encourage patients reporting taking less than 80% of their medications to take their medications regularly as prescribed.

11. What dose of the ALLHAT pravastatin is the patient being advised to take until the next visit?

3069 ..... 10 mg ☐ 1
20 mg ☐ 2
40 mg ☐ 3
None ☐ 4

12. If ALLHAT pravastatin dosage has been decreased or stopped at this visit, or if the patient will not be taking the ALLHAT pravastatin, give reason (check all that apply).

a. Not app. (go to next section) ☐ 1 3070
b. Morbid event ☐ 1 3071
c. Symptomatic adverse effect ☐ 1 3072
d. Other adverse effect (e.g., abnormal blood test) ☐ 1 3073
e. Refusal ☐ 1 3074
f. Non-medical reason ☐ 1 3075
g. Other (specify) _____ 3077 _____ ☐ 1 3076

Ask the following questions of the participant at 2 years, 4 years and 6 years (refer to patient's visit schedule):

13. In general, would you say your health is: 3078
Excellent ☐ 1
Very good ☐ 2
Good ☐ 3
Fair ☐ 4
Poor ☐ 5
No answer/unknown ☐ 6

14. If you were to rate your current health on a scale of 0 to 100, with 100 being perfect health and 0 being death, what number would you rate yourself today? (Unknown = 999) 3079 ___

15. Have you ever smoked ***cigarettes***? 3080
Current smoker (past 30 days) ☐ 1
Past smoker (100+ cigarettes) ☐ 2
Never smoked ☐ 3
Unknown ☐ 4

16. Are you currently taking *aspirin* regularly? 3081
(Including aspirin-containing products; see Manual of Operations Chapter 2 for a list)
Yes ☐ 1
No ☐ 2
Don't know ☐ 3

17. ***For women only:*** Are you currently prescribed an estrogen supplement? 3117
Oral ☐ 1
Patch ☐ 2
No ☐ 3
Don't know ☐ 4

From clinic records (complete with 9's if not available):

18. Social Security number ___ 3083 ___ - 3084 ___ - ***3085*** ___

19. Medicare number (required for patients ≥65 years of age) ___ 3086 ___ - 3087 - 3088 ___ - 3089 ___

20. a. Are you re-dispensing Step 1 (blinded) medications that the patient returned at this visit? 3140
Dose 1 ☐ 1
Dose 2/3 ☐ 2
No ☐ 3

b. Are you re-dispensing ALLHAT pravastatin that the patient returned at this visit? 3091
Yes ☐ 1
No ☐ 2

21. Number of new bottles dispensed this visit

For items #21a-c, indicate the ***number*** of new bottles dispensed (do not use X or ✓). Differentiate between small and large bottles.

3093 a. Step 1 (blinded) Dose 1 __ small __ large 3094
(Small = 44-count, large = 134-count)
3095 b. Step 1 (blinded) Dose 2/3 __ small __ large 3096
3141 c. Pravastatin __
3118 d. No new bottles dispensed ☐ 1

22. Initials of person completing this form: 3104 ___

23. Signature of person completing this form 3105 _____

Place ID label here	**At Visit 3 or 4 (1 month or 3 months), if the participant is eligible and willing to participate in the lipid-lowering trial, perform lipid randomization. Patients randomized to the lipid-lowering trial at Visit 3 or 4 should have blood drawn for a lipid profile (panel ALL02 on the laboratory request slip).**
	Check patient's visit schedule to determine labwork and ECGs to be done at this visit.
Patient name:	**Schedule the patient's next ALLHAT visit according to their individual visit**

```
AL003 3 001I    1-  2 F3KPCOD          1        99 1
AL003 3 002IDR  3-  8 F3BDATE          1    999999 1
AL003 3 003A    9- 10 F3VFCOD          1         9 0
AL003 3 004IDR 11- 16 F3MODDT          1    999999 1
AL003 3 005I   17- 20 F3TIMMOD         1      9999 1
AL003 3 006I   21- 21 F3MODFLG         1         9 2
AL003 3 007I   22- 24 F3V2TCN          1       662 1       Y$
AL003 3 008I   25- 27 F3PNO            1       700 1       Y$
AL003 3 009I   28- 30 F3RCN            1       662 1       Y$
AL003 3 010I   35- 42 F3DATE8          1  99999999 1       Y$
AL003 3 011I   34- 34 F3VS             1         4 2       Y$
AL003 3 012I   35- 36 F3CENT          19        20 2       Y$
AL003 3 013IDR 37- 42 F03KEYDT         1    999999 1       Y$
AL003 3 014I   43- 43 F3SEQ            1         9 2       Y$
AL003 3 015A   44- 44 F3SITE           1         9 0       Y$
AL003 3 016A   45- 50 F3ACROS          1         9 0       Y$
AL003 3 017I   51- 52 F3EDIT           0         3 2       Y$
AL003 3 018A   53- 63 F3RINO           1         9 0       Y$
AL003 3 019I   64- 66 F3PAYCN          1       999 1       Y$
AL003 3 020A   70- 80 F3CKNO           1         9 0
AL003 3 021I   81- 82 F03FD021         0        99 1
AL003 3 130I   83- 83 F03FD130         1         3 2
AL003 3 023I   84- 86 F03FD023        60       300 1
AL003 3 024I   87- 89 F03FD024         0       200 1
AL003 3 025I   90- 92 F03FD025        60       300 1
AL003 3 026I   93- 95 F03FD026         0       200 1
AL003 3 027I   96- 98 F03FD027        60       300 1
AL003 3 028I   99-101 F03FD028         0       200 1
AL003 3 029A  102-104 F03FD029         1         9 0
AL003 3 030I  105-106 F03FD030         0        99 1
AL003 3 031I  107-108 F03FD031         0        99 1
AL003 3 032I  109-109 F03FD032         1         3 2
AL003 3 033I  110-110 F03FD033         1         3 2
AL003 3 034I  111-111 F03FD034         1         3 2
AL003 3 035I  112-112 F03FD035         1         3 2
AL003 3 036I  113-113 F03FD036         1         3 2
AL003 3 037I  114-114 F03FD037         1         3 2
AL003 3 116I  115-115 F03FD116         1         3 2
AL003 3 131I  116-116 F03FD131         1         3 2
AL003 3 038I  117-117 F03FD038         1         4 2
AL003 3 039I  118-120 F03FD039         0       999 1
AL003 3 040I  121-123 F03FD040         0       999 1
AL003 3 041I  124-124 F03FD041         1         4 2
AL003 3 048I  125-125 F03FD048         1         9 2
AL003 3 049I  126-126 F03FD049         0         1 2
AL003 3 050I  127-127 F03FD050         0         1 2
AL003 3 051I  128-128 F03FD051         1         9 2
AL003 3 052I  129-129 F03FD052         1         9 2
AL003 3 053I  130-130 F03FD053         1         9 2
AL003 3 054I  131-131 F03FD054         0         1 2
AL003 3 055I  132-132 F03FD055         0         1 2
AL003 3 056I  133-133 F03FD056         1         9 2
AL003 3 057I  134-134 F03FD057         0         1 2
AL003 3 058I  135-135 F03FD058         1         9 2
AL003 3 132I  136-136 F03FD132         0         1 2
AL003 3 133I  137-137 F03FD133         0         1 2
AL003 3 060I  138-138 F03FD060         0         1 2
AL003 3 061I  139-139 F03FD061         0         1 2
AL003 3 062I  140-140 F03FD062         0         1 2
AL003 3 134I  141-141 F03FD134         0         1 2
AL003 3 135I  142-142 F03FD135         0         1 2
AL003 3 136I  143-143 F03FD136         0         1 2
AL003 3 137I  144-144 F03FD137         0         1 2
```

```
AL003 3 063I  145-145 F03FD063         0         1 2
AL003 3 138I  146-146 F03FD138         0         1 2
AL003 3 064I  147-147 F03FD064         0         1 2
AL003 3 065I  148-148 F03FD065         0         1 2
AL003 3 139I  149-149 F03FD139         0         1 2
AL003 3 066I  150-150 F03FD066         0         4 2
AL003 3 067I  151-153 F03FD067         0       999 1
AL003 3 068I  154-156 F03FD068         0       999 1
AL003 3 069I  157-157 F03FD069         1         4 2
AL003 3 070I  158-158 F03FD070         1         9 2
AL003 3 071I  159-159 F03FD071         0         1 2
AL003 3 072I  160-160 F03FD072         0         1 2
AL003 3 073I  161-161 F03FD073         0         1 2
AL003 3 074I  162-162 F03FD074         0         1 2
AL003 3 075I  163-163 F03FD075         0         1 2
AL003 3 076I  164-164 F03FD076         1         9 2
AL003 3 077I  165-165 F03FD077         0         1 2
AL003 3 078I  166-166 F03FD078         0         6 0
AL003 3 079I  167-169 F03FD079         0       100 0
AL003 3 080I  170-170 F03FD080         0         4 0
AL003 3 081I  171-171 F03FD081         0         3 0
AL003 3 117I  172-172 F03FD117         0         3 0
AL003 3 083A  173-175 F03FD083         1         9 2
AL003 3 084A  176-177 F03FD084         1         9 2
AL003 3 085A  178-181 F03FD085         1         9 2
AL003 3 086A  182-184 F03FD086         1         9 2
AL003 3 087A  185-186 F03FD087         1         9 2
AL003 3 088A  187-190 F03FD088         1         9 2
AL003 3 089A  191-192 F03FD089         1         9 0
AL003 3 140I  193-193 F03FD140         1         3 2
AL003 3 091I  194-194 F03FD091         0         2 2
AL003 3 093I  195-196 F03FD093         0        99 1
AL003 3 094I  197-198 F03FD094         0        99 1
AL003 3 095I  199-200 F03FD095         0        99 1
AL003 3 096I  201-202 F03FD096         0        99 1
AL003 3 141I  203-204 F03FD141         0        99 1
AL003 3 118I  205-205 F03FD118         0        99 1
AL003 3 104A  206-208 F03FD104         1         9 0
AL003 3 105I  209-209 F03FD105         0         1 2
```

AL003 Version 4

ALLHAT FOLLOW-UP VISIT FORM - VERSION 4

Place ID label here

Patient name: _____

1.a. Today's date (mm-dd-yyyy): __ __ - __ __ - __ __ __ __

b. Visit # (range 03 - 28): __ __

c. Type of visit (check one): . . . . . .Clinic visit ☐ 1
Telephone visit ☐ 2
Postcard information ☐ 3

2. a. Seated blood pressure readings (mmHg) (use 999 for telephone visits and postcard information) __ __ __ / __ __ __

__ __ __ / __ __ __

Average: __ __ __ / __ __ __

Patient should be seated for five minutes without smoking, feet flat on the floor, in an erect but comfortable position. Be sure to use the correct cuff size: pediatric (16.0-22.5 cm), regular arm (22.6 - 30.0 cm), large arm (30.1 - 37.5 cm), thigh (37.6 - 43.7 cm). See Manual of Operations, Appendix B, for further instructions.
Blood pressure goals are <90 mmHg diastolic and <140 mmHg systolic.

b. Initials of person performing blood pressure measurements (use 999 for telephone visits and postcard information) . . . . . __ __ __

Interval History:

3. Number of overnight hospitalizations since the patient's last ALLHAT visit (none = 00, unknown = 99) . . . . . __ __

4. Number of visits to any doctor's office or clinic since the patient's last ALLHAT visit (none = 00, unknown = 99) . __ __
(Includes interim visits to ***ALLHAT*** clinic for blood pressure measurements and/or drug titration.)

5. Since the last visit, has the participant experienced any new occurrence of the following:
(Please check one box for each of the items #5a-k.)

	Hospitalized	Diagnosis Only	Treatment Only	No
a. Acute myocardial infarction (including evolving MI with thrombolysis)	☐ 1		☐ 2	☐ 3
b. Stroke (not TIA or "ministroke")	☐ 1		☐ 2	☐ 3
c. Cancer (a new ***primary*** diagnosis; excluding non-melanoma skin cancer)	☐ 1	☐ 4	☐ 2	☐ 3
d. Congestive heart failure	☐ 1		☐ 2	☐ 3
e. Angina pectoris (actual episode of chest pain)	☐ 1		☐ 2	☐ 3
f. Lower extremity peripheral arterial disease	☐ 1		☐ 2	☐ 3
g. Accident or attempted suicide	☐ 1		☐ 2	☐ 3

Any of the following procedures?	Yes	No
h. Kidney transplant or start of chronic dialysis	☐ 1	☐ 2
i. Coronary artery bypass graft (CABG)	☐ 1	☐ 2
j. Coronary PTCA (angioplasty), stent or atherectomy	☐ 1	☐ 2
k. Lower extremity peripheral revascularization/bypass/angioplasty	☐ 1	☐ 2

Complete an Event Reporting Form (AL04) for all boxed events in Items 5a-k.

6. Considering the Step 1 (blinded) ALLHAT antihypertensive medication, what percent of ALLHAT antihypertensive medication does the patient report having taken since the last visit? . . . Less than 80% ☐ 1
80% or more ☐ 2
Not on ALLHAT Step 1 (blinded) medication ☐ 3
Unable to determine ☐ 4

Encourage patients taking less than 80% of their medications to take their medications regularly as prescribed.

7. What dose of the ALLHAT Step 1 (blinded) antihypertensive medication is the patient being advised to take until the next visit? . . . . . Dose 1 ☐ 1
Dose 2 ☐ 2
Dose 3 ☐ 3
None ☐ 4

If Item #7 is "None", complete Items #8 and #9. Otherwise, skip to Item #10.

8. If the patient will not be taking the Step 1 (blinded) antihypertensive study drug, please give reasons (*check all that apply*).

a. Morbid event ☐ 1
b. Symptomatic adverse effect ☐ 1
c. Other adverse effect (e.g., abnormal blood test) ☐ 1
d. Blood pressure too high ☐ 1
e. Blood pressure too low ☐ 1
f. Refusal ☐ 1
g. Other non-medical reason ☐ 1
h. Other (specify) _____ ☐ 1

9. When will you be restarting Step 1 (blinded) study drug?

Will restart at the next visit ☐ 1
Can't tell at this time ☐ 2
No plan to restart ☐ 3

10. Which of the following medications is the patient being advised to take until the next visit? (*check all that apply*)

a. None (go to #11) ☐ 1
b. Diuretic 1-2 times per week ☐ 1
c. Diuretic 3 or more times per week ☐ 1
d. Calcium channel blocker ☐ 1
e. ACE inhibitor ☐ 1
f. Alpha blocker ☐ 1
g. Atenolol ☐ 1
h. Clonidine ☐ 1
i. Reserpine ☐ 1
j. Hydralazine ☐ 1
k. Other antihypertensive medication, regardless of indication (specify) _____ ☐ 1
l. HMG CoA reductase inhibitor (including ALLHAT pravastatin) ☐ 1
m. Other lipid-lowering medication (including niacin, resins and probucol) ☐ 1
n. Potassium chloride or other potassium supplement ☐ 1

This refers to any open-label antihypertensive or lipid-lowering medication, including medications provided by ALLHAT or from another source, **and regardless of reason for prescription.**

11. What percent of ALLHAT pravastatin tablets does the patient report having taken since the last visit?

Not on ALLHAT pravastatin ☐ 3
Less than 80% ☐ 1
80% or more ☐ 2
Unable to determine ☐ 4

If the patient is not in the lipid-lowering part of ALLHAT, or is assigned to Usual Care, or is assigned to pravastatin but not advised to take the ALLHAT pravastatin at the last visit, check "Not on ALLHAT pravastatin" for #11.

Encourage patients taking less than 80% of their medications to take their medications regularly as prescribed.

12. What dose of the ALLHAT pravastatin is the patient being advised to take until the next visit?

Not applicable ☐ 5
10 mg ☐ 1
20 mg ☐ 2
40 mg ☐ 3
None ☐ 4

If the patient is not in the lipid-lowering part of ALLHAT, or is assigned to Usual Care, check "Not applicable" for #12.

Reminder: ALLHAT protocol starting dose is 40 mg/day.

Place ID label here

Patient name: _____

If Item #12 is "None", complete Items #13 and #14. Otherwise, skip to next section.

13. If the patient will not be taking the ALLHAT pravastatin, give reasons (check all that apply).

a. Morbid event	☐ 1
b. Symptomatic adverse effect	☐ 1
c. Other adverse effect (e.g., abnormal blood test)	☐ 1
d. Refusal	☐ 1
e. Other non-medical reason	☐ 1
f. Other (specify) _____	☐ 1

14. When will you be restarting pravastatin?

Will restart at the next visit	☐ 1
Can't tell at this time	☐ 2
No plan to restart	☐ 3

Ask the following questions of the participant at 2 years, 4 years and 6 years, and record a 12-lead ECG (refer to patient's visit schedule):

15. In general, would you say your health is: ..... Excellent ☐ 1
Very good ☐ 2
Good ☐ 3
Fair ☐ 4
Poor ☐ 5
No answer/unknown ☐ 6

16. If you were to rate your current health on a scale of 0 to 100, with 100 being perfect health and 0 being death, what number would you rate yourself today? (Unknown = 999) ..... ___ ___ ___

17. Have you ever smoked ***cigarettes***? ..... Current smoker (past 30 days) ☐ 1
Past smoker (100+ cigarettes) ☐ 2
Never smoked ☐ 3
Unknown ☐ 4

18. Are you currently taking *aspirin* regularly? ..... Yes ☐ 1
(Including aspirin-containing products; see Manual of Operations Chapter 2 for a list) No ☐ 2
Don't know ☐ 3

19. ***For women only:*** Are you currently prescribed an estrogen supplement? ..... Yes ☐ 1
No ☐ 2
Don't know ☐ 3

From clinic records (complete with 9's if not available):

20. Social Security number ..... ___ ___ ___ - ___ ___ - ___ ___ ___ ___

21. Medicare number (required for patients ≥65 years of age) ..... ___ ___ ___ - ___ ___ - ___ ___ ___ ___ - ___ ___

22. Initials of person completing this form: ..... ___ ___ ___

23. Signature of person completing this form ..... _____

Place ID label here

Patient name: _____

Check patient's visit schedule for labwork and ECGs to be done at this visit.

Be sure that the patient has enough ALLHAT medication to last until their next visit. Check the bottle label to be sure that the correct bottle number is dispensed.

Be sure that the patient contact information is up to date, at least annually.

Schedule the patient's next ALLHAT visit according to their visit schedule.

Fields-Marked Version

ALLHAT FOLLOW-UP VISIT FORM - VERSION 4

3010 - 8 digit date

Place ID label here

Patient name: _____

1.a. Today's date (mm-dd-yyyy): ___-___-_____ 3013

Diamon after 12 142

b. Visit # (range 03 - 28): 3021

c. Type of visit (check one): .....Clinic visit ☐ 1
Telephone visit ☐ 2 3130
Postcard information ☐ 3

2. a. Seated blood pressure readings (mmHg) (use 999 for telephone visits and postcard information) 3023 / 3024
3025 / 3026
Average: 3027 / 3028

Patient should be seated for five minutes without smoking, feet flat on the floor, in an erect but comfortable position. Be sure to use the correct cuff size: pediatric (16.0-22.5 cm), regular arm (22.6 - 30.0 cm), large arm (30.1 - 37.5 cm), thigh (37.6 - 43.7 cm). See Manual of Operations, Appendix B, for further instructions.
Blood pressure goals are <90 mmHg diastolic and <140 mmHg systolic.

b. Initials of person performing blood pressure measurements (use 999 for telephone visits and postcard information) 3029

Interval History:

3. Number of overnight hospitalizations since the patient's last ALLHAT visit (none = 00, unknown = 99) 3030

4. Number of visits to any doctor's office or clinic since the patient's last ALLHAT visit (none = 00, unknown = 99) 3031
(Includes interim visits to ***ALLHAT*** clinic for blood pressure measurements and/or drug titration.)

5. Since the last visit, has the participant experienced any new occurrence of the following:
(Please check one box for each of the items #5a-k.)

	Hospitalized	Diagnosis Only	Treatment Only	No
a. Acute myocardial infarction (including evolving MI with thrombolysis)	☐ 1 3032		☐ 2	☐ 3
b. Stroke (not TIA or "ministroke")	☐ 1	3033	☐ 2	☐ 3
c. Cancer (a new ***primary*** diagnosis; excluding non-melanoma skin cancer)	☐ 1 3037	☐ 4	☐ 2	☐ 3
d. Congestive heart failure	☐ 1	3034	☐ 2	☐ 3
e. Angina pectoris (actual episode of chest pain)	☐ 1 3035		☐ 2	☐ 3
f. Lower extremity peripheral arterial disease	☐ 1	3036	☐ 2	☐ 3
g. Accident or attempted suicide	☐ 1 3116		☐ 2	☐ 3

Any of the following procedures?		Yes	No
h. Kidney transplant or start of chronic dialysis	143 143	☐ 1	☐ 2
i. Coronary artery bypass graft (CABG)	144 144	☐ 1	☐ 2
j. Coronary PTCA (angioplasty), stent or atherectomy	145 145	☐ 1	☐ 2
k. Lower extremity peripheral revascularization/bypass/angioplasty	146 146	☐ 1	☐ 2

Complete an Event Reporting Form (AL04) for all boxed events in items 5a-k.

6. Considering the Step 1 (blinded) ALLHAT antihypertensive medication, what percent of ALLHAT antihypertensive medication does the patient report having taken since the last visit? 3038
Less than 80% ☐ 1
80% or more ☐ 2
Not on ALLHAT Step 1 (blinded) medication ☐ 3
Unable to determine ☐ 4

Encourage patients taking less than 80% of their medications to take their medications regularly as prescribed.

7. What dose of the ALLHAT Step 1 (blinded) antihypertensive medication is the patient being advised to take until the next visit? 3041
Dose 1 ☐ 1
Dose 2 ☐ 2
Dose 3 ☐ 3
None ☐ 4

If Item #7 is "None", complete Items #8 and #9. Otherwise, skip to Item #10.

8. If the patient will not be taking the Step 1 (blinded) antihypertensive study drug, please give reasons (*check all that apply*).

a. Morbid event	☐ 1
b. Symptomatic adverse effect	☐ 1
c. Other adverse effect (e.g., abnormal blood test)	☐ 1
d. Blood pressure too high	☐ 1
e. Blood pressure too low	☐ 1
f. Refusal	☐ 1
g. Other non-medical reason	☐ 1
h. Other (specify) _____	☐ 1

9. When will you be restarting Step 1 (blinded) study drug?

Will restart at the next visit	☐ 1
Can't tell at this time	☐ 2
No plan to restart	☐ 3

10. Which of the following medications is the patient being advised to take until the next visit? (*check all that apply*)

This refers to any open-label antihypertensive or lipid-lowering medication, including medications provided by ALLHAT or from another source, **and regardless of reason for prescription**.

a. None (go to #11)	☐ 1
b. Diuretic 1-2 times per week	☐ 1
c. Diuretic 3 or more times per week	☐ 1
d. Calcium channel blocker	☐ 1
e. ACE inhibitor	☐ 1
f. Alpha blocker	☐ 1
g. Atenolol	☐ 1
h. Clonidine	☐ 1
i. Reserpine	☐ 1
j. Hydralazine	☐ 1
k. Other antihypertensive medication, regardless of indication (specify) _____	☐ 1
l. HMG CoA reductase inhibitor (including ALLHAT pravastatin)	☐ 1
m. Other lipid-lowering medication (including niacin, resins and probucol)	☐ 1
n. Potassium chloride or other potassium supplement	☐ 1

11. What percent of ALLHAT pravastatin tablets does the patient report having taken since the last visit?

If the patient is not in the lipid-lowering part of ALLHAT, or is assigned to Usual Care, or is assigned to pravastatin but not advised to take the ALLHAT pravastatin at the last visit, check "Not on ALLHAT pravastatin" for #11.

Not on ALLHAT pravastatin	☐ 3
Less than 80%	☐ 1
80% or more	☐ 2
Unable to determine	☐ 4

Encourage patients taking less than 80% of their medications to take their medications regularly as prescribed.

12. What dose of the ALLHAT pravastatin is the patient being advised to take until the next visit?

If the patient is not in the lipid-lowering part of ALLHAT, or is assigned to Usual Care, check "Not applicable" for #12.

Not applicable	☒ 5
10 mg	☐ 1
20 mg	☐ 2
40 mg	☐ 3
None	☐ 4

Reminder: ALLHAT protocol starting dose is 40 mg/day.

Place ID label here

Patient name: _____

If Item #12 is "None", complete Items #13 and #14. Otherwise, skip to next section.

13. If the patient will not be taking the ALLHAT pravastatin, give reasons (check all that apply).

a. Morbid event	3071	☐ 1
b. Symptomatic adverse effect	3072	☐ 1
c. Other adverse effect (e.g., abnormal blood test)	3073	☐ 1
d. Refusal	3074	☐ 1
e. Other non-medical reason	3075	☐ 1
f. Other (specify) _____	3077	☐ 1
	3076	

14. When will you be restarting pravastatin?

Will restart at the next visit	148 / 148	☐ 1
Can't tell at this time		☐ 2
No plan to restart		☐ 3

Ask the following questions of the participant at 2 years, 4 years and 6 years, and record a 12-lead ECG (refer to patient's visit schedule):

15. In general, would you say your health is: 3078 / 3078

☐ 1 Excellent
☐ 2 Very good
☐ 3 Good
☐ 4 Fair
☐ 5 Poor
☐ 6 No answer/unknown

16. If you were to rate your current health on a scale of 0 to 100, with 100 being perfect health and 0 being death, what number would you rate yourself today? (Unknown = 999) 3079 ___

17. Have you ever smoked ***cigarettes***? 3080

☐ 1 Current smoker (past 30 days)
☐ 2 Past smoker (100+ cigarettes)
☐ 3 Never smoked
☐ 4 Unknown

18. Are you currently taking *aspirin* regularly? 3081
(Including aspirin-containing products; see Manual of Operations Chapter 2 for a list)

☐ 1 Yes
☐ 2 No
☐ 3 Don't know

19. ***For women only:*** Are you currently prescribed an estrogen supplement? ~~148~~ 149

☐ 1 Yes
☐ 2 No
☐ 3 Don't know

From clinic records (complete with 9's if not available):

20. Social Security number 3083 3084 3085 ___ ___ ___

21. Medicare number (required for patients ≥65 years of age) 3086 3087 3088 3089 ___ ___ ___ ___

22. Initials of person completing this form: 3104 ___

23. Signature of person completing this form 3105 _____

Place ID label here

Patient name: _____

Check patient's visit schedule for labwork and ECGs to be done at this visit.

Be sure that the patient has enough ALLHAT medication to last until their next visit. Check the bottle label to be sure that the correct bottle number is dispensed.

Be sure that the patient contact information is up to date, at least annually.

Schedule the patient's next ALLHAT visit according to their visit schedule.

```
AL003 4 001I    1-  2 F3KPCOD          1        99 1
AL003 4 002IDR  3-  8 F3BATDAT         1        99 1
AL003 4 003A    9- 10 F3VFCOD          1        99 0
AL003 4 004IDR 11- 16 F3DATMOD         1        99 1
AL003 4 005I   17- 20 F3TIMMOD         1        99 1
AL003 4 006I   21- 21 F3MODFLG         1        99 1
AL003 4 007I   22- 24 F3V2TCN          1        99 1       Y$
AL003 4 008I   25- 27 F3PNO            0       900 1       Y$
AL003 4 009I   28- 30 F3RCN            0       700 1       Y$
AL003 4 010I   35- 42 F3DATE8          1  99999999 1       Y$
AL003 4 011I   34- 34 F3VS             1        99 1       Y$
AL003 4 012I   35- 36 F3CENDT         19        20 1       Y$
AL003 4 013IDR 37- 42 F3KEYDT          1    999999 1       Y$
AL003 4 014I   43- 43 F3SEQ            1        99 1       Y$
AL003 4 015A   44- 44 F3SITE           1        99 0       Y$
AL003 4 016A   45- 50 F3ACROS          1        99 0       Y$
AL003 4 017I   51- 52 F3EDIT           1        99 1
AL003 4 018A   53- 63 F3RINO           1        99 0
AL003 4 019I   64- 66 F3PAYCN          1       999 1       Y$
AL003 4 142I   67- 69 DUMMY            1        99 1
AL003 4 020A   70- 80 F3CKNO           1        99 0
AL003 4 021I   81- 82 F3Q1B            0        28 1
AL003 4 130I   83- 83 F3Q1C            0         3 2
AL003 4 023I   84- 86 F3Q2BS1          60       300 1
AL003 4 024I   87- 89 F3Q2BD1           0       200 1
AL003 4 025I   90- 92 F3Q2BS2          60       300 1
AL003 4 026I   93- 95 F3Q2BD2           0       200 1
AL003 4 027I   96- 98 F3Q2BS3          60       300 1
AL003 4 028I   99-101 F3Q2BD3           0       200 1
AL003 4 029A  102-104 F3Q2B            1        99 0
AL003 4 030I  105-106 F3Q3             0        99 1
AL003 4 031I  107-108 F3Q4             0        99 1
AL003 4 032I  109-109 F3V4Q5A          0         3 2
AL003 4 033I  110-110 F3V4Q5B          0         3 2
AL003 4 037I  111-111 F3V4Q5C          0         4 2
AL003 4 034I  112-112 F3V4Q5D          0         3 2
AL003 4 035I  113-113 F3V4Q5E          0         3 2
AL003 4 036I  114-114 F3V4Q5F          1         9 2
AL003 4 116I  115-115 F3V4Q5G          0         3 2
AL003 4 143I  116-116 F3V4Q5H          0         2 2
AL003 4 144I  117-117 F3V4Q5I          0         2 2
AL003 4 145I  118-118 F3V4Q5J          0         2 2
AL003 4 146I  119-119 F3V4Q5K          0         2 2
AL003 4 038I  120-120 F3V4Q6           0         4 2
AL003 4 041I  121-121 F3V4Q7           0         4 2
AL003 4 049I  122-122 F3V4Q8A          0         1 2
AL003 4 050I  123-123 F3V4Q8B          0         1 2
AL003 4 051I  124-124 F3V4Q8C          1         9 2
AL003 4 052I  125-125 F3V4Q8D          1         9 2
AL003 4 053I  126-126 F3V4Q8E          1         9 2
AL003 4 054I  127-127 F3V4Q8F          0         1 2
AL003 4 055I  128-128 F3V4Q8G          0         1 2
AL003 4 056I  129-129 F3V4Q8H1         1         9 2
AL003 4 057I  130-130 F3V4Q8H2         0         1 2
AL003 4 147I  131-131 F3V4Q9           0         3 2
AL003 4 058I  132-132 F3V4Q10A         1         9 2
AL003 4 132I  133-133 F3V4Q10B         0         1 2
AL003 4 133I  134-134 F3V4Q10C         0         1 2
AL003 4 060I  135-135 F3V4Q10D         0         1 2
AL003 4 061I  136-136 F3V4Q10E         0         1 2
AL003 4 062I  137-137 F3V4Q10F         0         1 2
AL003 4 134I  138-138 F3V4Q10G         0         1 2
```

```
AL003 4 135I  139-139 F3V4Q10H         0         1 2
AL003 4 136I  140-140 F3V4Q10I         0         1 2
AL003 4 137I  141-141 F3V4Q10J         0         1 2
AL003 4 063I  142-142 F3V4Q10K         0         1 2
AL003 4 138I  143-143 F3V4Q10X         0         1 2
AL003 4 064I  144-144 F3V4Q10L         0         1 2
AL003 4 065I  145-145 F3V4Q10M         0         1 2
AL003 4 139I  146-146 F3V4Q10N         0         1 2
AL003 4 066I  147-147 F3V4Q11          0         4 2
AL003 4 069I  148-148 F3V4Q12          0         5 2
AL003 4 071I  149-149 F3V4Q13A         0         1 2
AL003 4 072I  150-150 F3V4Q13B         0         1 2
AL003 4 073I  151-151 F3V4Q13C         0         1 2
AL003 4 074I  152-152 F3V4Q13D         0         1 2
AL003 4 075I  153-153 F3V4Q13E         0         1 2
AL003 4 076I  154-154 F3V4Q13F         1         9 2
AL003 4 077I  155-155 F3V4Q13X         0         1 2
AL003 4 148I  156-156 F3V4Q14          0         3 2
AL003 4 078I  157-157 F3V4Q15          0         6 2
AL003 4 079I  158-160 F3V4Q16          0       100 1
AL003 4 080I  161-161 F3V4Q17          0         4 2
AL003 4 081I  162-162 F3V4Q18          0         3 2
AL003 4 149I  163-163 F3V4Q19          0         4 2
AL003 4 083A  164-166 F3V4Q20A         1         9 2
AL003 4 084A  167-168 F3V4Q20B         1         9 2
AL003 4 085A  169-172 F3V4Q20C         1         9 2
AL003 4 086A  173-175 F3V4Q21A         1         9 0
AL003 4 087A  176-177 F3V4Q21B         1         9 0
AL003 4 088A  178-181 F3V4Q21C         1         9 0
AL003 4 089A  182-183 F3V4Q21D         1         9 0
AL003 4 104A  184-186 F3V4Q22          1         9 0
AL003 4 105I  187-187 F3V4Q23          0         1 2
```

AL004 - ALLHAT Event Reporting Form

Corresponding documentation inventoried on AL011 - ALLHAT Receipt of Endpoint Documentation Form.

Versions:
Version 1 – 01/94
Unique fields to version 1: F04023, F04024, F04025, F04033, F04042, F04043, F04032A, F04042, F04043.

Version 2 – 06/94
Unique fields to version 2: F04061; F04062 has different use than in version 3.

Version 3 – 07/98
Unique fields to version 3: F04063, F04064, F04065, F04066, F04067, F04068, F04069, F04070, F04071, F04072, F04073, F04074, F04075 (F04063- F04075 non-fatal events occurring prior to death during the fatal hospitalization); F04076, F04077, F04078, F04079, F04080, F04081, F04082, F04083.

Fields unique to version 1 and 2 only: F04034, F04035, F04036, F04037, F04038, F04039, F04040, F04041.

Fields unique to version 2 and 3 only: F04032B, F04047, F04048, F04049, F04050, F04051 F04052, F04053, F04054, F04055, F04056, F04057, F04058, F04059, F04060.

Modified Fields for LADS Master File:
Blanked:
F04018 (versions 1,2,3)
F04019
F04020
F04044 (versions 2,3)

Changed reverse date (yymmdd) to days since randomization:
F04021 (version 3); F04062 (version 3) Century Date is subsumed in this field in version 3 before modification

Changed date (mmddyy) to days since randomization:
F04021 (versions 1,2)

Coding Details:
Fields F04061, F04062 (Version 2), F04082, and F04083 were coded by the Coordinating Center for the primary cancer site based on the pathology report provided with the form.

1 = Adrenal
2 = Bone
3 = Brain
4 = Esophagus
5 = Gall bladder/biliary
6 = Hematopoietic malignancies
7 = Kidney
8 = Liver
9 = Melanoma
10 = Ovary
11 = Pancreas
12 = Pituitary
13 = Salivary gland
14 = Sinus
15 = Small intestine
16 = Sarcoma
17 = Stomach
18 = Tongue
19 = Throat
20 = Thyroid
21 = Uterus
22 = Vagina/vulva
23 = Unknown primary
24 = Anus
25 = Lip
26 = Oral cavity
27 = Testicular/penile/scrotal
28 = Malignant fibrous histiocytoma
29 = Squamous cell carcinoma of skin
30 = Malignant mesothelioma
31 = Ureter/ureto-vesicle junction
32 = Neuroendocrine
99 = Other

AL004 Version 1

ALLHAT EVENT REPORTING FORM

This form is to be completed for all hospitalizations or procedures involving MI, stroke, CHF, angina, peripheral arterial disease, or a new diagnosis of cancer, and for non-hospitalized but treated MIs and strokes. *Please attach hospital discharge summary and, if applicable, death certificate.*

Place ID label here

Patient name: _____

1. Today's date: __ __ - __ __ - __ __

2. Date of event: __ __ - __ __ - __ __

3. Is a death being reported? ..... Yes ☐ 1
(Go to #5) ☚ No ☐ 2

4. a. Cause of death (check *one*) ..... Myocardial infarction ☐ 1
Sudden death (< 24 hours) ☐ 2
Stroke ☐ 3
Congestive heart failure ☐ 4
Other cardiovascular disease ☐ 5
Cancer (primary site _____) ☐ 6
Accident, suicide, homicide ☐ 7
Other noncardiovascular disease ☐ 8
Unknown cause ☐ 9

b. Is death certificate attached? ..... Yes ☐ 1
No ☐ 2

5. Type of nonfatal event (check all that apply) ..... a. Myocardial infarction ☐ 1
b. Stroke ☐ 1
c. Hospitalized congestive heart failure ☐ 1
d. Hospitalized angina ☐ 1
e. Hospitalized peripheral arterial disease ☐ 1
f. New nonfatal cancer diagnosis (primary site _____) ☐ 1

g. Is discharge summary attached? ..... Yes ☐ 1
No ☐ 2

Procedures (check all that apply) ..... h. None (go to #6) ☐ 1
i. CABG ☐ 1
j. Coronary angioplasty ☐ 1
k. Thrombolysis ☐ 1
l. Other coronary revascularization ☐ 1
m. Peripheral arterial revascularization ☐ 1
n. Other (specify _____) ☐ 1

6. If death certicate or discharge summary required, but not attached, please check primary reason: ..... Patient/family refusal ☐ 1
Unable to locate records ☐ 2
Pending ☐ 3
Other (specify) _____ ☐ 4

7. Initials of person completing this form ..... __ __ __

8. Signature of person completing this form ..... _____

Fields-Marked Version

ALLHAT EVENT REPORTING FORM

This form is to be completed for all hospitalizations or procedures involving MI, stroke, CHF, angina, peripheral arterial disease, or a new diagnosis of cancer, and for non-hospitalized but treated MIs and strokes. *Please attach hospital discharge summary and, if applicable, death certificate.*

(4007) TCENTER (4010) FORM
(4008) PNUMBER **Place ID label here** (4012) VSN
(4009) RCENTER (4015) SITE (4014) SEQ
Patient name: _____

(4013)
1. Today's date: ___-___-___
2. Date of event: ___-___-___ (4021)
(4016) ACROSTIC

3. Is a death being reported? ..... Yes ☐ 1 (4022)
(Go to #5) No ☐ 2

4. a. Cause of death (check *one*) ..... Myocardial infarction ☐ 1
Sudden death (< 24 hours) ☐ 2 (4023)
Stroke ☐ 3
Congestive heart failure ☐ 4
Other cardiovascular disease ☐ 5
Cancer (primary site ▷ (4024)) ☐ 6
Accident, suicide, homicide ☐ 7
Other noncardiovascular disease ☐ 8
Unknown cause ☐ 9

b. Is death certificate attached? ..... Yes ☐ 1 (4025)
No ☐ 2

(4026)
5. Type of nonfatal event (check all that apply) ..... a. Myocardial infarction ☐ 1
b. Stroke ☐ 1 → (4027)
(4028) c. Hospitalized congestive heart failure ☐ 1
d. Hospitalized angina ☐ 1 → (4029)
(4030) e. Hospitalized peripheral arterial disease ☐ 1
f. New nonfatal cancer diagnosis (primary site ▷ (4032)) ☐ 1 → (4031)

g. Is discharge summary attached? ..... Yes ☐ 1
(4033) No ☐ 2

(4034)
Procedures (check all that apply) ..... h. None (go to #6) ☐ 1 (4035)
i. CABG ☐ 1 →
(4036) j. Coronary angioplasty ☐ 1
(4038) k. Thrombolysis ☐ 1 → (4037)
l. Other coronary revascularization ☐ 1
m. Peripheral arterial revascularization ☐ 1 → (403
n. Other (specify ▷ (4041)) ☐ 1 → (4040)

6. If death certicate or discharge summary required, but not attached, please check primary reason: ..... Patient/family refusal ☐ 1
Unable to locate records ☐ 2 (4042)
Pending ☐ 3
Other (specify) (4043) ▷ _____ ☐ 4

7. Initials of person completing this form ..... (4044) ___

8. Signature of person completing this form ..... ▷ (4045) _____

(4046) QUALITY CONTROL STUDY FLAG

```
AL004 1 001I    1-  2 F4KPCOD          1        99 1
AL004 1 002IDR  3-  8 F4BATDAT         1    999999 1
AL004 1 003A    9- 10 F4VERF           1         9 0
AL004 1 004IDR 11- 16 F4DATMOD         1    999999 1
AL004 1 005I   17- 20 F4TIMMOD         1      9999 1
AL004 1 006I   21- 21 F4MODFLG         1         9 2
AL004 1 007I   22- 24 F4TCN            1       662 1       Y$
AL004 1 008I   25- 27 F4PNO            1       700 1       Y$
AL004 1 009I   28- 30 F4RCN            1       662 1       Y$
AL004 1 010I   35- 42 F4DATE8          1  99999999 1       Y$
AL004 1 011I   34- 34 F4VS             1         3 2       Y$
AL004 1 012I   35- 36 F4CENT          19        20 2       Y$
AL004 1 013IDR 37- 42 F04KEYDT         1    999999 1       Y$
AL004 1 014I   43- 43 F4SEQ            1         9 2       Y$
AL004 1 015A   44- 44 F4SITE           1         9 0       Y$
AL004 1 016A   45- 50 F4ACROS          1         9 0       Y$
AL004 1 017I   51- 52 F4EDIT           0         3 2       Y$
AL004 1 018A   53- 63 F4RINO           1         9 0       Y$
AL004 1 019I   64- 66 F4PAYCN          1       999 1       Y$
AL004 1 020A   70- 80 F4CKNO           1         9 0       Y$
AL004 1 021ID  81- 86 F04FD021         1    999999 1
AL004 1 022I   87- 87 F04FD022         1         2 2
AL004 1 023I   88- 88 F04FD023         1         9 2
AL004 1 024I   89- 89 F04FD024         0         1 2
AL004 1 025I   90- 90 F04FD025         1         2 2
AL004 1 026I   91- 91 F04FD026         0         1 2
AL004 1 027I   92- 92 F04FD027         0         1 2
AL004 1 028I   93- 93 F04FD028         0         1 2
AL004 1 029I   94- 94 F04FD029         0         1 2
AL004 1 030I   95- 95 F04FD030         0         1 2
AL004 1 031I   96- 96 F04FD031         0         1 2
AL004 1 032I   97- 97 F04FD032         1         9 2
AL004 1 033I   98- 98 F04FD033         1         2 2
AL004 1 034I   99- 99 F04FD034         0         1 2
AL004 1 035I  100-100 F04FD035         0         1 2
AL004 1 036I  101-101 F04FD036         0         1 2
AL004 1 037I  102-102 F04FD037         0         1 2
AL004 1 038I  103-103 F04FD038         0         1 2
AL004 1 039I  104-104 F04FD039         0         1 2
AL004 1 040I  105-105 F04FD040         1         9 2
AL004 1 041I  106-106 F04FD041         1         9 2
AL004 1 042I  107-107 F04FD042         1         4 2
AL004 1 043I  108-108 F04FD043         0         1 2
AL004 1 044A  109-111 F04FD044         1         9 0
AL004 1 045I  112-112 F04FD045         0         1 2
AL004 1 046I  113-113 F04FD046         1         9 2
```

AL004 Version 2

ALLHAT EVENT REPORTING FORM

This form is to be completed for all hospitalizations or procedures involving MI, stroke, CHF, angina, peripheral arterial disease, a new diagnosis of cancer, and nonfatal accidents or attempted suicides, and for non-hospitalized but treated MIs and strokes. *Please attach hospital discharge summary and, if applicable, death certificate.*

Place ID label here

Patient name: _____

1. Today's date: __ __ - __ __ - __ __
2. Date of event: __ __ - __ __ - __ __

3. Does this form report a death or non-fatal event? . . . . . Death ☐ 1
Non-fatal event ☐ 2

For all deaths - Complete Items #4 - 9. Attach death certificate and, if applicable, face sheet.

4. a. Cause of death (check only one) . . . . . Definite MI ☐ 1
Definite CHD ☐ 2
Possible CHD ☐ 3
Stroke ☐ 4
CHF ☐ 5
Other cardiovascular disease ☐ 6
Cancer (list primary site in Item #6) ☐ 7
Accident, suicide, homicide ☐ 8
Other noncardiovascular disease ☐ 9
Unknown cause ☐ 10

5. If MI or definite or possible CHD, did death occur within 24 hours of symptoms? . . . . . Yes ☐ 1
No ☐ 2
DK ☐ 3

6. If cancer, give ***primary*** site . . . . . Lung ☐ 1
Colon ☐ 2
Breast ☐ 3
Prostate ☐ 4
Bladder ☐ 5
Other (specify) _____ ☐ 6
DK ☐ 7

7. a. Was patient hospitalized, or taken to a hospital during fatal event? . . . . . Yes ☐ 1
No ☐ 2
DK ☐ 3

b. If yes, is face sheet attached? . . . . . Yes ☐ 1
No ☐ 2

8. Is death certificate attached? . . . . . Yes ☐ 1
No ☐ 2

9. If death certificate or face sheet is not attached, give primary reason . . . . . Pending ☐ 1
Patient/family refusal ☐ 2
Unable to locate records ☐ 3
Other (specify in comments) ☐ 4

For all nonfatal events, complete Items #10 - 14. Attach face sheet.

10. Type of nonfatal event (check all that apply) . . . . . a. MI ☐ 1
b. Stroke ☐ 1
c. Hospitalized/procedure for CHF ☐ 1
d. Hospitalized/procedure for angina ☐ 1
e. Hospitalized/procedures for peripheral arterial disease ☐ 1
f. Hospitalized/procedure for new cancer diagnosis (list primary site in Item #11) ☐ 1
g. Accident or attempted suicide ☐ 1

11. If cancer, give ***primary*** site . . . . . Lung ☐ 1
Colon ☐ 2
Breast ☐ 3
Prostate ☐ 4
Bladder ☐ 5
Other (specify) _____ ☐ 6
DK ☐ 7

12. a. Was patient hospitalized? . . . . . Yes ☐ 1
No ☐ 2
DK ☐ 3

b. If yes, is face sheet attached? . . . . . Yes ☐ 1
No ☐ 2

13. Procedures (check all that apply) . . . . . a. None ☐ 1
b. CABG ☐ 1
c. Coronary angioplasty ☐ 1
d. Thrombolysis ☐ 1
e. Other coronary revascularization ☐ 1
f. Peripheral arterial revascularization ☐ 1
g. Other (specify _____) ☐ 1

14. If face sheet is not attached, give primary reason . . . . . Pending ☐ 1
Patient/family refusal ☐ 2
Unable to locate records ☐ 3
Other (specify in comments) ☐ 4

For all events -- Comments, signatures

15. Comments: _____

_____

_____

_____

16. Initials of person completing this form . . . . . _ _ _

17. Signature of person completing this form . . . . . _____

Fields-Marked Version

ALLHAT EVENT REPORTING FORM

This form is to be completed for all hospitalizations or procedures involving MI, stroke, CHF, angina, peripheral arterial disease, a new diagnosis of cancer, and nonfatal accidents or attempted suicides, and for non-hospitalized but treated MIs and strokes. *Please attach hospital discharge summary and, if applicable, death certificate.*

Place ID label here

Patient name: _____

1. Today's date: __ __ - __ __ - __ __ (4013)
2. Date of event: __ __ - __ __ - __ __ (4021)

3. Does this form report a death or non-fatal event? ..... (4022)
   Death ☐ 1
   Non-fatal event ☐ 2

For all deaths - Complete items #4 - 9. Attach death certificate and, if applicable, face sheet.

4. a. Cause of death (check only one) ..... (4047)
   Definite MI ☐ 1
   Definite CHD ☐ 2
   Possible CHD ☐ 3
   Stroke ☐ 4
   CHF ☐ 5
   Other cardiovascular disease ☐ 6
   Cancer (list primary site in Item #6) ☐ 7
   Accident, suicide, homicide ☐ 8
   Other noncardiovascular disease ☐ 9
   Unknown cause ☐ 10

5. If MI or definite or possible CHD, did death occur within 24 hours of symptoms? ..... (4048)
   Yes ☐ 1
   No ☐ 2
   DK ☐ 3

6. If cancer, give ***primary*** site ..... (4049)
   Lung ☐ 1
   Colon ☐ 2
   Breast ☐ 3
   Prostate ☐ 4
   Bladder ☐ 5
   Other (specify) (4050) _____ ☐ 6
   DK ☐ 7

7. a. Was patient hospitalized, or taken to a hospital during fatal event? ..... (4051)
   Yes ☐ 1
   No ☐ 2
   DK ☐ 3

   b. If yes, is face sheet attached? ..... (4052)
   Yes ☐ 1
   No ☐ 2

8. Is death certificate attached? ..... (4053)
   Yes ☐ 1
   No ☐ 2

9. If death certificate or face sheet is not attached, give primary reason ..... (4054)
   Pending ☐ 1
   Patient/family refusal ☐ 2
   Unable to locate records ☐ 3
   Other (specify in comments) ☐ 4

For all nonfatal events, complete items #10 - 14. Attach face sheet.

10. Type of nonfatal event (check all that apply) 4026
a. MI ☐ 1
b. Stroke ☐ 1 4027
4028 c. Hospitalized/procedure for CHF ☐ 1
d. Hospitalized/procedure for angina ☐ 1 4029
4030 e. Hospitalized/procedures for peripheral arterial disease ☐ 1
f. Hospitalized/procedure for new cancer diagnosis (list primary site in Item #11) ☐ 1 4031
4032 g. Accident or attempted suicide ☐ 1

11. If cancer, give ***primary*** site 4055
Lung ☐ 1
Colon ☐ 2
Breast ☐ 3
Prostate ☐ 4
Bladder ☐ 5
Other (specify) _____ 4056 _____ ☐ 6
DK ☐ 7

12. a. Was patient hospitalized? 4057
Yes ☐ 1
No ☐ 2
DK ☐ 3

b. If yes, is face sheet attached? 4058
Yes ☐ 1
No ☐ 2

13. Procedures (check all that apply) ..... a. None ☐ 1 4034
4035 b. CABG ☐ 1
c. Coronary angioplasty ☐ 1 4036
4037 d. Thrombolysis ☐ 1
e. Other coronary revascularization ☐ 1 4038
4039 f. Peripheral arterial revascularization ☐ 1
g. Other (specify _____ 4041 _____) ☐ 1 4040

14. If face sheet is not attached, give primary reason 4059
Pending ☐ 1
Patient/family refusal ☐ 2
Unable to locate records ☐ 3
Other (specify in comments) ☐ 4

For all events – Comments, signatures

15. Comments: _____ 4060 _____
_____
_____
_____

16. Initials of person completing this form ..... 4044 _ _ _

17. Signature of person completing this form ..... 4045 _____

Quality control flag (CCCT added): _ 4046

```
AL004 2 001I    1-  2 F4KPCOD          1        99 1
AL004 2 002IDR  3-  8 F4BATDAT         1    999999 1
AL004 2 003A    9- 10 F4VERF           1         9 0
AL004 2 004IDR 11- 16 F4DATMOD         1    999999 1
AL004 2 005I   17- 20 F4TIMMOD         1      9999 1
AL004 2 006I   21- 21 F4MODFLG         1         9 2
AL004 2 007I   22- 24 F4TCN            1       662 1       Y$
AL004 2 008I   25- 27 F4PNO            1       700 1       Y$
AL004 2 009I   28- 30 F4RCN            1       662 1       Y$
AL004 2 010I   35- 42 F4DATE8          1  99999999 1       Y$
AL004 2 011I   34- 34 F4VS             1         4 2       Y$
AL004 2 012I   35- 36 F4CENT          19        20 2       Y$
AL004 2 013IDR 37- 42 F04KEYDT         1    999999 1       Y$
AL004 2 014I   43- 43 F4SEQ            1         9 2       Y$
AL004 2 015A   44- 44 F4SITE           1         9 0       Y$
AL004 2 016A   45- 50 F4ACROS          1         9 0       Y$
AL004 2 017I   51- 52 F4EDIT           0         3 2       Y$
AL004 2 018A   53- 63 F4RINO           1         9 0       Y$
AL004 2 019I   64- 66 F4PAYCN          1       999 1       Y$
AL004 2 020A   70- 80 F4CKNO           1         9 0       Y$
AL004 2 021ID  81- 86 F04FD021         1    999999 1
AL004 2 022I   87- 87 F04FD022         1         2 2
AL004 2 047I   88- 89 F04FD047         1         9 2
AL004 2 048I   90- 90 F04FD048         1         3 2
AL004 2 049I   91- 91 F04FD049         1         7 2
AL004 2 050I   92- 92 F04FD050         0         1 2
AL004 2 051I   93- 93 F04FD051         1         3 2
AL004 2 052I   94- 94 F04FD052         1         2 2
AL004 2 053I   95- 95 F04FD053         1         2 2
AL004 2 054I   96- 96 F04FD054         1         4 2
AL004 2 026I   97- 97 F04FD026         0         1 2
AL004 2 027I   98- 98 F04FD027         0         1 2
AL004 2 028I   99- 99 F04FD028         0         1 2
AL004 2 029I  100-100 F04FD029         0         1 2
AL004 2 030I  101-101 F04FD030         0         1 2
AL004 2 031I  102-102 F04FD031         0         1 2
AL004 2 032I  103-103 F04FD032         0         1 2
AL004 2 055I  104-104 F04FD055         1         7 2
AL004 2 056I  105-105 F04FD056         0         1 2
AL004 2 057I  106-106 F04FD057         1         3 2
AL004 2 058I  107-107 F04FD058         1         2 2
AL004 2 034I  108-108 F04FD034         0         1 2
AL004 2 035I  109-109 F04FD035         0         1 2
AL004 2 036I  110-110 F04FD036         0         1 2
AL004 2 037I  111-111 F04FD037         0         1 2
AL004 2 038I  112-112 F04FD038         0         1 2
AL004 2 039I  113-113 F04FD039         0         1 2
AL004 2 040I  114-114 F04FD040         0         1 2
AL004 2 041I  115-115 F04FD041         0         1 2
AL004 2 059I  116-116 F04FD059         1         4 2
AL004 2 060I  117-117 F04FD060         0         1 2
AL004 2 044A  118-120 F04FD044         0         9 0
AL004 2 045I  121-121 F04FD045         0         1 2
AL004 2 046I  122-122 F04FD046         0         1 2
AL004 2 061I  123-124 F04CANC1         1        99 2
AL004 2 062I  125-126 F04CANC1         1        99 2
```

AL004 Version 3

ALLHAT EVENT REPORTING FORM - VERSION 3

Attach hospital discharge summary and, if applicable, death certificate. For cancers diagnosed out of hospital, please attach pathology report.

Place ID label here

Patient name: _____

1. Today's date: __ __ - __ __ - __ __
2. Date of event: __ __ - __ __ - __ __
3. Type of event: Death ☐ 1
   Non-fatal event ☐ 2

For all deaths - Complete Items #4 - 10. Attach death certificate and, if applicable, discharge summary.

4. Cause of death (check *only one*) . . . . . Definite MI ☐ 1
   Definite CHD ☐ 2
   Possible CHD ☐ 3
   Stroke ☐ 4
   CHF ☐ 5
   Other cardiovascular disease ☐ 6
   Cancer (list primary site in Item #6) ☐ 7
   Kidney disease ☐11
   Accident, suicide, homicide ☐ 8
   Other noncardiovascular disease ☐ 9
   Unknown cause ☐ 10

5. If MI or definite or possible CHD, did death occur within 24 hours of symptoms? . . . . . Yes ☐ 1
   No ☐ 2
   DK ☐ 3

6. If cancer, give ***primary*** site . . . . . Lung ☐ 1
   Colon ☐ 2
   Breast ☐ 3
   Prostate ☐ 4
   Bladder ☐ 5
   Other (specify) _____ ☐ 6
   DK ☐ 7

7. a. Was patient hospitalized, or taken to a hospital, during fatal event? . . . . . Yes ☐ 1
   No (go to #8) ☐ 2
   DK (go to #8) ☐ 3

   b. If yes, is discharge summary attached? . . . . . Yes ☐ 1
   No ☐ 2

   c. If hospitalized or taken to a hospital, what other events occurred during this hospitalization, other than the cause of death checked in #4?
   a. None ☐ 1
   b. Acute myocardial infarction (including evolving MI with thrombolysis) ☐ 1
   c. Stroke (not TIA or "ministroke") ☐ 1
   d. Cancer (a new primary diagnosis; excluding non-melanoma skin cancer) ☐ 1
   e.Congestive heart failure ☐ 1
   f. Angina pectoris (actual episode of chest pain) ☐ 1
   g. Lower extremity arterial disease ☐ 1
   h. Accident or attempted suicide ☐ 1
   i. Kidney transplant ☐ 1
   j. Start of chronic kidney dialysis ☐ 1
   k. Coronary artery bypass graft (CABG) ☐ 1
   l. Coronary PTCA (angioplasty), stent or atherectomy ☐ 1
   m. Lower extremity peripheral revascularization/bypass/angioplasty ☐ 1

8. Is death certificate attached? ..... Yes ☐ 1
No ☐ 2

9. If death certificate or discharge summary is not attached, give primary reason ..... Pending ☐ 1
Patient/family refusal ☐ 2
Unable to locate records ☐ 3
Other (specify in comments) ☐ 4

For all nonfatal events, complete Items #10 - 13. Attach discharge summary.

10. Type of nonfatal event (check all that apply)
a. Hospitalized for acute myocardial infarction (including evolving MI with thrombolysis) ☐ 1
b. Hospitalized for stroke (not TIA or "ministroke") ☐ 1
c. Cancer (a new primary diagnosis; excluding non-melanoma skin cancer) ☐ 1
d. Hospitalized for congestive heart failure ☐ 1
e. Hospitalized for angina pectoris (actual episode of chest pain) ☐ 1
f. Hospitalized for lower extremity arterial disease ☐ 1
g. Hospitalized for accident or attempted suicide ☐ 1
h. Kidney transplant ☐ 1
i. Start of chronic kidney dialysis ☐ 1
j. Coronary artery bypass graft (CABG) ☐ 1
k. Coronary PTCA (angioplasty), stent or atherectomy ☐ 1
l. Lower extremity peripheral revascularization/bypass/angioplasty ☐ 1

11. If cancer, give ***primary*** site ..... Lung ☐ 1
Colon ☐ 2
Breast ☐ 3
Prostate ☐ 4
Bladder ☐ 5
Other (specify) _____ ☐ 6
DK ☐ 7

12. a. Was patient hospitalized? ..... Yes ☐ 1
No ☐ 2
DK ☐ 3

b. If yes, is discharge summary attached? ..... Yes ☐ 1
No ☐ 2

13. If discharge summary is not attached, give primary reason ..... Pending ☐ 1
Patient/family refusal ☐ 2
Unable to locate records ☐ 3
Other (specify in comments) ☐ 4

For all events, please describe symptoms and your assessment/diagnosis

Place ID label here

Patient name: _____

14. Comments: _____

_____

_____

_____

15. Initials of person completing this form ..... ___ ___ ___

16. Signature of person completing this form _____

17. Signature of investigator _____

Fields-Marked Version

ALLHAT EVENT REPORTING FORM - VERSION 3

Attach hospital discharge summary and, if applicable, death certificate. For cancers diagnosed out of hospital, please attach pathology report.

Place ID label here

Patient name: _____

1. Today's date: (4021) ___-___-___ Century date = (4078)
2. Date of event: (4013) ___-___-___ Century Date = (4012)
3. Type of event: Death ☐ 1 (4022)
   Non-fatal event ☐ 2

For all deaths - Complete Items #4 - 10. Attach death certificate and, if applicable, discharge summary.

4. Cause of death (check *only one*) ..... Definite MI ☐ 1
   Definite CHD ☐ 2
   (4047) Possible CHD ☐ 3
   Stroke ☐ 4
   CHF ☐ 5
   Other cardiovascular disease ☐ 6
   Cancer (list primary site in Item #6) ☐ 7
   Kidney disease ☐11
   Accident, suicide, homicide ☐ 8
   Other noncardiovascular disease ☐ 9
   Unknown cause ☐ 10

5. If MI or definite or possible CHD, did death occur within 24 hours of symptoms? ..... Yes ☐ 1
   (4048) No ☐ 2
   DK ☐ 3

6. If cancer, give ***primary*** site ..... Lung ☐ 1
   Colon ☐ 2
   (4049) Breast ☐ 3
   Prostate ☐ 4
   Bladder ☐ 5
   Other (specify) (4050) ☐ 6
   DK ☐ 7

7. a. Was patient hospitalized, or taken to a hospital, during fatal event? ..... Yes ☐ 1
   (4051) No (go to #8) ☐ 2
   DK (go to #8) ☐ 3

   b. If yes, is discharge summary attacned? ..... Yes ☐ 1
   (4052) No ☐ 2

   c. If hospitalized or taken to a hospital, what other events occurred during this hospitalization, other than the cause of death checked in #4?
   (4063) a. None ☐ 1
   (4064) b. Acute myocardial infarction (including evolving MI with thrombolysis) ☐ 1
   (4065) c. Stroke (not TIA or "ministroke") ☐ 1
   (4066) d. Cancer (a new primary diagnosis; excluding non-melanoma skin cancer) ☐ 1
   (4067) e.Congestive heart failure ☐ 1
   (4068) f. Angina pectoris (actual episode of chest pain) ☐ 1
   (4069) g. Lower extremity arterial disease ☐ 1
   (4070) h. Accident or attempted suicide ☐ 1
   (4071) i. Kidney transplant ☐ 1
   (4072) j. Start of chronic kidney dialysis ☐ 1
   (4073) k. Coronary artery bypass graft (CABG) ☐ 1
   (4074) l. Coronary PTCA (angioplasty), stent or atherectomy ☐ 1
   (4075) m. Lower extremity peripheral revascularization/bypass/angioplasty ☐ 1

8. Is death certificate attached? ..... 4053 Yes ☐ 1 No ☐ 2

9. If death certificate or discharge summary is not attached, give primary reason ..... 4054 Pending ☐ 1
Patient/family refusal ☐ 2
Unable to locate records ☐ 3
Other (specify in comments) ☐ 4

For all nonfatal events, complete items #10 - 13. Attach discharge summary.

10. Type of nonfatal event (check all that apply)

a. Hospitalized for acute myocardial infarction (including evolving MI with thrombolysis) ☐ 1 4026
b. Hospitalized for stroke (not TIA or "ministroke") ☐ 1 4027
c. Cancer (a new primary diagnosis; excluding non-melanoma skin cancer) ☐ 1 4031
d. Hospitalized for congestive heart failure ☐ 1 4028
e. Hospitalized for angina pectoris (actual episode of chest pain) ☐ 1 4029
f. Hospitalized for lower extremity arterial disease ☐ 1 4030
g. Hospitalized for accident or attempted suicide ☐ 1 4032
h. Kidney transplant ☐ 1 4076
i. Start of chronic kidney dialysis ☐ 1 4077
j. Coronary artery bypass graft (CABG) ☐ 1 4078
k. Coronary PTCA (angioplasty), stent or atherectomy ☐ 1 4079
l. Lower extremity peripheral revascularization/bypass/angioplasty ☐ 1 4080

11. If cancer, give ***primary*** site ..... Lung ☐ 1
Colon ☐ 2
Breast ☐ 3
Prostate ☐ 4
Bladder ☐ 5
Other (specify) 4056 ☐ 6
DK ☐ 7
4055

12. a. Was patient hospitalized? ..... Yes ☐ 1
No ☐ 2
DK ☐ 3
4057

b. If yes, is discharge summary attached? ..... 4058 Yes ☐ 1
No ☐ 2

13. If discharge summary is not attached, give primary reason ..... Pending ☐ 1
Patient/family refusal ☐ 2
Unable to locate records ☐ 3
Other (specify in comments) ☐ 4
4059

For all events, please describe symptoms and your assessment/diagnosis

14. Comments: 4060

Place ID label here

Patient name: _____

15. Initials of person completing this form ..... 4044 ___

16. Signature of person completing this form 4045 _____

17. Signature of investigator 4081 _____

QC-Flag 4046

```
AL004 3 001I    1-  2 F4KPCOD          1         9 2
AL004 3 002IDR  3-  8 F4BATDAT         1         9 2
AL004 3 003A    9- 10 F4VERF           1         9 0
AL004 3 004IDR 11- 16 F4DATMOD         1         9 2
AL004 3 005I   17- 20 F4TIMMOD         1         9 2
AL004 3 006I   21- 21 F4MODFLG         1         9 2
AL004 3 007I   22- 24 F4TCN            1         9 2       Y$
AL004 3 008I   25- 27 F4PNO            1       900 1       Y$
AL004 3 009I   28- 30 F4RCN            1       700 1       Y$
AL004 3 010I   35- 42 F4DATE8          1  99999999 1       Y$
AL004 3 011I   34- 34 F4VS             1         9 2       Y$
AL004 3 012I   35- 36 F4CENT           1         9 2       Y$
AL004 3 013IDR 37- 42 F04KEYDT         1         9 2       Y$
AL004 3 014I   43- 43 F4SEQ            1         9 2       Y$
AL004 3 015A   44- 44 F4SITE           1         9 0       Y$
AL004 3 016A   45- 50 F4ACROS          1         9 0       Y$
AL004 3 017I   51- 52 F4EDIT           1         9 2
AL004 3 018A   53- 63 F4RINO           1         9 0
AL004 3 019I   64- 66 PAYCN            1         9 0
AL004 3 061I   67- 69 DUMMY            1         9 2
AL004 3 020A   70- 80 F4CKNO           1         9 0
AL004 3 062I   81- 82 F4FDTCEN         1         9 2
AL004 3 021IDR 83- 88 F4Q2DD           1         9 2
AL004 3 022I   89- 89 F4Q3             1         2 2
AL004 3 047I   90- 91 F4Q4A            1         9 2
AL004 3 048I   92- 92 F4Q5             0         3 2
AL004 3 049I   93- 93 F4Q6             0         7 2
AL004 3 050I   94- 94 F4OTHFLG         1         9 2
AL004 3 051I   95- 95 F4Q7A            0         3 2
AL004 3 052I   96- 96 F4Q7B            0         2 2
AL004 3 063I   97- 97 F4Q7Ca           1         9 2
AL004 3 064I   98- 98 F4Q7Cb           1         9 2
AL004 3 065I   99- 99 F4Q7Cc           1         9 2
AL004 3 066I  100-100 F4Q7Cd           1         9 2
AL004 3 067I  101-101 F4Q7Ce           1         9 2
AL004 3 068I  102-102 F4Q7Cf           1         9 2
AL004 3 069I  103-103 F4Q7Cg           1         9 2
AL004 3 070I  104-104 F4Q7Ch           1         9 2
AL004 3 071I  105-105 F4Q7Ci           1         9 2
AL004 3 072I  106-106 F4Q7Cj           1         9 2
AL004 3 073I  107-107 F4Q7Ck           1         9 2
AL004 3 074I  108-108 F4Q7Cl           1         9 2
AL004 3 075I  109-109 F4Q7Cm           1         9 2
AL004 3 053I  110-110 F4Q8             0         2 2
AL004 3 054I  111-111 F4Q9             0         4 2
AL004 3 026I  112-112 F4Q10A           0         1 2
AL004 3 027I  113-113 F4Q10B           0         1 2
AL004 3 031I  114-114 F4Q10C           1         9 2
AL004 3 028I  115-115 F4Q10D           0         1 2
AL004 3 029I  116-116 F4Q10E           0         1 2
AL004 3 030I  117-117 F4Q10F           1         9 2
AL004 3 032I  118-118 F4Q10G           0         1 2
AL004 3 076I  119-119 F4Q10H           1         9 2
AL004 3 077I  120-120 F4Q10I           1         9 2
AL004 3 078I  121-121 F4Q10J           1         9 2
AL004 3 079I  122-122 F4Q10K           1         9 2
AL004 3 080I  123-123 F4Q10L           0         1 2
AL004 3 055I  124-124 F4Q11            0         7 2
AL004 3 056I  125-125 F4Q11FLG         0         1 2
AL004 3 057I  126-126 F4Q12A           0         3 2
AL004 3 058I  127-127 F4Q12B           0         2 2
AL004 3 059I  128-128 F4Q13            1         9 2
```

```
AL004 3 060I  129-129 F4Q14           1         9 0
AL004 3 044A  130-132 F4Q15           1         9 0
AL004 3 045I  133-133 F4Q16           0         1 2
AL004 3 081I  134-134 F4Q17           1         9 2
AL004 3 046I  135-135 F4QCFLG         1         9 2
AL004 3 082I  136-137 F4QCANC1        1        99 2
AL004 3 083I  138-139 F4QCANC2        1        99 2
```

"Unblinding" form.

Versions:
Version 1 – 01/94

Version 2 – 06/94
Unique fields to version 2: F06034.

Version 3 – 02/96
Unique fields to version 3: F06077, F06078, F06079, F06080, F06081, F06082, F06083, F06084, F06085, F06086.

Fields unique to version 1 and version 2: F06018, F06023, F06024, F06025, F06026, F06027, F06028, F06029, F06030, F06032, F06033.

Modified Fields for LADS Master File:
Blanked:
F06032 (versions 1,2)
F06078 (version 3)
F06080 (version 3)
F06081 (version 3)
F06082 (version 3)

Changed date (mmddyy) to days since randomization:
F06018 (versions 1,2)

Coding details:
Time disclosed (F06077) is coded as "9999" for missing/invalid values.

AL006 Version 1

ALLHAT REPORT OF STUDY DRUG DISCLOSURE

Place ID label here

Patient name: _____

1. Date of disclosure (mm-dd-yy): __ __ - __ __ - __ __

2. Date this form completed (mm-dd-yy): __ __ - __ __ - __ __

3. Reason for disclosure (check all that apply): . . . . . a. Suspect adverse reaction ☐ 1
   b. Diagnostic test and/or surgery ☐ 1
   c. Other medical reason (specify below) ☐ 1
   d. Other non-medical reason (specify below) ☐ 1

4. The following persons are aware of which drug the patient is assigned (check all that apply): . . . . . a. Patient ☐ 1
   b. ALLHAT staff ☐ 1
   c. Non-ALLHAT physician ☐ 1
   c. Pharmacy ☐ 1
   d. Other (specify below) ☐ 1

5. Outside of the local ***ALLHAT*** clinic staff, who was contacted regarding this disclosure (check all that apply): . . . . a. Regional Coordinator ☐ 1
   b. Clinical Trials Center ☐ 1
   c. NHLBI ☐ 1

6. Comments: _____

   _____

   _____

7. Initials of person completing this form . . . . . __ __ __

8. Signature of person completing this form . . . . . _____

Fields-Marked Version

ALLHAT REPORT OF STUDY DRUG DISCLOSURE

(6007) TCENTER (6010) FORM (6016) ACROSTIC

(6008) ***Place ID label here*** (6011) VSN

(6009) (6015) SITE (6014) SEQ

Patient name: _____

1. Date of disclosure (mm-dd-yy): (6018) __ __ - __ __ - __ __

2. Date this form completed (mm-dd-yy): __ __ - __ __ - __ __ (6013)

3. Reason for disclosure (check all that apply): . . . . . a. Suspect adverse reaction ☐ 1 → (6019)
   b. Diagnostic test and/or surgery ☐ 1 (6020)
   c. Other medical reason (specify below) ☐ 1 → (6021)
   d. Other non-medical reason (specify below) ☐ 1 (6022)

4. The following persons are aware of which drug the patient is assigned (check all that apply): . . . . . a. Patient ☐ 1 → (6023)
   (6024) b. ALLHAT staff ☐ 1
   c. Non-ALLHAT physician ☐ 1 → (6025)
   (6026) → c. Pharmacy ☐ 1
   d. Other (specify below) ☐ 1 → (6027)

5. Outside of the local ***ALLHAT*** clinic staff, who was contacted regarding this disclosure (check all that apply): . . . . a. Regional Coordinator ☐ 1 (6028)
   b. Clinical Trials Center ☐ 1 → (6029)
   c. NHLBI ☐ 1 (6030)

6. Comments: P (6031) _____

_____

_____

7. Initials of person completing this form . . . . . (6032) ___

8. Signature of person completing this form . . . . . P (6033) _____

```
AL006 1 001I    1-  2 F6KPCD          1         9 2
AL006 1 002IDR  3-  8 F6BATDT         1         9 2
AL006 1 003A    9- 10 F6VFCD          1         9 0
AL006 1 004IDR 11- 16 F6DATMOD        1         9 2
AL006 1 005I   17- 20 F6TIMMOD        1         9 2
AL006 1 006I   21- 21 F6TYPMOD        1         9 2
AL006 1 007I   22- 24 F6TCN           1       662 1       Y$
AL006 1 008I   25- 27 F6PNO           1       700 1       Y$
AL006 1 009I   28- 30 F6RCN           1       662 1       Y$
AL006 1 010I   35- 42 F6DATE8         1  99999999 1       Y$
AL006 1 011I   34- 34 F6VS            1         9 2       Y$
AL006 1 012I   35- 36 F6CENT          1         9 2       Y$
AL006 1 013IDR 37- 42 F06KEYDT        1         9 2       Y$
AL006 1 014I   43- 43 F6SEQ           1         9 2       Y$
AL006 1 015A   44- 44 F6SITE          1         9 0       Y$
AL006 1 016A   45- 50 F6ACROS         1         9 0       Y$
AL006 1 017I   51- 52 F6EDIT          0         3 3
AL006 1 018AD  53- 58 F6Q1YR          1         9 0
AL006 1 019A   59- 59 F6Q3A           1         9 0
AL006 1 020A   60- 60 F6Q3B           1         9 0
AL006 1 021A   61- 61 F6Q3C           1         9 0
AL006 1 022A   62- 62 F6Q3D           1         9 0
AL006 1 023A   63- 63 F6Q4A           1         9 0
AL006 1 024A   64- 64 F6Q6B           1         9 0
AL006 1 025A   65- 65 F6Q4C           1         9 0
AL006 1 026A   66- 66 F6Q4D           1         9 0
AL006 1 027I   67- 67 F6Q4E           1         9 2
AL006 1 028A   68- 68 F6Q5A           1         9 0
AL006 1 029A   69- 69 F6Q5B           1         9 0
AL006 1 030A   70- 70 F6Q5C           1         9 0
AL006 1 031A   71- 71 F6Q6            1         9 0
AL006 1 032A   72- 74 F6Q7            1         9 0
AL006 1 033A   75- 75 F6Q7            1         9 0
```

AL006 Version 2

ALLHAT REPORT OF STUDY DRUG DISCLOSURE

Place ID label here

Patient name: _____

1. Date of disclosure (mm-dd-yy) . . . . . __ __ - __ __ - __ __

2. Date this form completed (mm-dd-yy) . . . . . __ __ - __ __ - __ __

3. Reason for disclosure (check all that apply): . . . . . a. Suspect adverse reaction ☐ 1
   b. Diagnostic test and/or surgery ☐ 1
   c. Other medical reason (specify below) ☐ 1
   d. Other non-medical reason (specify below) ☐ 1

4. The following persons are aware of which drug the patient is assigned (check all that apply): . . . . . a. Patient ☐ 1
   b. ALLHAT staff ☐ 1
   c. Non-ALLHAT physician ☐ 1
   c. Pharmacy ☐ 1
   d. Other (specify below) ☐ 1

5. Outside of the local ***ALLHAT*** clinic staff, who was contacted regarding this disclosure (check all that apply): . . . . . a. Clinical Trials Center ☐ 1
   b. Central unblinding facility ☐ 1
   c. Regional Coordinator ☐ 1
   d. NHLBI ☐ 1

6. Comments: _____

   _____

   _____

7. Initials of person completing this form . . . . . __ __ __

8. Signature of person completing this form . . . . . _____

Fields-Marked Version

ALLHAT REPORT OF STUDY DRUG DISCLOSURE

Place ID label here

Patient name: _____

1. Date of disclosure (mm-dd-yy) ..... 6018 __ __ - __ __ - __ __

2. Date this form completed (mm-dd-yy) ..... 6013 __ __ - __ __ - __ __

3. Reason for disclosure (check all that apply):.....a. Suspect adverse reaction ☐ 1 6019
   6020 b. Diagnostic test and/or surgery ☐ 1
   c. Other medical reason (specify below) ☐ 1 6021
   d. Other non-medical reason (specify below) ☐ 1 6022

4. The following persons are aware of which drug the patient is assigned (check all that apply):..... a. Patient ☐ 1 6023
   b. ALLHAT staff ☐ 1 6024
   c. Non-ALLHAT physician ☐ 1 6025
   6026 * d. Pharmacy ☐ 1
   * e. Other (specify below) ☐ 1 6027

5. Outside of the local ***ALLHAT*** clinic staff, who was contacted regarding this disclosure (check all that apply):..... a. Clinical Trials Center ☐ 1 6029
   6034 b. Central unblinding facility ☐ 1
   c. Regional Coordinator ☐ 1 6028
   d. NHLBI ☐ 1 6030

6. Comments: 6031 _____

_____

_____

7. Initials of person completing this form..... 6032 __ __ __

8. Signature of person completing this form..... 6033 _____

* On clinic forms, these were coded as 4c and 4d.

```
AL006 2 001I    1-  2 F6KPCD          1         9 2
AL006 2 002IDR  3-  8 F6BATDT         1         9 2
AL006 2 003A    9- 10 F6VFCD          1         9 0
AL006 2 004IDR 11- 16 F6DATMOD        1         9 2
AL006 2 005I   17- 20 F6TIMMOD        1         9 2
AL006 2 006I   21- 21 F6TYPMOD        1         9 2
AL006 2 007I   22- 24 F6TCN           1       662 1       Y$
AL006 2 008I   25- 27 F6PNO           1       700 1       Y$
AL006 2 009I   28- 30 F6RCN           1       662 1       Y$
AL006 2 010I   35- 42 F6DATE8         1  99999999 1       Y$
AL006 2 011I   34- 34 F6VS            1         9 2       Y$
AL006 2 012I   35- 36 F6CENT          1         9 2       Y$
AL006 2 013IDR 37- 42 F06KEYDT        1         9 2       Y$
AL006 2 014I   43- 43 F6SEQ           1         9 2       Y$
AL006 2 015A   44- 44 F6SITE          1         9 0       Y$
AL006 2 016A   45- 50 F6ACROS         1         9 0       Y$
AL006 2 017I   51- 52 F6EDIT          0         3 3
AL006 2 018AD  53- 58 F6Q1YR          1         9 0
AL006 2 019A   59- 59 F6Q3A           1         9 0
AL006 2 020A   60- 60 F6Q3B           1         9 0
AL006 2 021A   61- 61 F6Q3C           1         9 0
AL006 2 022A   62- 62 F6Q3D           1         9 0
AL006 2 023A   63- 63 F6Q4A           1         9 0
AL006 2 024A   64- 64 F6Q6B           1         9 0
AL006 2 025A   65- 65 F6Q4C           1         9 0
AL006 2 026A   66- 66 F6Q4D           1         9 0
AL006 2 027I   67- 67 F6Q4E           1         9 2
AL006 2 029A   68- 68 F6Q5A           1         9 0
AL006 2 034I   69- 69 F6Q5B           0         1 2
AL006 2 028A   70- 70 F6Q5C           1         9 0
AL006 2 030A   71- 71 F6Q5D           1         9 0
AL006 2 031A   72- 72 F6Q6            1         9 0
AL006 2 032A   73- 75 F6Q7            1         9 0
AL006 2 033A   76- 76 F6Q8            1         9 0
```

AL006 Version 3

FOUND ON DRUG BOTTLE

Patient Name: _____

Patient ID: __|__|__-__|__|__-__|__|__

Acrostic: ___|___|___|___|___|___

ALLHAT REPORT OF STUDY DRUG DISCLOSURE

Date of Disclosure: ____ - ____ - ____

Military Time of Disclosure: _____

Please refer all unblinding calls during weekday hours 8am - 5pm to the ALLHAT Clinical Trials Center, 1-800-690-7870. Otherwise:

A) Inquire whether call is for a medical emergency. If it is, go to Item C below.

B) If it is **not** a medical emergency, ask if the caller has tried to contact the ***ALLHAT*** staff person listed on the drug bottle label.

- **If caller persists** in his or her request for disclosure of the bottle contents, proceed to Item C.
- **If caller agrees** to contact the patient's ***ALLHAT*** Clinic (or physician or pharmacist), nothing else need be done. Please advise the caller that **clinical center personnel cannot unblind medication.**

C) **If it is a medical emergency** or the caller insists on knowing the bottle's content, request the following information and give the caller the name of the ***ALLHAT*** drug that corresponds to the **bottle code** and the actual dose which corresponds to the dose number.

1. Caller's Name: _____

2. Caller is: (Patient = 1, ALLHAT Staff = 2, Anesthesiologist/Surgeon = 3, ER Staff = 4, Unknown = 8, Other ***See Comments*** = 9) . . . . . _____

3. Caller's phone number: . . . . . __|__|__-__|__|__-__|__|__|__

4. Caller's City: __|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__ State: ___|___

Note: Remind the caller to keep the information on actual contents and dose unknown to as many people as possible. If possible, they should not reveal the information to the ***ALLHAT*** investigator, staff, or to the patient.

5. Reason for disclosure (check all that apply) . . . . . a. Suspect Adverse reaction ☐ 1

b. Diagnostic Test and/or surgery ☐ 1

c. Other medical reason (specify below) ☐ 1

d. Other non-medical reason (specify below) ☐ 1

6. Bottle code: . . . . . ___|___

7. Dose: (Dose-0 = 0, dose-1 = 1, dose-2 = 2, dose 3 = 3, unknown = 9) . . . . . _____

8. Drug name given to caller: (Chlorthalidone = 1, Amlodipine = 2, Lisinopril = 3, Doxazosin = 4) . . . . . _____

mg/day . . . . . __|__.__

9. Comments: _____

_____

_____

Fax a copy of this form to the ALLHAT Clinical Trial Center as soon as possible. Questions: Call Charles E. Ford, Ph.D. or Sara Pressel.

UTSPH, 1200 Herman Pressler Ste. 801, Houston, 77003 FAX: 792-4401 PHONE: 792-4480

Fields-Marked Version

ALLHAT RANDOMIZATION VISIT FORM EF: __

+----------+ ID: ___-___-___ Form: 006 Ver 3
!DE:06 REC:001030 VF:08!DTDIS: 10-11-2000 Seq: 1 Site: A
!MOD:001101 1057 F:1 ! MO-DY YR Acrostic: _____

B. Time of Disclosure (Military time) ..06077.....: [1425]
C. If it is an emergency:
1. Caller's Name .....: [06078]
2. Caller's is: (1=Patient; 2=ALLHAT Staff; 3=Anesthesiologist/Surgeon, 4=ER Staff; 8=Unknown, 9=See comments) 06079 [3]
3. Caller's Phone Number....06080.....: [___]-[___]-[____]
4. Caller's City/State 06081/82 City: [_____] State: [__]
5. Reason for Disclosure:
a. Suspect Adverse Reaction .....: [_]
b. Diagnostic Test and/or surgery .....: [1]
c. Other medical reason (specify below) .....: [_]
d. Other non-medical reason (specify) .....: [_]
6. Bottle Code .06083.....: [40]
7. Dose (0=Dose-0; 1=Dose 1; 2=Dose 2; 3=dose 3; 9=Unknown) 06084 .....: [1]
8. Drug Name (Chlor=1; Amlod.=2; Lisin.=3; Doxaz.=4; Partial=5) 06085 [1]
8.a Mg/Day .....06086.....: [12].[5]
9. Comments (Flag) .....[1]

```
AL006 3 001I    1-  2 F6KPCD          1         9 2
AL006 3 002IDR  3-  8 F6BDATE         1    999999 1
AL006 3 003A    9- 10 F6VFCD          1         9 0
AL006 3 004IDR 11- 16 F6MDATE         1    999999 1
AL006 3 005I   17- 20 F6TIMMOD        1         9 2
AL006 3 006I   21- 21 F6TYPMOD        1         9 2
AL006 3 007I   22- 24 F6TCN           1       662 1       Y$
AL006 3 008I   25- 27 F6PNO           1       700 1       Y$
AL006 3 009I   28- 30 F6RCN           1       662 1       Y$
AL006 3 010I   35- 42 F6DATE8         1  99999999 1       Y$
AL006 3 011I   34- 34 F6VS            1         9 2       Y$
AL006 3 012A   35- 36 F6CEN           1         9 0       Y$
AL006 3 013IDR 37- 42 F06KEYDT        1    999999 1       Y$
AL006 3 014I   43- 43 F6SEQ           1         9 2       Y$
AL006 3 015A   44- 44 F6SITE          1         9 0       Y$
AL006 3 016A   45- 50 F6ACROS         1         9 0       Y$
AL006 3 017A   51- 52 F6EDIT          1         3 2
AL006 3 077A   53- 56 F6MTIME         1      9999 0
AL006 3 078A   57- 86 F6V3C1          1         9 0
AL006 3 079I   87- 87 F06FD079        1         4 2
AL006 3 080A   88- 97 F06FD080        1         9 0
AL006 3 081A   98-117 F06FD081        1         9 0
AL006 3 082A  118-119 F06FD082        1         9 0
AL006 3 019I  120-120 F06FD019        0         1 2
AL006 3 020I  121-121 F06FD020        0         1 2
AL006 3 021I  122-122 F06FD021        0         1 2
AL006 3 022I  123-123 F06FD022        0         1 2
AL006 3 083A  124-125 F06FD083        1         9 0
AL006 3 084I  126-126 F06FD084        0         3 2
AL006 3 085I  127-127 F06FD085        1         4 2
AL006 3 086I  128-130 F06FD086        1       999 1
AL006 3 031I  131-131 F06FD031        0         1 2
```

AL007 - ALLHAT Report of Refusal or Loss to Follow-up Form

This form provides documentation of refusals or losses to follow-up.

Versions:
Version 1 – 01/94

Version 2 – 10/98 (no field marked version available; fields identical to version 1 with item numbers 3 and 4 switched in order).

Version 3 – 01/01

Version details:
The number of fields and their definitions are basically the same on all three versions of the AL007 with the following exceptions:
- F07019 is different on version 3 because there are nine possible responses versus four responses on version 1 and version 2. Field F07019 on versions 1 and 2 has been recoded to conform with the version 3 value labels.
- F07020 requires a skip-out on versions 2 and 3 if answered yes (F07020=1). In this case, much of the remainder of the form will be blank.

Modified Fields for LADS Master File:
Blanked:
F07031 (versions 1,2,3)

Changed date (mmddyy) to days since randomization:
F07033 (versions 1*,2,3)

*not marked on field-marked version of form

Data details:
- F07021 through F07028 flag fields should always be 0 or 1 but one record contains 9 in each of these fields and would normally be counted as a non-response equivalent to 0.

AL007 Version 1

ALLHAT REPORT OF REFUSAL OR LOSS TO FOLLOW-UP

This form is to be used to document: (1) patients who are currently refusing to attend the ALLHAT clinic or refusing to allow data to be transmitted to the CTC; and (2) final attempts to contact patients who have missed two consecutive follow-up visits, with all attempts to contact unsuccessful (lost to follow-up).

Place ID label here

Patient name: _____

1. Date form completed: __ __ - __ __ - __ __

2. This form documents (check one): . . . . . .Refusal ☐ 1
Lost to follow-up ☐ 2

Refusals - complete items #3, #4, and #6

3. Primary reason for refusal (check one): . . . . . Problem with study medication ☐ 1
Intervening illness ☐ 2
Advice of another physician ☐ 3
Other (specify below) ☐ 4

4. Is the patient willing to be contacted by telephone for required ALLHAT follow-up? . . . . . Yes ☐ 1
No ☐ 2

Loss to follow-up - complete items #5 and #6 - Please see ALLHAT Manual of Operations for other ideas in locating patients who are lost to follow-up.

5. Check attempts to locate participant: . . . . . a. Telephone ☐ 1
b. Regular mail ☐ 1
c. Certified mail, return receipt requested ☐ 1
d. Contacting patient's other physicians ☐ 1
e. Contacting patient's family members ☐ 1
f. Other known contacts ☐ 1
g. Contacting place of employment ☐ 1
h. Contacting insurance companies ☐ 1
i. Other attempts (specify below) ☐ 1

Comments

6. _____

_____

_____

_____

7. Initials of person completing this form . . . . . __ __ __

8. Signature of person completing this form . . . . . _____

Fields-Marked Version

ALLHAT REPORT OF REFUSAL OR LOSS TO FOLLOW-UP

This form is to be used to document: (1) patients who are currently refusing to attend the ALLHAT clinic or refusing to allow data to be transmitted to the CTC; and (2) final attempts to contact patients who have missed two consecutive follow-up visits, with all attempts to contact unsuccessful (lost to follow-up).

7007 TCENTER
7010 FORM
7008 PNUMBER
Place ID label here
7011 VSN
7009 RCENTER
7015 SITE
7014 SEQ
Patient name: _____

7016 ACROSTIC

7013

1. Date form completed: __ __ - __ __ - __ __

2. This form documents (check one): . . . . . Refusal ☐1
07018 Lost to follow-up ☐2

Refusals - complete items #3, #4, and #6

3. Primary reason for refusal (check one): . . . . . Problem with study medication ☐ 1
07019 Intervening illness ☐ 2
Advice of another physician ☐ 3
Other (specify below) ☐ 4

4. Is the patient willing to be contacted by telephone for required ALLHAT follow-up? . . . . . Yes ☐ 1
07020 No ☐ 2

Loss to follow-up - complete items #5 and #6 - Please see ALLHAT Manual of Operations for other ideas in locating patients who are lost to follow-up.

5. Check attempts to locate participant: . . . . . 7022 a. Telephone ☐ 1
b. Regular mail ☐ 1
c. Certified mail, return receipt requested ☐ 1
7024 d. Contacting patient's other physicians ☐ 1
e. Contacting patient's family members ☐ 1
7026 f. Other known contacts ☐ 1
g. Contacting place of employment ☐ 1
7028 h. Contacting insurance companies ☐ 1
i. Other attempts (specify below) ☐ 1

Comments

P 7030

6. _____

_____

_____

_____

7034

7. Initials of person completing this form . . . . . ___ ___ ___

P 7032

8. Signature of person completing this form . . . . . _____

```
AL007 1 001I    1-  2 F7KPCOD         1         9 2
AL007 1 002IDR  3-  8 F7BATDT         1         9 2
AL007 1 003A    9- 10 F7VFCOD         1         9 0
AL007 1 004IDR 11- 16 F7DATMOD        1         9 2
AL007 1 005I   17- 20 F7TIMMOD        1         9 2
AL007 1 006I   21- 21 F7TYPMOD        1         9 2
AL007 1 007I   22- 24 F7TCN           1       662 1       Y$
AL007 1 008I   25- 27 F7PNO           1       700 1       Y$
AL007 1 009I   28- 30 F7RCN           1       662 1       Y$
AL007 1 010I   35- 42 F7DATE8         1  99999999 1       Y$
AL007 1 011I   34- 34 F7VS            1         9 2       Y$
AL007 1 012I   35- 36 F7CENT          1         9 2       Y$
AL007 1 013IDR 37- 42 F07KEYDT        1         9 2       Y$
AL007 1 014I   43- 43 F7SEQ           1         9 2       Y$
AL007 1 015A   44- 44 F7SITE          1         9 0       Y$
AL007 1 016A   45- 50 F7ACROS         1         9 0       Y$
AL007 1 017I   51- 52 F7EDIT          0         3 2       Y$
AL007 1 018I   53- 53 F07FD018        1         2 2
AL007 1 019I   54- 54 F07FD019        1         4 2
AL007 1 020I   55- 55 F07FD020        1         2 2
AL007 1 021I   56- 56 F07FD021        0         1 2
AL007 1 022I   57- 57 F07FD022        0         1 2
AL007 1 023I   58- 58 F07FD023        0         1 2
AL007 1 024I   59- 59 F07FD024        0         1 2
AL007 1 025I   60- 60 F07FD025        0         1 2
AL007 1 026I   61- 61 F07FD026        0         1 2
AL007 1 027I   62- 62 F07FD027        0         1 2
AL007 1 028I   63- 63 F07FD028        0         1 2
AL007 1 029I   64- 64 F07FD029        0         1 2
AL007 1 030I   65- 65 F07FD030        0         1 2
AL007 1 031A   66- 68 F07FD031        0       999 0
AL007 1 032I   69- 69 F07FD032        0         1 0
AL007 1 033ID  70- 77 F07FD033        0  99999999 0
```

AL007 Version 2

ALLHAT REPORT OF REFUSAL OR LOSS TO FOLLOW-UP – Version 2 – 10/98

This form is to be used to document: (1) patients who **refuse** to allow any further information to be collected for ALLHAT; and (2) final attempts to contact patients who have missed two consecutive follow-up visits with all attempts to contact unsuccessful (**lost to follow-up**).

Place ID label here Patient name: _____	1. Date form completed: __ __ - __ __ - __ __ 2. This form documents (check one): Refusal ☐ 1 Lost to follow-up ☐ 2

Refusals - complete Items #3, #4, and #6. This category *only* includes patients who are refusing to allow any further information to be collected for ALLHAT. This category does *not* include patients who decide not to take the study medication or who are still or can be followed routinely in the clinic or by home visit, phone or postcard – do not complete an AL07 for these patients. If an AL07 is appropriate for this patient, remember that the patient can come back into ALLHAT any time in the future with either clinics visits or telephone visits.

3. Will patient allow follow-up in the clinic or at home or by phone or post-card? ..... Yes (**STOP – DO NOT COMPLETE AL07**) ☐ 1
No ☐ 2

4. Primary reason for refusal (check one): ..... Problem with study medication ☐ 1
Intervening illness ☐ 2
Advice of another physician ☐ 3
Other (explain in #6) ☐ 4

Lost to follow-up - complete Items #5 and #6. This category includes patients who have moved with no forwarding address; who cannot be contacted through relatives, neighbors or other contacts; and who have missed their last two consecutive visits. Periodic attempts should still be made to locate the patient. Please see ALLHAT Manual of Operations for other ideas for locating patients who are lost to follow-up. If an AL07 is appropriate for this patient, remember that patients who are lost to follow-up now can come back to ALLHAT in the future!

5. Check all attempts to locate participant: ..... a. Telephone ☐ 1
b. Regular mail ☐ 1
c. Certified mail, return receipt requested ☐ 1
d. Contacting patient's other physicians ☐ 1
e. Contacting patient's family members ☐ 1
f. Other known contacts ☐ 1
g. Contacting place of employment ☐ 1
h. Contacting insurance companies ☐ 1
i. Other (explain in #6) ☐ 1

Comments – Complete this section for all patients. AL07's which do not have a completed comments section (#6) will be returned to you for further information. A CTC representative may contact you for further details.

6. _____
_____
_____
_____

7. Initials of person completing this form ..... __ __ __

8. Signature of person completing this form ..... _____

```
AL007 2 001I    1-  2 F7KPCOD          1         9 2
AL007 2 002IDR  3-  8 F7BATDT          1         9 2
AL007 2 003A    9- 10 F7VFCOD          1         9 0
AL007 2 004IDR 11- 16 F7DATMOD         1         9 2
AL007 2 005I   17- 20 F7TIMMOD         1         9 2
AL007 2 006I   21- 21 F7TYPMOD         1         9 2
AL007 2 007I   22- 24 F7TCN            1       662 1       Y$
AL007 2 008I   25- 27 F7PNO            1       700 1       Y$
AL007 2 009I   28- 30 F7RCN            1       662 1       Y$
AL007 2 010I   35- 42 F7DATE8          1  99999999 1       Y$
AL007 2 011I   34- 34 F7VS             1         9 2       Y$
AL007 2 012I   35- 36 F7CENT           1         9 2       Y$
AL007 2 013IDR 37- 42 F07KEYDT         1         9 2       Y$
AL007 2 014I   43- 43 F7SEQ            1         9 2       Y$
AL007 2 015A   44- 44 F7SITE           1         9 0       Y$
AL007 2 016A   45- 50 F7ACROS          1         9 0       Y$
AL007 2 017I   51- 52 F7EDIT           0         3 2       Y$
AL007 2 018I   53- 53 F07FD018         1         2 2
AL007 2 019I   54- 54 F07FD019         1         4 2
AL007 2 020I   55- 55 F07FD020         1         2 2
AL007 2 021I   56- 56 F07FD021         0         1 2
AL007 2 022I   57- 57 F07FD022         0         1 2
AL007 2 023I   58- 58 F07FD023         0         1 2
AL007 2 024I   59- 59 F07FD024         0         1 2
AL007 2 025I   60- 60 F07FD025         0         1 2
AL007 2 026I   61- 61 F07FD026         0         1 2
AL007 2 027I   62- 62 F07FD027         0         1 2
AL007 2 028I   63- 63 F07FD028         0         1 2
AL007 2 029I   64- 64 F07FD029         0         1 2
AL007 2 030I   65- 65 F07FD030         0         1 2
AL007 2 031A   66- 68 F07FD031         0       999 0
AL007 2 032I   69- 69 F07FD032         0         1 0
AL007 2 033ID  70- 77 F07FD033         0  99999999 0
```

AL007 Version 3

ALLHAT REPORT OF REFUSAL OR LOSS TO FOLLOW-UP – Version 3 – 01/2001

Place ID label here Patient name: _____	1. Date form completed: __ __ - __ __ - __ __ __ __ 2. Date last known alive: __ __ - __ __ - __ __ __ __ 3. This form documents (check one): Refusal ☐ 1 Lost to follow-up ☐ 2

Refusals - complete Items #4, #5, #7, #8 and #9. This category *only* includes patients who are refusing to allow any further information to be collected for ALLHAT. If an AL07 is appropriate for this patient, remember that the patient can come back into ALLHAT any time in the future with either clinics visits or telephone visits.

4. Will patient allow follow-up in the clinic or at home or by phone or post-card? ..... Yes (**STOP – DO NOT COMPLETE AL07**) ☐ 1
No ☐ 2

5. Primary reason for refusal (check one): ..... Problem with study medication ☐ 1
Illness ☐ 2
Involvement of other physician ☐ 3
Problem related to clinic ☐ 4
Patient relocation ☐ 5
Other study-related (e.g., poor BP control) ☐ 6
Family reason ☐ 7
No longer wishes to participate, no other reason given ☐ 8
Other (explain in #7) ☐ 9

Lost to follow-up - complete Items #6 through #9. This category includes patients who have moved with no forwarding address; who cannot be contacted through relatives, neighbors or other contacts; and who have missed their last two consecutive visits. Periodic attempts should still be made to locate the patient. Please see ALLHAT ***Adherence Survival Kit (ASK)*** for other ideas for locating patients who are lost to follow-up. If an AL07 is appropriate for this patient, remember that patients who are lost to follow-up now can come back to ALLHAT in the future!

6. Check all attempts to locate participant: ..... a. Telephone ☐ 1
b. Regular mail ☐ 1
c. Certified mail, return receipt requested ☐ 1
d. Contacting patient's other physicians ☐ 1
e. Contacting patient's family members ☐ 1
f. Other known contacts ☐ 1
g. Contacting place of employment ☐ 1
h. Contacting insurance companies ☐ 1
i. Other (explain in #7) ☐ 1

Comments – Complete this section for all patients. AL07's which do not have a completed comments section (#7) will be returned to you for further information. A CTC representative may contact you for further details.

7. _____
_____
_____

8. Initials of person completing this form ..... __ __ __

9. Signature of person completing this form ..... _____

Fields-Marked Version

ALLHAT REPORT OF REFUSAL OR LOSS TO FOLLOW-UP – Version 3 – 01/2001

Place ID label here Patient name: _____	1. Date form completed: __ __ - __ __ - __ __ __ __ (7013) 2. Date last known alive: __ __ - __ __ - __ __ __ __ (7033) 3. This form documents (check one): Refusal ❑ 1, Lost to follow-up ❑ 2 (7018)

Refusals - complete Items #4, #5, #7, #8 and #9. This category *only* includes patients who are refusing to allow any further information to be collected for ALLHAT. If an AL07 is appropriate for this patient, remember that the patient can come back into ALLHAT any time in the future with either clinics visits or telephone visits.

4. Will patient allow follow-up in the clinic or at home or by phone or post-card? ..... Yes (**STOP – DO NOT COMPLETE AL07**) ❑ 1; No ❑ 2 (7020)

5. Primary reason for refusal (check one): ..... (7019)
   - Problem with study medication ❑ 1
   - Illness ❑ 2
   - Involvement of other physician ❑ 3
   - Problem related to clinic ❑ 4
   - Patient relocation ❑ 5
   - Other study-related (e.g., poor BP control) ❑ 6
   - Family reason ❑ 7
   - No longer wishes to participate, no other reason given ❑ 8
   - Other (explain in #7) ❑ 9

Lost to follow-up - complete Items #6 through #9. This category includes patients who have moved with no forwarding address; who cannot be contacted through relatives, neighbors or other contacts; and who have missed their last two consecutive visits. Periodic attempts should still be made to locate the patient. Please see ALLHAT ***Adherence Survival Kit (ASK)*** for other ideas for locating patients who are lost to follow-up. If an AL07 is appropriate for this patient, remember that patients who are lost to follow-up now can come back to ALLHAT in the future!

6. Check all attempts to locate participant: .....
   - (7021) a. Telephone ❑ 1
   - (7022) b. Regular mail ❑ 1
   - (7023) c. Certified mail, return receipt requested ❑ 1
   - (7024) d. Contacting patient's other physicians ❑ 1
   - (7025) e. Contacting patient's family members ❑ 1
   - (7026) f. Other known contacts ❑ 1
   - (7027) g. Contacting place of employment ❑ 1
   - (7028) h. Contacting insurance companies ❑ 1
   - (7029) i. Other (explain in #7) ❑ 1

Comments – Complete this section for all patients. AL07's which do not have a completed comments section (#7) will be returned to you for further information. A CTC representative may contact you for further details.

7. _____ (7030)

Initials of person completing this form ..... (7031)

9. Signature of person completing this form ..... (7032)

```
AL007 3 001I    1-  2 F7KPCOD          1         9 2
AL007 3 002IDR  3-  8 F7BATDT          1         9 2
AL007 3 003A    9- 10 F7VFCOD          1         9 0
AL007 3 004IDR 11- 16 F7DATMOD         1         9 2
AL007 3 005I   17- 20 F7TIMMOD         1         9 2
AL007 3 006I   21- 21 F7TYPMOD         1         9 2
AL007 3 007I   22- 24 F7TCN            1       662 1       Y$
AL007 3 008I   25- 27 F7PNO            1       700 1       Y$
AL007 3 009I   28- 30 F7RCN            1       662 1       Y$
AL007 3 010I   35- 42 F7DATE8          1  99999999 1       Y$
AL007 3 011I   34- 34 F7VS             1         9 2       Y$
AL007 3 012I   35- 36 F7CENT           1         9 2       Y$
AL007 3 013IDR 37- 42 F07KEYDT         1         9 2       Y$
AL007 3 014I   43- 43 F7SEQ            1         9 2       Y$
AL007 3 015A   44- 44 F7SITE           1         9 0       Y$
AL007 3 016A   45- 50 F7ACROS          1         9 0       Y$
AL007 3 017I   51- 52 F7EDIT           0         3 2       Y$
AL007 3 018I   53- 53 F07FD018         1         2 2
AL007 3 019I   54- 54 F07FD019         1         4 2
AL007 3 020I   55- 55 F07FD020         1         2 2
AL007 3 021I   56- 56 F07FD021         0         1 2
AL007 3 022I   57- 57 F07FD022         0         1 2
AL007 3 023I   58- 58 F07FD023         0         1 2
AL007 3 024I   59- 59 F07FD024         0         1 2
AL007 3 025I   60- 60 F07FD025         0         1 2
AL007 3 026I   61- 61 F07FD026         0         1 2
AL007 3 027I   62- 62 F07FD027         0         1 2
AL007 3 028I   63- 63 F07FD028         0         1 2
AL007 3 029I   64- 64 F07FD029         0         1 2
AL007 3 030I   65- 65 F07FD030         0         1 2
AL007 3 031A   66- 68 F07FD031         0       999 0
AL007 3 032I   69- 69 F07FD032         0         1 0
AL007 3 033ID  70- 77 F07FD033         0         1 0
```

AL011 – ALLHAT Receipt of Endpoint Documentation Form

Inventory sheet for documentation received with AL004 – ALLHAT Event Reporting Form.

Version 1 – 01/94 (only version)

Modified Fields for LADS Master File:
Blanked:
F11018
F11019
F11020
F11027
F11029

Changed date (mmddyy) to days since randomization:
F11021
F11026

AL011 Version 1

RECEIPT OF ENDPOINT DOCUMENTATION

ALLHAT Clinical Trials Center Use Only

1. Date AL04 received (mm-dd-yy) . . . . . __ __ - __ __ - __ __

2. Patient ID . . . . . __ __ __ - __ __ __ - __ __ __

3. Site code . . . . . __

4. Acrostic . . . . . __ __ __ __ __ __

5. Event date from AL04 (mm-dd-yy) . . . . . __ __ - __ __ - __ __

6. Event type . . . . . Death ☐ 1
   Nonfatal event ☐ 2

7. Documentation received
   (check all that apply) . . . . . a. Death certificate ☐ 1
   b. Face sheet ☐ 1
   c. Other records ☐ 1

8. Date documentation complete (mm-dd-yy) . . . . . __ __ - __ __ - __ __

9. Code of CTC monitor . . . . . __ __

10. Signature of CTC monitor _____

Fields-Marked Version

JF AS Form:AL11V1 SHOWMODE: Your in DISPLAY Mode Page 1 of 1

ALLHAT RECEIPT OF ENDPOINT DOCUMENTATION EF: __

+----------+ ID: ___-___-___ Form: 011 Ver 1 RI: _____

!DE:__ REC:_____ VF:__!FMDT: __(11013)__ Seq: _ Site: _ PAYCN: ___ ___

!MOD:_____ ____ F:_ ! MO-DY YR Acrostic: _____ PO: _____

+----------+

******NOTE******: FMDT is the Item 5 (Date of Event)

1. Date AL04 Receive (mm/dd/yy)..... (11021) [__/__/__]

6. Event type (1=Death; 2=Nonfatal event) ..... (11022) [_]

7. Documentation received

a. Death certificate..... (11023) [_]

b. Face sheet..... (11024) [_]

c. Other records..... (11025) [_]

8. Date Documentation complete..... (11026) [__/__/__]

9. Initials of CTC monitor..... (11027) [___]

10. Signiture Flag..... (11028) [_]

11: Comment: [(11029)_____]

```
AL011 1 001I    1-  2 F11KPCOD         1         9 2
AL011 1 002IDR  3-  8 F11BATDT         1         9 2
AL011 1 003A    9- 10 F11VFCOD         1         9 0
AL011 1 004IDR 11- 16 F11DTMOD         1         9 2
AL011 1 005I   17- 20 F11TMMOD         1         9 2
AL011 1 006I   21- 21 F11MDFLG         1         9 2
AL011 1 007I   22- 24 F11TCN           1       662 1       Y$
AL011 1 008I   25- 27 F11PNO           1       700 1       Y$
AL011 1 009I   28- 30 F11RCN           1       662 1       Y$
AL011 1 010I   35- 42 F11DATE8         1  99999999 1       Y$
AL011 1 011I   34- 34 F11VS            1         9 2       Y$
AL011 1 012I   35- 36 F11CENT          1         9 2       Y$
AL011 1 013IDR 37- 42 F11KEYDT         1         9 2       Y$
AL011 1 014I   43- 43 F11SEQ           1         9 2       Y$
AL011 1 015A   44- 44 F11SITE          1         9 0       Y$
AL011 1 016A   45- 50 F11ACR           1         9 0       Y$
AL011 1 017I   51- 52 F11EDIT          0         3 2       Y$
AL011 1 018A   53- 63 F11RINO          1         9 0       Y$
AL011 1 019I   64- 66 F11PAYCN         1       999 1       Y$
AL011 1 020A   70- 80 F11CKNO          1         9 0       Y$
AL011 1 021ID  81- 86 F11FD021         1         9 2
AL011 1 022I   87- 87 F11FD022         1         2 2
AL011 1 023I   88- 88 F11FD023         0         1 0
AL011 1 024I   89- 89 F11FD024         0         1 2
AL011 1 025I   90- 90 F11FD025         0         1 2
AL011 1 026ID  91- 96 F11FD026         1         9 2
AL011 1 027A   97- 99 F11FD027         1         9 0
AL011 1 028A  100-100 F11FD028         1         9 0
AL011 1 029A  101-165 F11FD029         1         9 0
AL011 1 030I  166-166 F11Q8B           0         1 0
```

AL012 - ALLHAT Endpoint Quality Control Selection and Documentation Form

This form was generated by the Coordinating Center for a sample of MI's and Strokes to obtain additional documentation from the site concerning the sampled event. The documentation was sent to two coders for evaluation. If the coders agreed with each other as to the event diagnosis (regardless of agreement with the clinical site diagnosis), then the form was complete. If they did not agree with each other, then a third coder was asked to adjudicate.

Version 1 – 06/94, modified 08/96

Modified Fields for LADS Master File:

Blanked:

F12018
F12019
F12020
F12042
F12046
F12049
F12066
F12083
F12105

Changed date (mmddyy) to days since randomization:

F12021
F12044
F12045
F12048
F12065
F12082
F12100
F12101
F12103
F12104

AL012 Version 1

ALLHAT ENDPOINT QUALITY CONTROL SELECTION AND DOCUMENTATION

The event listed below has been selected as part of ALLHAT's endpoint quality control documentation. Please obtain the records requested and send them with this cover sheet to the Clinical Trials Center with your regular shipment of study forms.

PLEASE KEEP A PHOTOCOPY OF THIS FORM FOR YOUR FILES.

1. Date this request generated: .....

   Sequence Number: .....

2. Patient ID: .....

3. Site code: .....

4. Acrostic: .....

5. Event date from AL04 (mm-dd-yy): .....

6. Event type: ..... a. MI death
   b. Definite CHD death
   c. Possible CHD death
   d. Stroke death
   e. Nonfatal MI X
   f. Nonfatal stroke

7. The following additional documents are requested: ..... a. ECGs X
   b. Enzymes X
   c. Reports of CT or MRI scans
   d. Lumbar puncture results
   e. Reports from neurologists
   f. Discharge summary X

****

For clinical site use: Label all additional records with patient ID, acrostic and event date

8. The following additional records are enclosed: ..... a. None (explain) __
   b. ECGs __
   c. Enzymes __
   d. Reports of CT or MRI scans __
   e. Lumbar puncture results __
   f. Reports from neurologists __
   g. Discharge summary __

9. Comments: _____

_____

_____

10. Initials of clinical site staff person completing form: ..... __ __ __

11. Signature: ..... _____

****

Clinical Trials Center Use Only:

12. Date additional documentation received: ..... __ __ - __ __ - __ __

13. Date completed: ..... __ __ - __ __ - __ __

14. Initials of CTC monitor: ..... __ __ __

15. Signature of CTC monitor: ..... _____

ALLHAT ENDPOINT QUALITY CONTROL CODING RESULT - CODER #1

****

Patient ID: .....

Site code: .....

Acrostic: .....

Event date from AL04 (mm-dd-yy): .....

Event type: ..... Nonfatal MI

****

16. Date of coding (mm-dd-yy): ..... __ __ - __ __ - __ __

17. Coder's initials: ..... __ __ __

18. Coding result *(definite and possible CHD deaths must also agree on timing)*:

Agree **(STOP)** ☐ 1
Disagree on major classification (specify below) ☐ 2
Disagree on timing only (specify below) ☐ 3

For deaths only:

19. Cause of death (check only one): ..... MI death ☐ 1
Definite CHD death ☐ 2
Possible CHD death ☐ 3
Stroke death ☐ 4
CHF death ☐ 5
Other CVD death ☐ 6
Cancer death (also check primary site, Item #22) ☐ 7
Accidental death, suicide, homicide ☐ 8
Other non-CVD death ☐ 9
Unknown cause of death ☐10

20. If definite or possible CHD, did death occur within 24 hours of symptoms?: Yes ☐ 1
No ☐ 2
DK ☐ 3

For nonfatal events only:

21. Type of nonfatal event (check all that apply): ..... a. Nonfatal MI ☐ 1
b. Nonfatal stroke ☐ 1
c. Hospitalized/procedure for CHF ☐ 1
d. Hospitalized/procedure for angina ☐ 1
e. Hospitalized/procedure for peripheral arterial disease ☐ 1
f. Hosp/proc for new cancer (also check primary site, Item #22) ☐ 1
g. Accident or attempted suicide ☐ 1
h. Kidney transplant or start of chronic dialysis ☐ 1
i. Other (specify) _____ ☐ 1

For all cancers:

22. Give primary site: ..... Lung ☐ 1
Colon ☐ 2
Breast ☐ 3
Prostate ☐ 4
Bladder ☐ 5
Other (specify) _____ ☐ 6
Unknown ☐ 7

ALLHAT ENDPOINT QUALITY CONTROL CODING RESULT - CODER #2

****

Patient ID: .....

Site code: .....

Acrostic: .....

Event date from AL04 (mm-dd-yy): .....

Event type: ..... Nonfatal MI

****

23. Date of coding (mm-dd-yy): ..... __ __ - __ __ - __ __

24. Coder's initials: ..... __ __ __

25. Coding result *(definite and possible CHD deaths must also agree on timing)*:

Agree **(STOP)** ☐ 1
Disagree on major classification (specify below) ☐ 2
Disagree on timing only (specify below) ☐ 3

For deaths only:

26. Cause of death (check only one): ..... MI death ☐ 1
Definite CHD death ☐ 2
Possible CHD death ☐ 3
Stroke death ☐ 4
CHF death ☐ 5
Other CVD death ☐ 6
Cancer death (also check primary site, Item #22) ☐ 7
Accidental death, suicide, homicide ☐ 8
Other non-CVD death ☐ 9
Unknown cause of death ☐10

27. If definite or possible CHD, did death occur within 24 hours of symptoms?: Yes ☐ 1
No ☐ 2
DK ☐ 3

For nonfatal events only:

28. Type of nonfatal event (check all that apply): ..... a. Nonfatal MI ☐ 1
b. Nonfatal stroke ☐ 1
c. Hospitalized/procedure for CHF ☐ 1
d. Hospitalized/procedure for angina ☐ 1
e. Hospitalized/procedure for peripheral arterial disease ☐ 1
f. Hosp/proc for new cancer (also check primary site, Item #22) ☐ 1
g. Accident or attempted suicide ☐ 1
h. Kidney transplant or start of chronic dialysis ☐ 1
i. Other (specify) _____ ☐ 1

For all cancers:

29. Give primary site: ..... Lung ☐ 1
Colon ☐ 2
Breast ☐ 3
Prostate ☐ 4
Bladder ☐ 5
Other (specify) _____ ☐ 6
Unknown ☐ 7

ALLHAT ENDPOINT QUALITY CONTROL RESULTS OF ADJUDICATION

****

Patient ID: .....

Site code: .....

Acrostic: .....

Event date from AL04 (mm-dd-yy): .....

Event type: ..... Nonfatal MI

****

30. Date of coding (mm-dd-yy): ..... __ __ - __ __ - __ __

31. Coding committee recorder's initials: ..... __ __ __

32. Coding result *(definite and possible CHD deaths must also agree on timing)*:

Agree **(STOP)** ☐ 1
Disagree on major classification (specify below) ☐ 2
Disagree on timing only (specify below) ☐ 3

For deaths only:

33. Cause of death (check only one): ..... MI death ☐ 1
Definite CHD death ☐ 2
Possible CHD death ☐ 3
Stroke death ☐ 4
CHF death ☐ 5
Other CVD death ☐ 6
Cancer death (also check primary site, Item #22) ☐ 7
Accidental death, suicide, homicide ☐ 8
Other non-CVD death ☐ 9
Unknown cause of death ☐ 10

34. If definite or possible CHD, did death occur within 24 hours of symptoms?: Yes ☐ 1
No ☐ 2
DK ☐ 3

For nonfatal events only:

35. Type of nonfatal event (check all that apply): ..... a. Nonfatal MI ☐ 1
b. Nonfatal stroke ☐ 1
c. Hospitalized/procedure for CHF ☐ 1
d. Hospitalized/procedure for angina ☐ 1
e. Hospitalized/procedure for peripheral arterial disease ☐ 1
f. Hosp/proc for new cancer (also check primary site, Item #22) ☐ 1
g. Accident or attempted suicide ☐ 1
h. Kidney transplant or start of chronic dialysis ☐ 1
i. Other (specify) _____ ☐ 1

For all cancers:

36. Give primary site: ..... Lung ☐ 1
Colon ☐ 2
Breast ☐ 3
Prostate ☐ 4
Bladder ☐ 5
Other (specify) _____ ☐ 6
Unknown ☐ 7

Fields-Marked Version

ALLHAT ENDPOINT QUALITY CONTROL SELECTION AND DOCUMENTATION

The event listed below has been selected as part of ALLHAT's endpoint quality control documentation. Please obtain the records requested and send them with this cover sheet to the Clinical Trials Center with your regular shipment of study forms.

PLEASE KEEP A PHOTOCOPY OF THIS FORM FOR YOUR FILES.

1. Date this request generated: ..... __-__-__ (13)(14)
   Sequence Number: ..... __ (7)(8)(9)
2. Patient ID: ..... __-__-__ (15)(16)
3. Site code: ..... __ (21)
4. Acrostic: ..... _ _ _ _ _ _
5. Event date from AL04 (mm-dd-yy): ..... __-__-__
6. Event type: ..... a. MI death __ (22)
   b. Definite CHD death __ (23)
   c. Possible CHD death __ (24)
   d. Stroke death __ (25)
   e. Nonfatal MI __ (26)
   f. Nonfatal stroke __ (27)
7. The following additional documents are requested: ..... a. ECGs __ (28)
   b. Enzymes __ (29)
   c. Reports of CT or MRI scans __ (30)
   d. Lumbar puncture results __ (31)
   e. Reports from neurologists __ (32)
   f. Discharge summary __ (33)

****

For clinical site use: Label all additional records with patient ID, acrostic and event date

8. The following additional records are enclosed: ..... a. None (explain) __ (34)
   b. ECGs __ (35)
   c. Enzymes __ (36)
   d. Reports of CT or MRI scans __ (37)
   e. Lumbar puncture results __ (38)
   f. Reports from neurologists __ (39)
   g. Discharge summary __ (40)
9. Comments: (41) P _____

_____

_____

10. Initials of clinical site staff person completing form: ..... ___ (42)
11. Signature: ..... (43) P _____

****

Clinical Trials Center Use Only:

12. Date additional documentation received: ..... __-__-__ (44)
13. Date completed: ..... __-__-__ (45)
14. Initials of CTC monitor: ..... ___ (46)
15. Signature of CTC monitor: ..... (47) P _____

ALLHAT ENDPOINT QUALITY CONTROL CODING RESULT - CODER #1

****

Patient ID: .....

Site code: .....

Acrostic: .....

Event date from AL04 (mm-dd-yy): .....

Event type: .....

****

16. Date of coding (mm-dd-yy): ..... __-___-__ (48)

17. Coder's initials: ..... ___ (49)

18. Coding result *(definite and possible CHD deaths must also agree on timing)*:

Agree **(STOP)** ☐ 1 (50)
Disagree on major classification (specify below) ☐ 2
Disagree on timing only (specify below) ☐ 3

For deaths only:

19. Cause of death (check only one): ..... MI death ☐ 1 (51)
Definite CHD death ☐ 2
Possible CHD death ☐ 3
Stroke death ☐ 4
CHF death ☐ 5
Other CVD death ☐ 6
Cancer death (also check primary site, Item #22) ☐ 7
Accidental death, suicide, homicide ☐ 8
Other non-CVD death ☐ 9
Unknown cause of death ☐ 10

20. If definite or possible CHD, did death occur within 24 hours of symptoms?: Yes ☐ 1 (52)
No ☐ 2
DK ☐ 3

For nonfatal events only:

21. Type of nonfatal event (check all that apply): ..... a. Nonfatal MI ☐ 1 (53)
b. Nonfatal stroke ☐ 1 (54)
c. Hospitalized/procedure for CHF ☐ 1 (55)
d. Hospitalized/procedure for angina ☐ 1 (56)
e. Hospitalized/procedure for peripheral arterial disease ☐ 1 (57)
f. Hosp/proc for new cancer (also check primary site, Item #22) ☐ 1 (58)
g. Accident or attempted suicide ☐ 1 (59)
h. Kidney transplant or start of chronic dialysis ☐ 1 (60)
i. Other (specify) (62) P _____ ☐ 1 (61)

For all cancers:

22. Give primary site: ..... Lung ☐ 1 (63)
Colon ☐ 2
Breast ☐ 3
Prostate ☐ 4
Bladder ☐ 5
Other (specify) (64) P _____ ☐ 6
Unknown ☐ 7

ALLHAT ENDPOINT QUALITY CONTROL CODING RESULT - CODER #2

****

Patient ID: .....

Site code: .....

Acrostic: .....

Event date from AL04 (mm-dd-yy): .....

Event type: .....

****

23. Date of coding (mm-dd-yy): ..... __ __ - __ __ - __ __ (65)

24. Coder's initials: ..... __ __ __ (66)

25. Coding result *(definite and possible CHD deaths must also agree on timing)*:

Agree **(STOP)** ☐ 1 (67)
Disagree on major classification (specify below) ☐ 2
Disagree on timing only (specify below) ☐ 3

For deaths only:

26. Cause of death (check only one): ..... MI death ☐ 1 (68)
Definite CHD death ☐ 2
Possible CHD death ☐ 3
Stroke death ☐ 4
CHF death ☐ 5
Other CVD death ☐ 6
Cancer death (also check primary site, Item #22) ☐ 7
Accidental death, suicide, homicide ☐ 8
Other non-CVD death ☐ 9
Unknown cause of death ☐ 10

27. If definite or possible CHD, did death occur within 24 hours of symptoms?: Yes ☐ 1 (69)
No ☐ 2
DK ☐ 3

For nonfatal events only:

28. Type of nonfatal event (check all that apply): ..... a. Nonfatal MI ☐ 1 (70)
b. Nonfatal stroke ☐ 1 (71)
c. Hospitalized/procedure for CHF ☐ 1 (72)
d. Hospitalized/procedure for angina ☐ 1 (73)
e. Hospitalized/procedure for peripheral arterial disease ☐ 1 (74)
f. Hosp/proc for new cancer (also check primary site, Item #22) ☐ 1 (75)
g. Accident or attempted suicide ☐ 1 (76)
h. Kidney transplant or start of chronic dialysis ☐ 1 (77)
i. Other (specify) (79) P _____ ☐ 1 (78)

For all cancers:

29. Give primary site: ..... Lung ☐ 1 (80)
Colon ☐ 2
Breast ☐ 3
Prostate ☐ 4
Bladder ☐ 5
Other (specify) (81) P _____ ☐ 6
Unknown ☐ 7

ALLHAT ENDPOINT QUALITY CONTROL RESULTS OF ADJUDICATION

****

Patient ID: .....

Site code: .....

Acrostic: .....

Event date from AL04 (mm-dd-yy): .....

Event type: .....

****

30. Date of coding (mm-dd-yy): ..... __ __ - __ __ - __ __ (82)

31. Coding committee recorder's initials: ..... __ __ __ (83)

32. Coding result *(definite and possible CHD deaths must also agree on timing)*:

Agree **(STOP)** ☐ 1 (84)
Disagree on major classification (specify below) ☐ 2
Disagree on timing only (specify below) ☐ 3

For deaths only:

33. Cause of death (check only one): ..... MI death ☐ 1 (85)
Definite CHD death ☐ 2
Possible CHD death ☐ 3
Stroke death ☐ 4
CHF death ☐ 5
Other CVD death ☐ 6
Cancer death (also check primary site, Item #22) ☐ 7
Accidental death, suicide, homicide ☐ 8
Other non-CVD death ☐ 9
Unknown cause of death ☐ 10

34. If definite or possible CHD, did death occur within 24 hours of symptoms?: Yes ☐ 1 (86)
No ☐ 2
DK ☐ 3

For nonfatal events only:

35. Type of nonfatal event (check all that apply): ..... a. Nonfatal MI ☐ 1 (87)
b. Nonfatal stroke ☐ 1 (88)
c. Hospitalized/procedure for CHF ☐ 1 (89)
d. Hospitalized/procedure for angina ☐ 1 (90)
e. Hospitalized/procedure for peripheral arterial disease ☐ 1 (91)
f. Hosp/proc for new cancer (also check primary site, Item #22) ☐ 1 (92)
g. Accident or attempted suicide ☐ 1 (93)
h. Kidney transplant or start of chronic dialysis ☐ 1 (94)
i. Other (specify) (96) P ☐ 1 (95)

For all cancers:

36. Give primary site: ..... Lung ☐ 1 (97)
Colon ☐ 2
Breast ☐ 3
Prostate ☐ 4
Bladder ☐ 5
Other (specify) (98) P ☐ 6
Unknown ☐ 7

ALLHAT ENDPOINT QUALITY CONTROL

Completion of ECG coding (complete if ECG's requested in Item 7a):

	Number of ECG's	Date Sent to Coding Center	Date Received Back at CTC
Batch 1	(99) __ __	(100) __ __/__ __/__ __	(101) __ __/__ __/__ __
Batch 2	(102) __ __	(103) __ __/__ __/__ __	(104) __ __/__ __/__ __

```
AL012 1 001I    1-  2 F12KPCOD         1         9 2
AL012 1 002IDR  3-  8 F12BATDT         1         9 2
AL012 1 003A    9- 10 F12VFDAT         1         9 0
AL012 1 004IDR 11- 16 F12DTMOD         1         9 2
AL012 1 005I   17- 20 F12TMMOD         1         9 2
AL012 1 006I   21- 21 F12MDFLG         1         9 2
AL012 1 007I   22- 24 F12TCN           1       662 1       Y$
AL012 1 008I   25- 27 F12PNO           1       700 1       Y$
AL012 1 009I   28- 30 F12RCN           1       662 1       Y$
AL012 1 010I   35- 42 F12DATE8         1  99999999 1       Y$
AL012 1 011I   34- 34 F12VS            1         9 2       Y$
AL012 1 012I   35- 36 F12CENT          1         9 0       Y$
AL012 1 013IDR 37- 42 F12KEYDT         1         9 2       Y$
AL012 1 014I   43- 43 F12SEQ           1         9 2       Y$
AL012 1 015A   44- 44 F12SITE          1         9 0       Y$
AL012 1 016A   45- 50 F12ACR           1         9 0       Y$
AL012 1 017I   51- 52 F12EDIT          0         3 2       Y$
AL012 1 018A   53- 63 F12RINO          1         9 0       Y$
AL012 1 019I   64- 66 F12PAYCN         1       999 1       Y$
AL012 1 020A   70- 80 F12CKNO          1         9 0       Y$
AL012 1 021ID  81- 86 F12FD021         1    999999 1
AL012 1 022I   87- 87 F12FD022         0         1 2
AL012 1 023I   88- 88 F12FD023         0         1 2
AL012 1 024I   89- 89 F12FD024         0         1 2
AL012 1 025I   90- 90 F12FD025         0         1 2
AL012 1 026I   91- 91 F12FD026         0         1 2
AL012 1 027I   92- 92 F12FD027         0         1 2
AL012 1 028I   93- 93 F12FD028         0         1 2
AL012 1 029I   94- 94 F12FD029         0         1 2
AL012 1 030I   95- 95 F12FD030         0         1 2
AL012 1 031I   96- 96 F12FD031         0         1 2
AL012 1 032I   97- 97 F12FD032         0         1 2
AL012 1 033I   98- 98 F12FD033         0         1 2
AL012 1 034I   99- 99 F12FD034         0         1 2
AL012 1 035I  100-100 F12FD035         0         1 2
AL012 1 036I  101-101 F12FD036         0         1 2
AL012 1 037I  102-102 F12FD037         0         1 2
AL012 1 038I  103-103 F12FD038         0         1 2
AL012 1 039I  104-104 F12FD039         0         1 2
AL012 1 040I  105-105 F12FD040         0         1 2
AL012 1 041I  106-106 F12FD041         0         1 2
AL012 1 042A  107-109 F12FD042         1         9 0
AL012 1 043I  110-110 F12FD043         1         9 2
AL012 1 044ID 111-116 F12FD044         1    999999 1
AL012 1 045ID 117-122 F12FD045         1    999999 1
AL012 1 046A  123-125 F12FD046         1         9 0
AL012 1 047A  126-126 F12FD047         1         9 0
AL012 1 048ID 127-132 F12FD048         1         9 1
AL012 1 049A  133-135 F12FD049         1         9 0
AL012 1 050I  136-136 F12FD050         1         3 2
AL012 1 051I  137-138 F12FD051         1        10 2
AL012 1 052I  139-139 F12FD052         1         3 2
AL012 1 053I  140-140 F12FD053         0         1 2
AL012 1 054I  141-141 F12FD054         0         1 2
AL012 1 055I  142-142 F12FD055         0         1 2
AL012 1 056I  143-143 F12FD056         0         1 2
AL012 1 057I  144-144 F12FD057         0         1 2
AL012 1 058I  145-145 F12FD058         0         1 2
```

```
AL012 1 059I  146-146 F12FD059         0         1 2
AL012 1 060I  147-147 F12FD060         0         1 2
AL012 1 061I  148-148 F12FD061         0         1 2
AL012 1 062I  149-149 F12FD062         0         1 2
AL012 1 063I  150-150 F12FD063         1         7 2
AL012 1 064I  151-151 F12FD064         0         1 2
AL012 1 065ID 152-157 F12FD065         1         9 1
AL012 1 066A  158-160 F12FD066         1         9 0
AL012 1 067I  161-161 F12FD067         1         3 2
AL012 1 068I  162-163 F12FD068         1        10 2
AL012 1 069I  164-164 F12FD069         1         3 2
AL012 1 070I  165-165 F12FD070         0         1 2
AL012 1 071I  166-166 F12FD071         0         1 2
AL012 1 072I  167-167 F12FD072         0         1 2
AL012 1 073I  168-168 F12FD073         0         1 2
AL012 1 074I  169-169 F12FD074         0         1 2
AL012 1 075I  170-170 F12FD075         0         1 2
AL012 1 076I  171-171 F12FD076         0         1 2
AL012 1 077I  172-172 F12FD077         0         1 2
AL012 1 078I  173-173 F12FD078         0         1 2
AL012 1 079I  174-174 F12FD079         0         1 2
AL012 1 080I  175-175 F12FD080         1         7 2
AL012 1 081I  176-176 F12FD081         0         1 2
AL012 1 082ID 177-182 F12FD082         1         9 1
AL012 1 083A  183-185 F12FD083         1         9 0
AL012 1 084I  186-186 F12FD084         1         3 2
AL012 1 085I  187-188 F12FD085         1        10 2
AL012 1 086I  189-189 F12FD086         1         3 2
AL012 1 087I  190-190 F12FD087         0         1 2
AL012 1 088I  191-191 F12FD088         0         1 2
AL012 1 089I  192-192 F12FD089         0         1 2
AL012 1 090I  193-193 F12FD090         0         1 2
AL012 1 091I  194-194 F12FD091         0         1 2
AL012 1 092I  195-195 F12FD092         0         1 2
AL012 1 093I  196-196 F12FD093         0         1 2
AL012 1 094I  197-197 F12FD094         0         1 2
AL012 1 095I  198-198 F12FD095         0         1 2
AL012 1 096I  199-199 F12FD096         0         1 2
AL012 1 097I  200-200 F12FD097         1         7 2
AL012 1 098I  201-201 F12FD098         0         1 2
AL012 1 099I  202-203 F12FD099         0        99 2
AL012 1 100ID 204-209 F12FD100         0    999999 1
AL012 1 101ID 210-215 F12FD101         0    999999 1
AL012 1 102I  216-217 F12FD102         0        99 2
AL012 1 103ID 218-223 F12FD103         0    999999 1
AL012 1 104ID 224-229 F12FD104         0    999999 1
AL012 1 105I  230-230 F12Q13B          0         1 1
```

AL013 - ALLHAT Adverse Experience Form

Form for documenting possible relationship to study drug of serious adverse event. A version 1 form was replaced with the version 2 form on 04/96 (version 1 forms re-written to version 2 format).

Version 2 – 04/96, modified 12/99

Modified Fields for LADS Master File:
Blanked:
F13094 (version 2)
F13095 (version 2)
F13096 (version 2)
F13049 (version 2)

Changed date (mmddyy) to days since randomization:
F13071 (version 2)
F13020 (version 2)

Coding details:
F13020 - End date is coded as "999999" for missing/invalid values.

AL013 Version 1

ALLHAT ADVERSE EXPERIENCE FORM

ALL SERIOUS ADVERSE EXPERIENCES (SAES) *WHICH THE INVESTIGATOR DEEMS MAY BE CAUSED BY BLINDED STUDY DRUGS OR PRAVASTATIN* MUST BE REPORTED TO THE CTC. SAES INCLUDE DEATH, LIFE THREATENING EVENTS, EVENTS RESULTING IN PERMANENT DISABILITY, HOSPITALIZATIONS OR PROLONGATION OF HOSPITAL STAYS, CANCERS, OR DRUG OVERDOSES. IF AN SAE IS A DEATH OR LIFE-THREATENING EVENT, THE CTC SHOULD BE NOTIFIED BY PHONE OR FAX WITHIN ONE WORKING DAY OF DISCOVERY.

Place ID label here

Today's date (mm-dd-yy): ___ ___ - ___ ___ - ___ ___

ADVERSE EXPERIENCES

Adverse Experience: 1 = Death 2 = Life threatening event 3 = Event resulting in permanent disability 4 = Hospitalization 5 = Prolongation of hospital stay 6 = Cancer 7 = Drug overdose	Duration of Experience						In the physician's judgment, the cause of this adverse experience was: 1 = Blinded study drug 2 = Pravastatin 3 = Uncertain	Action taken (list all that apply): 1 = None 2 = Decreased dosage 3 = Symptomatic therapy required 4 = Study drug discontinued 5 = Hospitalization	Outcome: 1 = Recovered 2 = Abated with decreased dose 3 = Alive with sequelae 4 = Under treatment 5 = Death
	From			To					
	Mo	Day	Yr	Mo	Day	Yr			

Comments:_____

_____

_____

Initials of person completing this form: ___ ___ ___

Signature of person completing this form _____

White & Yellow - CTC Pink - Clinic record

PSF 060-314

Fields-Marked Version

ALLHAT ADVERSE EXPERIENCE FORM

ALL SERIOUS ADVERSE EXPERIENCES (SAES) *WHICH THE INVESTIGATOR DEEMS MAY BE CAUSED BY BLINDED STUDY DRUGS OR PRAVASTATIN* MUST BE REPORTED TO THE CTC. SAES INCLUDE DEATH, LIFE THREATENING EVENTS, EVENTS RESULTING IN PERMANENT DISABILITY, HOSPITALIZATIONS OR PROLONGATION OF HOSPITAL STAYS, CANCERS, OR DRUG OVERDOSES. IF AN SAE IS A DEATH OR LIFE-THREATENING EVENT, THE CTC SHOULD BE NOTIFIED BY PHONE OR FAX WITHIN ONE WORKING DAY OF DISCOVERY.

(7) Treatment Center (10) Form

(8) Participant Number
Place ID label here

(9) Randomization Center (11) Version

Today's date (mm-dd-yy): (13) __ __ - __ __ - __ __ (12) Century (14) Sequence (15) Site (16) Acrostic

ADVERSE EXPERIENCES

Adverse Experience: 1 = Death 2 = Life threatening event 3 = Event resulting in permanent disability 4 = Hospitalization 5 = Prolongation of hospital stay 6 = Cancer 7 = Drug overdose	Duration of Experience						In the physician's judgment, the cause of this adverse experience was: 1 = Blinded study drug 2 = Pravastatin 3 = Uncertain	Action taken (list all that apply): 1 = None 2 = Decreased dosage 3 = Symptomatic therapy required 4 = Study drug discontinued 5 = Hospitalization					Outcome: 1 = Recovered 2 = Abated with decreased dose 3 = Alive with sequelae 4 = Under treatment 5 = Death
	From			To				1P	2P	3P	4P	5P	
	Mo	Day	Yr	Mo	Day	Yr							
(18)		(19)			(20)		(21)	(22)	(23)	(24)	(25)	(26)	(27)
(28)		(29)			(30)		(31)	(32)	(33)	(34)	(35)	(36)	(37)
(38)		(39)			(40)		(41)	(42)	(43)	(44)	(45)	(46)	(47)
(48)		(49)			(50)		(51)	(52)	(53)	(54)	(55)	(56)	(57)
(58)		(59)			(60)		(61)	(62)	(63)	(64)	(65)	(66)	(67)

Comments: (68) P

Initials of person completing this form: (69) ___

Signature of person completing this form (70) P _____

White & Yellow - CTC Pink - Clinic record

```
AL013 1 001I    1-  2 F13KPCD          1         9 2
AL013 1 002IDR  3-  8 F13BATDT         1         9 2
AL013 1 003A    9- 10 F13VFCD          1         9 0
AL013 1 004IDR 11- 16 F13DATMD         1         9 2
AL013 1 005I   17- 20 F13TIMMD         1         9 2
AL013 1 006I   21- 21 F13TYPMD         1         9 2
AL013 1 007I   22- 24 F13TCN           1       662 1       Y$
AL013 1 008I   25- 27 F13PNO           1       700 1       Y$
AL013 1 009I   28- 30 F13RCN           1       662 1       Y$
AL013 1 010I   35- 42 F13DATE8         1  99999999 1       Y$
AL013 1 011I   34- 34 F13VS            1         9 2       Y$
AL013 1 012I   35- 36 F13CENT          1         9 2       Y$
AL013 1 013IDR 37- 42 F13KEYDT         1         9 2       Y$
AL013 1 014I   43- 43 F13SEQ           1         9 2       Y$
AL013 1 015A   44- 44 F13SITE          1         9 0       Y$
AL013 1 016A   45- 50 F13ACROS         1         9 0       Y$
AL013 1 017I   51- 52 F13EDIT          0         3 2       Y$
AL013 1 018I   53- 53 F13Q2A1          1         9 0
AL013 1 019ID  54- 59 F13Q2A2Y         1         9 0
AL013 1 020ID  60- 65 F13Q2A3Y         1         9 0
AL013 1 021I   66- 66 F13Q2A4          1         9 0
AL013 1 022I   67- 67 F13Q2A5          1         9 0
AL013 1 023I   68- 68 F13Q2A6          1         9 0
AL013 1 024I   69- 69 F13Q2A7          1         9 0
AL013 1 025I   70- 70 F13Q2A8          1         9 0
AL013 1 026I   71- 71 F13Q2A9          1         9 0
AL013 1 027I   72- 72 F13Q2A10         1         9 0
AL013 1 028I   73- 73 F13Q2B1          1         9 0
AL013 1 029ID  74- 79 F13Q2B2D         1         9 0
AL013 1 030ID  80- 85 F13FD030         1         9 0
AL013 1 031I   86- 86 F13FD031         1         9 0
AL013 1 032I   87- 87 F13FD032         1         9 0
AL013 1 033I   88- 88 F13FD033         1         9 0
AL013 1 034I   89- 89 F13FD034         1         9 0
AL013 1 035I   90- 90 F13FD035         1         9 0
AL013 1 036I   91- 91 F13FD036         1         9 0
AL013 1 037I   92- 92 F13FD037         1         9 0
AL013 1 038I   93- 93 F13FD038         1         9 0
AL013 1 039ID  94- 99 F13FD039         1         9 0
AL013 1 040ID 100-105 F13FD040         1         9 0
AL013 1 041I  106-106 F13FD041         1         9 0
AL013 1 042I  107-107 F13FD042         1         9 0
AL013 1 043I  108-108 F13FD043         1         9 0
AL013 1 044I  109-109 F13FD044         1         9 0
AL013 1 045I  110-110 F13FD045         1         9 0
AL013 1 046I  111-111 F13FD046         1         9 0
AL013 1 047I  112-112 F13FD047         1         9 0
AL013 1 048I  113-113 F13FD048         1         9 0
AL013 1 049ID 114-119 F13FD049         1         9 0
AL013 1 050ID 120-125 F13FD050         1         9 0
AL013 1 051I  126-126 F13FD051         1         9 0
AL013 1 052I  127-127 F13FD052         1         9 0
AL013 1 053I  128-128 F13FD053         1         9 0
AL013 1 054I  129-129 F13FD054         1         9 0
AL013 1 055I  130-130 F13FD055         1         9 0
AL013 1 056I  131-131 F13FD056         1         9 0
AL013 1 057I  132-132 F13FD057         1         9 0
AL013 1 058I  133-133 F13FD058         1         9 0
```

```
AL013 1 059ID 134-139 F13FD059         1         9 0
AL013 1 060ID 140-145 F13FD060         1         9 0
AL013 1 061I  146-146 F13FD061         1         9 0
AL013 1 062I  147-147 F13FD062         1         9 0
AL013 1 063I  148-148 F13FD063         1         9 0
AL013 1 064I  149-149 F13FD064         1         9 0
AL013 1 065I  150-150 F13FD065         1         9 0
AL013 1 066I  151-151 F13FD066         1         9 0
AL013 1 067I  152-152 F13FD067         1         9 0
AL013 1 068I  153-153 F13FD068         1         9 0
AL013 1 069A  154-156 F13FD069         1         9 0
AL013 1 070I  157-157 F13FD070         1         9 0
```

AL020 - ALLHAT Transition Form - Only for Participants Assigned to Doxazosin

To be completed on all doxazosin participants at the time of the close-out of the doxazosin treatment arm; for doxazosin, non-lipid trial participants, this was their close-out form.

Version 1 – 02/2000 (only version)

Modified Fields for LADS Master File:
Blanked:
F20018
F20019
F20020
F20028
F20051

Coding details:
F20021 and F20049 are character fields rather than numeric, but have been assigned the appropriate value labels.

Blood pressure fields (F20022 through F20027) may contain the value “999” if the information was collected by telephone.

F20028 may contain the initials "999" if the information was collected over the phone.

F20037 and F20038 count fields may contain the value “99” if unknown. These two fields have value labels assigned for 0 and 99 to indicate "none" and "unknown" respectively.

AL020 Version 1

ALLHAT TRANSITION FORM - ONLY FOR PARTICIPANTS ASSIGNED TO DOXAZOSIN
To be completed and sent to the CTC by the May 25, 2000 mail cutoff

Place ID label here _____ Patient name	1. Date of visit, or date last known alive (mm-dd-yyyy): __ __ - __ __ - __ __ __ __ 2. Location: ☐1 ALLHAT clinic ☐2 Home ☐3 Phone (after May 1, 2000) ☐4 Lost to follow-up (**Form complete - go to #9**) ☐5 Refusal (**Form complete - go to #9**) ☐6 Otherwise unable to contact participant (**Form complete - go to #9**)

3. a. Seated blood pressure readings (mmHg) (use 999 for telephone visits) ..... __ __ __ / __ __ __

Patient should be seated for 5 minutes without smoking, feet flat on the floor, in an erect but comfortable position. **Blood pressure goals are <90 mmHg diastolic and <140 mmHg systolic.**

__ __ __ / __ __ __

Average: __ __ __ / __ __ __

b. Initials of person performing blood pressure measurements (use 999 for telephone visits) ..... __ __ __

4. Collection of blinded Step 1 medication ..... Done ☐1
Not done ☐2
Not prescribed at last visit ☐3

5. Participant is advised to take the following antihypertensive medication:..... a. None of the below ☐1
b. ALLHAT chlorthalidone ☐1
c. ALLHAT atenolol ☐1
d. ALLHAT clonidine ☐1
e. ALLHAT reserpine ☐1
f. ALLHAT hydralazine ☐1
g. Other antihypertensive medication ☐1

6. Number of overnight hospitalizations since the patient's last ALLHAT visit (none = 00, unknown = 99) ..... __ __

7. Number of visits to any doctor's office or clinic since the patient's last ALLHAT visit (none = 00, unknown = 99) .. __ __
(Includes interim visits to ***ALLHAT*** clinic for blood pressure measurements and/or drug titration.)

8. Since the last ALLHAT visit, has the participant experienced any new occurrence of the following:
(Please check one for each of the items #8a-k.)

	Hospitalized	Diagnosis Only	Treatment Only	No
a. Acute myocardial infarction (including evolving MI with thrombolysis)	☐ 1		☐ 2	☐ 3
b. Stroke (not TIA or "ministroke") -	☐ 1		☐ 2	☐ 3
c. Cancer (a new *primary* diagnosis; excluding non-melanoma skin cancer)	☐ 1	☐ 4	☐ 2	☐ 3
d. Congestive heart failure	☐ 1		☐ 2	☐ 3
e. Angina pectoris (actual episode of chest pain)	☐ 1		☐ 2	☐ 3
f. Lower extremity peripheral arterial disease	☐ 1		☐ 2	☐ 3
g. Accident or attempted suicide	☐ 1		☐ 2	☐ 3

Any of the following procedures?	Yes	No
h. Kidney transplant or start of chronic dialysis	☐ 1	☐ 2
i. Coronary artery bypass graft (CABG) or transmyocardial laser revascularization	☐ 1	☐ 2
j. Coronary PTCA (angioplasty), stent or atherectomy	☐ 1	☐ 2
k. Lower extremity peripheral revascularization/bypass/angioplasty	☐ 1	☐ 2

Complete an Event Reporting Form (AL04) for all boxed events in Items #8a-k.

- ♥ **No participant** should retain any bottle (**whole or part**) of Step 1 blinded medication.
- ♥ Participants **in the lipid component <u>will continue</u>** with their routine ALLHAT visit schedule.
- ♥ Participants **not in the lipid component <u>will not continue</u>** with ALLHAT.
  - ✓ Update participant contact sheet & release of info for medical records.
  - ✓ Have participant sign release of information for study data to be sent to other private MD if applicable.

9. Signature and initials of person completing this form: _____ __ __ __

Fields-Marked Version

ALLHAT TRANSITION FORM - ONLY FOR PARTICIPANTS ASSIGNED TO DOXAZOSIN

To be completed and sent to the CTC by the May 25, 2000 mail cutoff

(13) -6 Digit

(7) T center P number

(8) **Place ID label here**

(9) R Center

(11) V S N (15) Site Acrostic

Patient name (16)

1. Date of visit, or date last known alive (mm-dd-yyyy): __-__-____ (10) 8 Digit

2. Location: (21)
   - ☐1 ALLHAT clinic
   - ☐2 Home
   - ☐3 Phone (after May 1, 2000)
   - ☐4 Lost to follow-up (**Form complete - go to #9**)
   - ☐5 Refusal (**Form complete - go to #9**)
   - ☐6 Otherwise unable to contact participant (**Form complete - go to #9**)

3. a. Seated blood pressure readings (mmHg) (use 999 for telephone visits) ..... (22)__ / (23)__

   Patient should be seated for 5 minutes without smoking, feet flat on the floor, in an erect but comfortable position. **Blood pressure goals are <90 mmHg diastolic and <140 mmHg systolic.**

   (24)__ / (25)__

   Average: (26)__ / (27)__

   b. Initials of person performing blood pressure measurements (use 999 for telephone visits) ..... (28)__

4. Collection of blinded Step 1 medication ..... Done ☐1 / Not done ☐2 (29) / Not prescribed at last visit ☐3

5. Participant is advised to take the following antihypertensive medication: ..... a. None of the below ☐1 (30)
   - b. ALLHAT chlorthalidone ☐1 (31)
   - c. ALLHAT atenolol ☐1 (32)
   - d. ALLHAT clonidine ☐1 (33)
   - e. ALLHAT reserpine ☐1 (34)
   - f. ALLHAT hydralazine ☐1 (35)
   - g. Other antihypertensive medication ☐1 (36)

6. Number of overnight hospitalizations since the patient's last ALLHAT visit (none = 00, unknown = 99) ..... (37)__

7. Number of visits to any doctor's office or clinic since the patient's last ALLHAT visit (none = 00, unknown = 99) .. (38)__
   (Includes interim visits to ***ALLHAT*** clinic for blood pressure measurements and/or drug titration.)

8. Since the last ALLHAT visit, has the participant experienced any new occurrence of the following:
   (Please check one for each of the items #8a-k.)

	Hospitalized	Diagnosis Only	Treatment Only	No
a. Acute myocardial infarction (including evolving MI with thrombolysis) (39)	☐1		☐2	☐3
b. Stroke (not TIA or "ministroke") - (40)	☐1		☐2	☐3
c. Cancer (a new *primary* diagnosis; excluding non-melanoma skin cancer) (41)	☐1	☐4	☐2	☐3
d. Congestive heart failure (42)	☐1		☐2	☐3
e. Angina pectoris (actual episode of chest pain) (43)	☐1		☐2	☐3
f. Lower extremity peripheral arterial disease (44)	☐1		☐2	☐3
g. Accident or attempted suicide (45)	☐1		☐2	☐3

Any of the following procedures?	Yes	No
h. Kidney transplant or start of chronic dialysis (46)	☐1	☐2
i. Coronary artery bypass graft (CABG) or transmyocardial laser revascularization (47)	☐1	☐2
j. Coronary PTCA (angioplasty), stent or atherectomy (48)	☐1	☐2
k. Lower extremity peripheral revascularization/bypass/angioplasty (49)	☐1	☐2

Complete an Event Reporting Form (AL04) for all boxed events in Items #8a-k.

- ♥ **No participant** should retain any bottle (**whole or part**) of Step 1 blinded medication.
- ♥ Participants **in the lipid component will continue** with their routine ALLHAT visit schedule.
- Participants **not in the lipid component will not continue** with ALLHAT.
  - ✓ Update participant contact sheet & release of info for medical records.
  - ✓ Have participant sign release of information for study data to be sent to other private MD if applicable.

9. Signature and initials of person completing this form: FLAG (50) __ (51)

```
AL020 1 001I    1-  2 F20KPCOD         1        99 1
AL020 1 002IDR  3-  8 F20BATDT         1        99 1
AL020 1 003A    9- 10 F20VFCOD         1        99 0
AL020 1 004IDR 11- 16 F20DTMOD         1        99 1
AL020 1 005I   17- 20 F20TMMOD         1        99 1
AL020 1 006I   21- 21 F20MDFLG         1        99 1
AL020 1 007I   22- 24 F20TCN           1        99 1       Y$
AL020 1 008I   25- 27 F20PNO           1       900 1       Y$
AL020 1 009I   28- 30 F20RCN           1       700 1       Y$
AL020 1 010I   35- 42 F20DATE8         1    999999 1       Y$
AL020 1 011I   34- 34 F20VS            1        99 1       Y$
AL020 1 012I   35- 36 F20CENT          1        99 1       Y$
AL020 1 013IDR 37- 42 F20KEYDT         1        99 1       Y$
AL020 1 014I   43- 43 F20SEQ           1        99 1       Y$
AL020 1 015A   44- 44 F20SITE          1        99 0       Y$
AL020 1 016A   45- 50 F20ACR           1        99 0       Y$
AL020 1 017A   51- 52 F20EDIT          1        99 0
AL020 1 018A   53- 63 F20RINO          1        99 0
AL020 1 019I   64- 66 F20PAYCN         1       999 0
AL020 1 020A   70- 80 F20CKNO          1        99 0
AL020 1 021I   81- 81 F20Q2            1         6 2
AL020 1 022I   82- 84 F20SBP1         60       300 1
AL020 1 023I   85- 87 F20DBP1          0       200 1
AL020 1 024I   88- 90 F20SBP2         60       300 1
AL020 1 025I   91- 93 F20DBP2          0       200 1
AL020 1 026I   94- 96 F20SBP3          0       200 1
AL020 1 027I   97- 99 F20DBP3          0       200 1
AL020 1 028A  100-102 F20Q3B           1        99 0
AL020 1 029I  103-103 F20Q4            1         3 2
AL020 1 030I  104-104 F20Q5A           0         1 2
AL020 1 031I  105-105 F20Q5B           0         1 2
AL020 1 032I  106-106 F20Q5C           0         1 2
AL020 1 033I  107-107 F20Q5D           0         1 2
AL020 1 034I  108-108 F20Q5E           0         1 2
AL020 1 035I  109-109 F20Q5F           0         1 2
AL020 1 036I  110-110 F20Q5G           0         1 2
AL020 1 037I  111-112 F20Q6            1        99 0
AL020 1 038I  113-114 F20Q7            1        99 0
AL020 1 039I  115-115 F20Q8A           1         3 2
AL020 1 040I  116-116 F20Q8B           1         3 2
AL020 1 041I  117-117 F20Q8C           1         4 2
AL020 1 042I  118-118 F20Q8D           1         3 2
AL020 1 043I  119-119 F20Q8E           1         3 2
AL020 1 044I  120-120 F20Q8F           1         3 2
AL020 1 045I  121-121 F20Q8G           1         3 2
AL020 1 046I  122-122 F20Q8H           1         2 2
AL020 1 047I  123-123 F20Q8I           1         2 2
AL020 1 048I  124-124 F20Q8J           1         2 2
AL020 1 049I  125-125 F20Q8K           1         2 2
AL020 1 050I  126-126 F20Q9A           0         1 2
AL020 1 051A  127-129 F20Q9B           1        99 0
```

AL022 - ALLHAT Closeout Form

Final close-out form; a doxazosin participant may have this form as well as an AL20 if a Lipid-Lowering Trial participant.

Version 1 – 06/2001 (only version)

Modified Fields for LADS Master File:

Blanked:
F22018
F22019
F22020
F22031
F22098
F22109

Changed date (mmddyy) to days since randomization:
F22023
F22024

AL022 Version 1

ALLHAT CLOSEOUT FORM
To be completed between October 1, 2001 and March 31, 2002 and received at the CTC by May 24, 2002

Place ID label here	1. Date this form is completed (mm-dd-yyyy): __ __ - __ __ - __ __ __ __
_____ Patient name	

2. a. Has participant moved outside the United States, Canada, Puerto Rico or the U.S. Virgin Islands? ..... Yes ☐1
No ☐2
Don't know ☐3

b. Type of visit (check one):
☐1 ALLHAT clinic
☐2 Home
☐3 Phone
→ c. Date of visit: __ __ - __ __ - __ __ __ __ (mmddyyyy) **(SKIP TO #3)**

OR

☐4 Lost to follow-up
☐5 Refusal
☐6 Otherwise unable to contact
→ d. Date last known alive: __ __ - __ __ - __ __ __ __ (mmddyyyy) **(SKIP TO #16)**

3. a. Seated blood pressure readings (mmHg) (use 999 for telephone visits) ..... __ __ __ / __ __ __

Patient should be seated for 5 minutes without smoking, feet flat on the floor, in an erect but comfortable position.

__ __ __ / __ __ __

Average: __ __ __ / __ __ __

b. Initials of person performing blood pressure measurements (use 999 for telephone visits) ..... __ __ __

4. What dose of the ALLHAT Step 1 (blinded) medication is the patient being advised to take? ..... Dose 1 ☐1
Dose 2 ☐2
Dose 3 ☐3
None ☐4

5. Which of the following medications is the patient being advised to take? ..... a. None of the below ☐1

This refers to any open-label antihypertensive or lipid-lowering medication, and potassium supplementation, including medications provided by ALLHAT or from another source, **and regardless of reasons for prescription. CHECK ALL THAT APPLY.**

b. Diuretic 1-2 times per week ☐1
c. Diuretic 3 or more times per week ☐1
d. Calcium-channel blocker ☐1
e. ACE inhibitor ☐1
f. Alpha blocker ☐1
g. Atenolol ☐1
h. Clonidine ☐1
i. Reserpine ☐1
j. Hydralazine ☐1
k. Other antihypertensive medication, regardless of indication ☐1
l. HMG CoA reductase inhibitor (including ALLHAT pravastatin) ☐1
m. Other lipid-lowering medication ☐1
n. Potassium supplement ☐1
o. Information not available ☐1

6. Number of overnight hospitalizations since the patient's last ALLHAT visit (none = 00, unknown = 99) ..... __ __

7. Number of visits to any doctor's office or clinic since the patient's last ALLHAT visit (none = 00, unknown = 99)... __ __
(Includes interim visits to ***ALLHAT*** clinic for blood pressure measurements and/or drug titration.)

8. Since the last ALLHAT visit, has the participant experienced any new occurrence of the following:
(Please check one for each of the items #8a-k.)

	Hospitalized	Diagnosis Only	Treatment Only	No
a. Acute myocardial infarction (including evolving MI with thrombolysis)	☐ 1		☐ 2	☐ 3
b. Stroke (not TIA or "ministroke") -	☐ 1		☐ 2	☐ 3
c. Cancer (a new *primary* diagnosis; excluding non-melanoma skin cancer)	☐ 1	☐ 4	☐ 2	☐ 3
d. Congestive heart failure	☐ 1		☐ 2	☐ 3
e. Angina pectoris (actual episode of chest pain)	☐ 1		☐ 2	☐ 3
f. Lower extremity peripheral arterial disease	☐ 1		☐ 2	☐ 3
g. Accident or attempted suicide	☐ 1		☐ 2	☐ 3

Any of the following procedures?	Yes	No
h. Kidney transplant or start of chronic dialysis	☐ 1	☐ 2
i. Coronary artery bypass graft (CABG) or transmyocardial laser revascularization	☐ 1	☐ 2
j. Coronary PTCA (angioplasty), stent or atherectomy	☐ 1	☐ 2
k. Lower extremity peripheral revascularization/bypass/angioplasty	☐ 1	☐ 2

Complete an Event Reporting Form (AL04) for all boxed events in Items #8a-k.

9. In general, would you say your health is:
Excellent ☐ 1
Very good ☐ 2
Good ☐ 3
Fair ☐ 4
Poor ☐ 5
No answer/unknown ☐ 6

10. If you were to rate your current health on a scale of 0 to 100, with 100 being perfect health and 0 being death, what number would you rate yourself today? (Unknown = 999) ... __ __ __

11. Have you ever smoked ***cigarettes***?
Current smoker (past 30 days) ☐ 1
Past smoker (100+ cigarettes) ☐ 2
Never smoked ☐ 3
Unknown ☐ 4

12. Are you currently taking *aspirin* regularly?
Yes ☐ 1
No ☐ 2
Don't know ☐ 3

13. ***For women only:*** Are you currently prescribed an estrogen supplement?
Yes ☐ 1
No ☐ 2
Don't know ☐ 3

Place ID label here

_____
Patient name

14. a. Were there any reasons that kept you from taking your ALLHAT medicine (the black and blue capsules) ?..... Yes ☐ 1
No (**skip to #15**) ☐ 2

What were the reasons? .....b. Size or taste of pills was a problem ☐ 1

Show the participant the laminated response card for #14 and let them tell you their response(s). CHECK ALL THAT APPLY.

c. Too many pills ☐ 1
d. I didn't like not knowing what the medicine was ☐ 1
e. It was hard to remember to take the medicine ☐ 1
f. I didn't think that I needed the medicine ☐ 1
g. I didn't understand how to take the medicine ☐ 1
h. I had a bad reaction to the medicine ☐ 1
i. I was worried about the health effects of the study medicine ☐ 1
j. Living in nursing home ☐ 1
k. Lack of support from family/friends ☐ 1
l. Another doctor told me to stop ☐ 1
m. My insurance changed ☐ 1
n. Other reason _____ ☐ 1
o. No reason given ☐ 1
p. Information not available ☐ 1

15. a. Were there any reasons that kept you from coming to the clinic? ..... Yes ☐ 1
No (**skip to #16**) ☐ 2

What were the reasons? ..... b. I didn't want to be in the study ☐ 1

Show the participant the laminated response card for #15 and let them tell you their response(s). CHECK ALL THAT APPLY.

c. I didn't want to come to the clinic ☐ 1
d. It was not convenient to attend clinic ☐ 1
e. I didn't like the clinic ☐ 1
f. I didn't like the visits ☐ 1
g. Transportation problems ☐ 1
h. Living in nursing home ☐ 1
i. Lack of support from family/friends ☐ 1
j. Another doctor told me to stop ☐ 1
k. My insurance changed ☐ 1
l. Other reason _____ ☐ 1
m. No reason given ☐ 1
n. Information not available ☐ 1

ITEMS #16, #17 & #18 ARE TO BE COMPLETED BY THE CLINICIAN WHO IS MOST FAMILIAR WITH THE PARTICIPANT

16. a. Initials of the person assessing drug assignment..... _ _ _

b. The person in #16a is (check the first that applies): ..... Principal Investigator ☐ 1
Other physician ☐ 2
Study coordinator ☐ 3
Other staff member ☐ 4

Place ID label here

_____
Patient name

17. To which medicine would you guess the participant was assigned in ALLHAT? ..... Diuretic (chlorthalidone) ☐ 1
Calcium-channel blocker (amlodipine) ☐ 2
ACE inhibitor (lisinopril) ☐ 3
Not applicable - participant was assigned to doxazosin **(skip to #19)** ☐ 4

Do not leave item #17 blank – please guess!

18. On which of the following do you base your guess? (Check all that apply.) ..... a. Drug code unblinded ☐ 1
b. Laboratory findings ☐ 1
c. Symptoms ☐ 1
d. Blood pressure control ☐ 1
e. Other reason _____ ☐ 1
f. No reason ☐ 1

19. Signature and initials of person completing this form: ..... _____ ___ ___ ___

***** ALLHAT CLOSEOUT VISIT REMINDERS *****

Do you have all of the following? (Check the list of missing items for this patient.)

- **The most recent required bloodwork?**
- **All of the required ECG's?**
- **All of the required event documentation?**
- **Release of information for documentation that you still need?**
- **Release of information to send participant's ALLHAT information to another physician, if required**
- **Updated participant contact sheet?**

Give the participant:

- A referral to another source of antihypertensive and lipid-lowering care, if needed
- Closeout *Health Matters* newsletter
- ALLHAT antihypertensive medication and potassium supplementation, if prescribed
- Pravastatin, as needed for those participants who were assigned to pravastatin in the lipid trial, if they are currently taking pravastatin (**1 bottle per participant only**)
- Other prescription, if necessary
- Certificate of appreciation
- ALLHAT patient history, if desired by the participant

Have you completed:

- All of the pending ALLHAT follow-up forms (AL03)?
- All of the pending ALLHAT Event Reporting forms (AL04)?
- Any pending Serious Adverse Effect Forms (AL13)?
- All of the pending edits (routine edits, event edits, HCFA/VA event queries, AL09's)

Place ID label here

_____
Patient name

Fields-Marked Version

ALLHAT CLOSEOUT FORM
To be completed between October 1, 2001 and March 31, 2002 and received at the CTC by May 24, 2002

Place ID label here	(1) DE (2) Batch (3) VF (4) mod DATE (5) mod TIME (6) MOD FLAG (7) TCN (8) PNO (9) RCN (10) 8 DIGIT FM DATE (11) VERSION (12) CENTURY
Patient name	1. Date this form is completed (mm-dd-yyyy): __ - __ - ____ (13) FM DATE (14) SEQ (15) SITE (16) ACROSTIC (17) EDIT FLAG

2. a. Has participant moved outside the United States, Canada, Puerto Rico or the U.S. Virgin Islands? (21) ..... Yes ☐1
No ☐2
Don't know ☐3

b. Type of visit (check one): (22)
- ☐1 ALLHAT clinic
- ☐2 Home
- ☐3 Phone

→ c. Date of visit: (23) __ - __ - ____ (mmddyyyy) **(SKIP TO #3)**

OR

- ☐4 Lost to follow-up
- ☐5 Refusal
- ☐6 Otherwise unable to contact

→ d. Date last known alive: (24) __ - __ - ____ (mmddyyyy) **(SKIP TO #16)**

3. a. Seated blood pressure readings (mmHg) (use 999 for telephone visits) ..... (25) ___ / (26) ___
(27) ___ / (28) ___
Average: (29) ___ / (30) ___

Patient should be seated for 5 minutes without smoking, feet flat on the floor, in an erect but comfortable position.

b. Initials of person performing blood pressure measurements (use 999 for telephone visits) ..... (31) ___

4. What dose of the ALLHAT Step 1 (blinded) medication is the patient being advised to take? ..... (32)
Dose 1 ☐1
Dose 2 ☐2
Dose 3 ☐3
None ☐4

5. Which of the following medications is the patient being advised to take? (33) .....
a. None of the below ☐1
(34) b. Diuretic 1-2 times per week ☐1
(35) c. Diuretic 3 or more times per week ☐1
(36) d. Calcium-channel blocker ☐1
(37) e. ACE inhibitor ☐1
(38) f. Alpha blocker ☐1
(39) g. Atenolol ☐1
(40) h. Clonidine ☐1
(41) i. Reserpine ☐1
(42) j. Hydralazine ☐1
(43) k. Other antihypertensive medication, regardless of indication ☐1
(44) l. HMG CoA reductase inhibitor (including ALLHAT pravastatin) ☐1
(45) m. Other lipid-lowering medication ☐1
(46) n. Potassium supplement ☐1
(47) o. Information not available ☐1

This refers to any open-label antihypertensive or lipid-lowering medication, and potassium supplementation, including medications provided by ALLHAT or from another source, **and regardless of reasons for prescription. CHECK ALL THAT APPLY.**

6. Number of overnight hospitalizations since the patient's last ALLHAT visit (none = 00, unknown = 99) ..... (48) __

7. Number of visits to any doctor's office or clinic since the patient's last ALLHAT visit (none = 00, unknown = 99)... 49 __ __
(Includes interim visits to ***ALLHAT*** clinic for blood pressure measurements and/or drug titration.)

8. Since the last ALLHAT visit, has the participant experienced any new occurrence of the following:
(Please check one for each of the items #8a-k.)

	Hospitalized	Diagnosis Only	Treatment Only	No
a. Acute myocardial infarction (including evolving MI with thrombolysis)	☐ 1		50 ☐ 2	☐ 3
b. Stroke (not TIA or "ministroke") -	☐ 1	51	☐ 2	☐ 3
c. Cancer (a new *primary* diagnosis; excluding non-melanoma skin cancer)	☐ 1	☐ 4	52 ☐ 2	☐ 3
d. Congestive heart failure	☐ 1	53	☐ 2	☐ 3
e. Angina pectoris (actual episode of chest pain)	☐ 1		54 ☐ 2	☐ 3
f. Lower extremity peripheral arterial disease	☐ 1	55	☐ 2	☐ 3
g. Accident or attempted suicide	☐ 1		56 ☐ 2	☐ 3

Any of the following procedures?	Yes		No
h. Kidney transplant or start of chronic dialysis	☐ 1	57	☐ 2
i. Coronary artery bypass graft (CABG) or transmyocardial laser revascularization	☐ 1	58	☐ 2
j. Coronary PTCA (angioplasty), stent or atherectomy	☐ 1	59	☐ 2
k. Lower extremity peripheral revascularization/bypass/angioplasty	☐ 1	60	☐ 2

Complete an Event Reporting Form (AL04) for all boxed events in Items #8a-k.

9. In general, would you say your health is: ..... Excellent ☐ 1
Very good ☐ 2
61 Good ☐ 3
Fair ☐ 4
Poor ☐ 5
No answer/unknown ☐ 6

10. If you were to rate your current health on a scale of 0 to 100, with 100 being perfect health and 0 being death, what number would you rate yourself <u>today</u>? (Unknown = 999) ..... 62 __ __ __

11. Have you ever smoked ***<u>cigarettes</u>***? ..... Current smoker (past 30 days) ☐ 1
Past smoker (100+ cigarettes) ☐ 2
63 Never smoked ☐ 3
Unknown ☐ 4

12. Are you currently taking ***<u>aspirin</u>*** regularly? ..... Yes ☐ 1
64 No ☐ 2
Don't know ☐ 3

13. ***For women only:*** Are you currently prescribed an estrogen supplement? ..... Yes ☐ 1
65 No ☐ 2
Don't know ☐ 3

Place ID label here

Patient name

14. a. Were there any reasons that kept you from taking your ALLHAT medicine (the black and blue capsules) ?..... (66) Yes ☐ 1
No (**skip to #15**) ☐ 2

What were the reasons? ..... (67)

Show the participant the laminated response card for #14 and let them tell you their response(s). CHECK ALL THAT APPLY.

b. Size or taste of pills was a problem ☐ 1
(68) c. Too many pills ☐ 1
(69) d. I didn't like not knowing what the medicine was ☐ 1
(70) e. It was hard to remember to take the medicine ☐ 1
(71) f. I didn't think that I needed the medicine ☐ 1
(72) g. I didn't understand how to take the medicine ☐ 1
(73) h. I had a bad reaction to the medicine ☐ 1
(74) i. I was worried about the health effects of the study medicine ☐ 1
(75) j. Living in nursing home ☐ 1
(76) k. Lack of support from family/friends ☐ 1
(77) l. Another doctor told me to stop ☐ 1
(78) m. My insurance changed ☐ 1
n. Other reason _____ (80) P (79) ☐ 1
(81) o. No reason given ☐ 1
(82) p. Information not available ☐ 1

15. a. Were there any reasons that kept you from coming to the clinic? ..... (83) Yes ☐ 1
No (**skip to #16**) ☐ 2

What were the reasons? ..... (84)

Show the participant the laminated response card for #15 and let them tell you their response(s). CHECK ALL THAT APPLY.

b. I didn't want to be in the study ☐ 1
(85) c. I didn't want to come to the clinic ☐ 1
(86) d. It was not convenient to attend clinic ☐ 1
(87) e. I didn't like the clinic ☐ 1
(88) f. I didn't like the visits ☐ 1
(89) g. Transportation problems ☐ 1
(90) h. Living in nursing home ☐ 1
(91) i. Lack of support from family/friends ☐ 1
(92) j. Another doctor told me to stop ☐ 1
(93) k. My insurance changed ☐ 1
l. Other reason _____ (95) P (94) ☐ 1
(96) m. No reason given ☐ 1
(97) n. Information not available ☐ 1

ITEMS #16, #17 & #18 ARE TO BE COMPLETED BY THE CLINICIAN WHO IS MOST FAMILIAR WITH THE PARTICIPANT

16. a. Initials of the person assessing drug assignment..... (98) ___

b. The person in #16a is (check the first that applies): ..... Principal Investigator ☐ 1
(99) Other physician ☐ 2
Study coordinator ☐ 3
Other staff member ☐ 4

Place ID label here

_____
Patient name

100

17. To which medicine would you guess the participant was assigned in ALLHAT? ..... Diuretic (chlorthalidone) ☐ 1
Calcium-channel blocker (amlodipine) ☐ 2
ACE inhibitor (lisinopril) ☐ 3
Not applicable - participant was assigned to doxazosin **(skip to #19)** ☐ 4

Do not leave item #17 blank – please guess!

18. On which of the following do you base your guess? (Check all that apply.) ..... 101 a. Drug code unblinded ☐ 1
102 b. Laboratory findings ☐ 1
103 c. Symptoms ☐ 1
104 d. Blood pressure control ☐ 1
e. Other reason _____ 106 105 ☐ 1
107 f. No reason ☐ 1

19. Signature and initials of person completing this form: ..... 108 _____ 109 ____

***** ALLHAT CLOSEOUT VISIT REMINDERS *****

Do you have all of the following? (Check the list of missing items for this patient.)

- **The most recent required bloodwork?**
- **All of the required ECG's?**
- **All of the required event documentation?**
- **Release of information for documentation that you still need?**
- **Release of information to send participant's ALLHAT information to another physician, if required**
- **Updated participant contact sheet?**

Give the participant:

- A referral to another source of antihypertensive and lipid-lowering care, if needed
- Closeout *Health Matters* newsletter
- ALLHAT antihypertensive medication and potassium supplementation, if prescribed
- Pravastatin, as needed for those participants who were assigned to pravastatin in the lipid trial, if they are currently taking pravastatin (**1 bottle per participant only**)
- Other prescription, if necessary
- Certificate of appreciation
- ALLHAT patient history, if desired by the participant

Have you completed:

- All of the pending ALLHAT follow-up forms (AL03)?
- All of the pending ALLHAT Event Reporting forms (AL04)?
- Any pending Serious Adverse Effect Forms (AL13)?
- All of the pending edits (routine edits, event edits, HCFA/VA event queries, AL09's)

Place ID label here

_____
Patient name

```
AL022 1 001I    1-  2 F22DE           1         9 2
AL022 1 002IDR  3-  8 F22BDAT         1         9 2
AL022 1 003A    9- 10 F22VERF         1         9 0
AL022 1 004IDR 11- 16 F22MODDT        1         9 2
AL022 1 005I   17- 20 F22MODTM        1         9 2
AL022 1 006I   21- 21 F22MODFG        1         9 2
AL022 1 007I   22- 24 F22TCN          1         9 2       Y$
AL022 1 008I   25- 27 F22PNUM         1       900 1       Y$
AL022 1 009I   28- 30 F22RCN          1       300 1       Y$
AL022 1 010I   35- 42 F22DATE8        1  99999999 1       Y$
AL022 1 011I   34- 34 F22VERSN        1         9 2       Y$
AL022 1 012I   35- 36 F22CEN          1         9 2       Y$
AL022 1 013IDR 37- 42 F22KEYDT        1         9 2       Y$
AL022 1 014I   43- 43 F22SEQ          1         9 2       Y$
AL022 1 015A   44- 44 F22SITE         1         9 0       Y$
AL022 1 016A   45- 50 F22ACOS         1         9 0       Y$
AL022 1 017I   51- 52 F22EDTFG        1         9 2
AL022 1 018A   53- 63 F22RINUM        1         9 0
AL022 1 019A   64- 66 F22PYCN1        1         9 0
AL022 1 020I   70- 80 F22CKNUM        1 999999999 0
AL022 1 021I   81- 81 F22FD21         1         3 2
AL022 1 022I   82- 82 F22Q2B          1         6 2
AL022 1 023ID  83- 90 F22Q2CD1        0        12 1
AL022 1 024ID  91- 98 F22Q2CD2        0        12 1
AL022 1 025I   99-101 F22Q3AS1        1       400 1
AL022 1 026I  102-104 F22Q3AD1        1       250 1
AL022 1 027I  105-107 F22Q3AS2        1       400 1
AL022 1 028I  108-110 F22Q3AD2        1       250 1
AL022 1 029I  111-113 F22Q3AS3        1       400 1
AL022 1 030I  114-116 F22Q3AD3        1       250 1
AL022 1 031A  117-119 F22Q3B          1         9 0
AL022 1 032I  120-120 F22Q4           1         4 2
AL022 1 033I  121-121 F22Q5a          0         9 2
AL022 1 034I  122-122 F22Q5B          0         1 2
AL022 1 035I  123-123 F22Q5C          0         1 2
AL022 1 036I  124-124 F22Q5D          0         1 2
AL022 1 037I  125-125 F22Q5E          0         1 2
AL022 1 038I  126-126 F22Q5F          0         1 2
AL022 1 039I  127-127 F22Q5G          0         1 2
AL022 1 040I  128-128 F22Q5H          0         1 2
AL022 1 041I  129-129 F22Q5I          0         1 2
AL022 1 042I  130-130 F22Q5J          0         1 2
AL022 1 043I  131-131 F22Q5K          0         1 2
AL022 1 044I  132-132 F22Q5L          0         1 2
AL022 1 045I  133-133 F22Q5M          0         1 2
AL022 1 046I  134-134 F22Q5N          0         1 2
AL022 1 047I  135-135 F22Q5O          0         1 2
AL022 1 048I  136-137 F22Q6           0        99 1
AL022 1 049I  138-139 F22Q7           0        99 1
AL022 1 050I  140-140 F22Q8A          1         3 2
AL022 1 051I  141-141 F22Q8B          0         3 2
AL022 1 052I  142-142 F22Q8C          0         4 2
AL022 1 053I  143-143 F22Q8D          0         3 2
AL022 1 054I  144-144 F22Q8E          0         3 2
AL022 1 055I  145-145 F22Q8F          1         3 2
AL022 1 056I  146-146 F22Q8G          0         3 2
AL022 1 057I  147-147 F22Q8H          0         2 2
AL022 1 058I  148-148 F22Q8I          0         2 2
AL022 1 059I  149-149 F22Q8J          0         2 2
AL022 1 060I  150-150 F22Q8K          0         2 2
```

```
AL022 1 061I  151-151 F22Q9            0         6 2
AL022 1 062I  152-154 F22Q10           0       100 1
AL022 1 063I  155-155 F22Q11           0         4 2
AL022 1 064I  156-156 F22Q12           0         3 2
AL022 1 065I  157-157 F22Q13           0         3 2
AL022 1 066I  158-158 F22Q14A          0         2 2
AL022 1 067I  159-159 F22Q14b          0         1 2
AL022 1 068I  160-160 F22Q14C          0         1 2
AL022 1 069I  161-161 F22Q14D          0         1 2
AL022 1 070I  162-162 F22Q14E          0         1 2
AL022 1 071I  163-163 F22Q14F          0         1 2
AL022 1 072I  164-164 F22Q14G          0         1 2
AL022 1 073I  165-165 F22Q14H          0         1 2
AL022 1 074I  166-166 F22Q14I          0         1 2
AL022 1 075I  167-167 F22Q14J          0         1 2
AL022 1 076I  168-168 F22Q14K          0         1 2
AL022 1 077I  169-169 F22Q14L          0         1 2
AL022 1 078I  170-170 F22Q14M          0         1 2
AL022 1 079I  171-171 F22Q14N          0         1 2
AL022 1 080I  172-172 F22Q14N1         0         1 2
AL022 1 081I  173-173 F22Q14O          0         1 2
AL022 1 082I  174-174 F22Q14P          0         1 2
AL022 1 083I  175-175 F22Q15A          1         9 0
AL022 1 084I  176-176 F22Q15B          0         1 2
AL022 1 085I  177-177 F22Q15C          0         1 2
AL022 1 086I  178-178 F22Q15d          0         1 2
AL022 1 087I  179-179 F22Q15E          0         1 2
AL022 1 088I  180-180 F22Q15F          0         1 2
AL022 1 089I  181-181 F22Q15G          0         1 2
AL022 1 090I  182-182 F22Q15H          0         1 2
AL022 1 091I  183-183 F22Q15I          0         1 2
AL022 1 092I  184-184 F22Q15J          0         1 2
AL022 1 093I  185-185 F22Q15K          0         1 2
AL022 1 094I  186-186 F22Q15L          0         1 2
AL022 1 095I  187-187 F22Q15L1         0         1 2
AL022 1 096I  188-188 F22Q15M          0         1 2
AL022 1 097I  189-189 F22Q15N          0         1 2
AL022 1 098A  190-192 F22Q16A          1         9 0
AL022 1 099I  193-193 F22Q16B          0         4 2
AL022 1 100I  194-194 F22Q17           1         4 2
AL022 1 101I  195-195 F22Q18A          0         1 2
AL022 1 102I  196-196 F22Q18B          0         1 2
AL022 1 103I  197-197 F22Q18C          0         1 2
AL022 1 104I  198-198 F22Q18D          0         1 2
AL022 1 105I  199-199 F22Q18E          0         1 2
AL022 1 106I  200-200 F22Q18EF         0         1 2
AL022 1 107I  201-201 F22Q18F          0         1 2
AL022 1 108I  202-202 F22Q19           0         1 2
AL022 1 109A  203-205 F22Q19IL         1        99 0
AL022 1 110I  206-206 F22CCCT          0         2 2
```

AL023 - ALLHAT CHF Quality Control Form

Two reviews are completed for each heart failure hospitalization received by February 2002.

Version 1 – 10/2001 (inventory sheet); reviewer coding portion of form 02/2002 (only version)

Modified Fields for LADS Master File:

Blanked:

F23018
F23019
F23021
F23038
F23044
F23046
F23107
F23109
F23111
F23160
F23221
F23223
F23225
F23274
F23335
F23337
F23339

Changed date (mmddyy) to days since randomization:

F23022
F23040
F23041
F23042
F23047
F23161
F23275

Data details:

Decimals need to be added to some fields, if they are completed. See the paper copy of the AL023 (F23096, F23098 and F23100).

Coding Details:

Measurement fields are filled with 9's if no measurement was available (F23091-F23093, F23095-F23100, F23105, F23113-F23115, F23118-F23120, and F23123-F23124).

AL023 Version 1

ALLHAT CHF QUALITY CONTROL

The CHF event listed below has been selected as part of ALLHAT'S endpoint quality control documentation. Please obtain the records requested and send them with this cover sheet to the Clinical Trials Center with your regular shipment of study forms.

PLEASE KEEP A PHOTOCOPY OF THIS FORM FOR YOUR FILES.

1. Date this request generated: ..... __-__-__
   Sequence Number: ..... _
2. Patient ID: ..... ___-___-___
3. Site code: ..... _
4. Acrostic: ..... _____
5. Event date from AL04 (mm-dd-yy): ..... __-__-__
6. Event type: ..... a. Hospitalized fatal CHF _
   b. Hospitalized nonfatal CHF _

****

For clinical site use:

Label all additional records with patient ID, acrostic and event date

The following additional documents are requested:

7. Please mark which records are enclosed: ..... a. None (explain) __
   b. Face sheet with diagnosis and procedure codes __
   c. Discharge summary __
   d. Admitting history and physical examination __
   e. Chest X-ray reports (first and second reports only) __
   f. Initial cardiology and pulmonary consultation notes __
   g. Cardiac catheterization reports/procedure notes __
   h. Echocardiography reports (including Doppler studies) __
   i. Radionuclide cardiac imaging reports __
   j. Emergency room notes __
   k. Pulmonary function test reports (first and last reports only) __
   l. Autopsy/coroner's reports __
8. Comments: _____

_____

_____

9. Initials of clinical site staff person completing form: ..... __ __ __
10. Signature: ..... _____

****

Clinical Trials Center Use Only:

11. Date additional documentation received: ..... __ __ - __ __ - __ __ __ __
12. Date completed: ..... __ __ - __ __ - __ __ __ __
13. Initials of CTC monitor: ..... __ __ __
14. Signature of CTC monitor: ..... _____

ALLHAT CHF REVIEW

1. ALLHAT ID: __ __ __ - __ __ __ - __ __ __
2. Acrostic: __ __ __ __ __ __
3. Date of CHF event: ____ / ____ / _____

4. Coder number: ____
5. Coding date: ____ / ____ / _____

Please review this case and provide your evaluation of the following:

Symptoms **6. No documentation ____ 1 (Skip to next section)**

	Yes (documented)	No (documented)	Not mentioned / Uncertain
7. Paroxysmal nocturnal dyspnea	___ 1	___ 2	___ 3
8. Orthopnea	___ 1	___ 2	___ 3
9. Dyspnea at rest	___ 1	___ 2	___ 3
10. Dyspnea on ordinary exertion	___ 1	___ 2	___ 3
11. New York Heart Association Class III (symptoms of CHF on less than ordinary exertion)	___ 1	___ 2	___ 3
12. Night cough	___ 1	___ 2	___ 3

Past medical history **13. No documentation ____ 1 (Skip to next section)**

(All ALLHAT participants have hypertension)

	Yes (documented)	No (documented)	Not mentioned / Uncertain
14. CHD	___ 1	___ 2	___ 3
15. Clinically significant valvular disease	___ 1	___ 2	___ 3
16. Clinically significant pericardial disease	___ 1	___ 2	___ 3
17. Other clinically significant cardiac abnormality/underlying disease process (e.g. defined cardiomyopathy, endocardial fibrosis)	___ 1	___ 2	___ 3

	Yes (documented)	No (documented)	Not mentioned / Uncertain
18. Persistent or permanent atrial fibrillation or flutter	___ 1	___ 2	___ 3
19. COPD/Chronic bronchitis/emphysema	___ 1	___ 2	___ 3
20. Severe lung disease other than COPD	___ 1	___ 2	___ 3
21. Smoking h/o 10 pack-years or more	___ 1	___ 2	___ 3

Signs/Treatment **22. No documentation ____ 1 (Skip to next section)**

	Yes (documented)	No (documented)	Not mentioned / Uncertain
23. Ankle edema 2+ or greater	___ 1	___ 2	___ 3
24. Bilateral ankle edema	___ 1	___ 2	___ 3
25. Tachycardia 120+	___ 1	___ 2	___ 3
26. Jugular venous distention	___ 1	___ 2	___ 3
27. Increased venous pressure			
a. > 8 and ≤ 16 cm H_20	___ 1	___ 2	___ 3
b. >16cm H_20	___ 1	___ 2	___ 3
28. Hepatojugular reflux	___ 1	___ 2	___ 3
29. Râles	___ 1	___ 2	___ 3
30. S_3 gallop	___ 1	___ 2	___ 3
31. Hepatomegaly	___ 1	___ 2	___ 3
32. Decrease in vital capacity by 1/3 from maximum	___ 1	___ 2	___ 3
33. Circulation time ≥25s arm-tongue	___ 1	___ 2	___ 3
34. I.V. therapy for CHF (diuretic, vasodilator or positive inotropic agents)	___ 1	___ 2	___ 3
35. Weight loss on CHF Rx: 10lbs/5days	___ 1	___ 2	___ 3
36. Diuresis of 10 pounds or 5 kilograms in response to diuretic treatment, with clinical improvement in congestive symptoms	___ 1	___ 2	___ 3

Chest X-ray

37. No documentation ____ 1
Done, but no result provided ____ 2
(Skip to next section)

	Yes (documented)	No (documented)	Not mentioned / Uncertain
38. Cardiomegaly	___ 1	___ 2	___ 3
39. Acute pulmonary edema	___ 1	___ 2	___ 3
40. Pleural effusion	___ 1	___ 2	___ 3
41. Pulmonary vascular engorgement	___ 1	___ 2	___ 3
42. Pulmonary vascular re-distribution	___ 1	___ 2	___ 3
43. Characteristic of CHF			
a. conclusion of reviewer	___ 1	___ 2	___ 3
b. conclusion on the radiology report	___ 1	___ 2	___ 3
44. Characteristic of lung disease			
a. conclusion of reviewer	___ 1	___ 2	___ 3
b. conclusion on the radiology report	___ 1	___ 2	___ 3

Echocardiogram

45. a. Echocardiogram done? ..... Yes ☐ 1 No ☐ 2 DK ☐ 3
(If No or DK, skip to #46)

b. If yes, give ejection fraction result (99 if numeric result is not provided) ..... __ __ %

If ejection fraction (#45b) not specifically provided, please complete either c or d -

c. Range of left ventricular systolic function ..... __ __ % to __ __ %

d. Description of left ventricular systolic function ..... In normal range ☐ 1
Borderline ☐ 2
Below normal (reduced, depressed) ☐ 3
No result provided ☐ 4

e. LV posterior wall thickness (all 9's if no measurement available) __ __ __ mm or __ . __ cm

f. LV septal wall thickness (all 9's if no measurement available)..... __ __ __ mm or __ . __ cm

g. Left atrial (LA) dimension (all 9's if no measurement available).. __ __ __ mm or __ . __ cm

h. Doppler flow studies done? ..... Yes ☐ 1 No ☐ 2 DK ☐ 3
(If No or DK, skip to #45m)

If yes, give the following -

i. Clinically significant valvular disease ..... Yes ☐ 1 No ☐ 2 DK ☐ 3

j. Moderate or greater regurgitation ..... Yes ☐ 1 No ☐ 2 DK ☐ 3

k. Aortic valve area <1.2 cm^2 ..... Yes ☐ 1 No ☐ 2 DK ☐ 3

l. Estimated PA systolic pressure ("99" if no measurement available) ..... __ __ mm Hg

Overall impressions:

Consistent with pericardial disease by echocardiogram and/or Doppler studies

m. Conclusion of the report and/or by treating physician(s) . . . . . Yes ☐ 1 No ☐ 2 DK ☐ 3

n. Conclusion of the reviewer . . . . . Yes ☐ 1 No ☐ 2 DK ☐ 3

Echocardiographic/Doppler evidence of severe valvular heart disease

o. Conclusion of the report and/or by treating physician(s) . . . . . Yes ☐ 1 No ☐ 2 DK ☐ 3

p. Conclusion of the reviewer . . . . . Yes ☐ 1 No ☐ 2 DK ☐ 3

Echocardiographic/Doppler evidence of moderate valvular heart disease

q. Conclusion of the report and/or by treating physician(s) . . . . . Yes ☐ 1 No ☐ 2 DK ☐ 3

r. Conclusion of the reviewer . . . . . Yes ☐ 1 No ☐ 2 DK ☐ 3

Radionuclide study

46. a. Radionuclide study done? ..... Yes ☐ 1 No ☐ 2 DK ☐ 3
(If No or DK, skip to #47)

b. If yes, give ejection fraction result (99 if numeric result is not provided) ..... __ __ %

If ejection fraction (#46b) not specifically provided, please complete either c or d -

c. Range of left ventricular systolic function ..... __ __ % to __ __ %

d. Description of left ventricular systolic function ..... In normal range ☐ 1
Borderline ☐ 2
Below normal (reduced, depressed) ☐ 3
No result provided ☐ 4

Cardiac catheterization

47. a. Cardiac catheterization done? ..... Yes ☐ 1 No ☐ 2 DK ☐ 3
(If No or DK, skip to #48)

b. If yes, give ejection fraction result (99 if numeric result is not provided) ..... __ __ %

If ejection fraction (#47b) not specifically provided, please complete either c or d -

c. Range of left ventricular systolic function ..... __ __ % to __ __ %

d. Description of left ventricular systolic function ..... In normal range ☐ 1
Borderline ☐ 2
Below normal (reduced, depressed) ☐ 3
No result provided ☐ 4

e. Coronary angiography – significant CAD (at least one lesion >70%) ..... Yes ☐ 1 No ☐ 2 DK ☐ 3

Provide the following, if available -

f. PCW pressure (99 if not available) ..... __ __ mm Hg

g. Cardiac index (9.9 if not available) ..... __ . __

Concurrent Conditions/Precipitating Factors **48. No documentation ____ 1 (Skip to next section)**

	Yes (documented)	No (documented)	Not mentioned / Uncertain
49. Pneumonia	___ 1	___ 2	___ 3
50. Infective endocarditis	___ 1	___ 2	___ 3
51. Other infections	___ 1	___ 2	___ 3
52. Anemia/blood loss	___ 1	___ 2	___ 3
53. Hemodynamically significant arrhythmias			
a. New onset or new episode of recurrent atrial fibrillation or flutter, or ventricular rate >100	___ 1	___ 2	___ 3
b. Other sustained supraventricular tachycardia (rate >100)	___ 1	___ 2	___ 3
c. Sustained ventricular tachycardia (lasting >30s)	___ 1	___ 2	___ 3
d. Sustained bradycardia (HR<50)	___ 1	___ 2	___ 3
54. Thyrotoxicosis	___ 1	___ 2	___ 3
55. Rheumatic and other forms of myocarditis	___ 1	___ 2	___ 3
56. Myocardial infarction			
a. prior to CHF	___ 1	___ 2	___ 3
b. associated with onset of CHF	___ 1	___ 2	___ 3
57. Pulmonary embolism	___ 1	___ 2	___ 3
58. Acute renal failure			
a. prior to CHF	___ 1	___ 2	___ 3
b. associated with onset of CHF	___ 1	___ 2	___ 3
59. Uncontrolled hypertension (SBP >180 mm Hg)	___ 1	___ 2	___ 3

	Yes (documented)	No (documented)	Not mentioned / Uncertain
60. Perioperative onset:			
a. cardiac surgery	___ 1	___ 2	___ 3
b. non-cardiac surgery	___ 1	___ 2	___ 3
61. Iatrogenic fluid overload:			
a. in context of surgery	___ 1	___ 2	___ 3
b. transfusion	___ 1	___ 2	___ 3
c. hydration	___ 1	___ 2	___ 3
d. other (e.g. excessive heat, physical exertion)	___ 1	___ 2	___ 3
62. New medications or dosage increase for heart failure at discharge			
a. Loop diuretics	___ 1	___ 2	___ 3
b. ACE inhibitors or ARBs	___ 1	___ 2	___ 3
c. Digoxin	___ 1	___ 2	___ 3
d. Beta-blocker	___ 1	___ 2	___ 3
e. Aldosterone antagonists	___ 1	___ 2	___ 3
f. Vasodilators	___ 1	___ 2	___ 3
g. Other	___ 1	___ 2	___ 3

Autopsy

63. Not applicable ____ 1
No documentation ____ 2
(Skip to next section)

	Yes (documented)	No (documented)	Not mentioned / Uncertain
64. Pulmonary edema or visceral congestion or cardiomegaly	___ 1	___ 2	___ 3

Case summary:

65. The reviewer suspects a non-cardiac etiology of symptoms ..... Yes ☐ 1 No ☐ 2 DK ☐ 3

66. Given all of the information, and in your clinical judgment, does this patient have congestive heart failure? ..... Yes ☐ 1 No ☐ 2 DK ☐ 3

67. Signature: _____

Fields-Marked Version

Form:AL23V1 SHOWMODE: Your in DISPLAY Mode Page 1 of 22

ALLHAT CHF QUALITY CONTROL EF:

ID: Form: 023 Ver 1 RI:

E: REC: VF: FMDT: Seq: 1 Site: A PAYCN:

OD: F:2 MO-DY-YR Acrostic: PO:

. Event date from AL04 (mm/dd/yy)..... : [ ]

. Event Type a.Hospitalized fatal [1] b. Hospitalized Nonfatal [0]

. a. None..... : a[ ]

b. Face sheet with diagnosis and procedure codes..... : b[ ]

c. Discharge Summary..... : c[1]

d. Admitting history and physical examination..... : d[ ]

e. Chest x-ray reports..... : e[1]

f. Inital cardiology and pulmonary consultation notes..... : f[ ]

g. Cardiac catherization reports/procedure notes..... : g[ ]

h. Echocardiography reports..... : h[ ]

i. Radionuclide cardiac imaging reports..... : i[ ]

j. Emergency room notes..... : j[1]

k. Pulmonary function test reports..... : k[ ]

l. Autopsy/coroner's reports..... : l[ ]

. Comments Flag: [1] 9. Init. Clinic Staff: [ ] 10. Signiture Flag: [1]

a Date additional documentation..... :[ ]

b CTC Query date ..... :[ ]

. DT Completed [ ] 12a. Comp. at CCCT:[ ] DMon: [ ] 14. Sign:[1]

ALLHAT CHF REVIEW OF CODER 1

ID: Form: 023 Ver 1 EF:

DE REC VF: MDT: Seq: 1 Site: A RI:

MOD: F:2 MO-DY YR Acrostic: PAYCN: 001

PO:

. Coder Number [ ] (46)
. Coding Date [ ] (47)
. No documentation [ ] (48) (Skip to next section)

1=Yes (documented) 2=No (documented) 3=Not mentioned/Uncertain

7. PND. A.F.....: 7. [3] (49)
8. Orthopnea..A.....: 8. [3] (50)
9. Dyspnea at rest.A.....: 9. [1] (51)
10. Dyspnea on ordinary exertion..F.....:10. [3] (52)
11. New York Heart Association Class III..A.....:11. [3] (53)
12. Night Cough..F.....:12. [3] (54)
13. No documentation (Skip to next section) (1=Yes; 2=No; 3=Not ment...:13. [ ] (55)
14. CHD.....:14. [3] (56)
15. Valvular disease.....:15. [3] (57)
16. Clnically Significant pericardial disease.....:16. [3] (58)
17. Other clinically sign. Cardiac Abnormaity.....:17. [3] (59)
18. Persistent/Perm atrial fibrillation/flutter.....:18. [3] (60)
19. COPD/Chronic bronchitis/emphysema.A.....:19. [1] (61)
20. Severe lung disease other then COPDA.....:20. [1] (62)

Coder 1 46 - 159

Coder 2 160 - 273

Adjudicator 274 - 387

ALLHAT CHF REVIEW OF CODER 1

DE: EC: VF FMDT: ID: Form: 023 Ver 1 EF:
MOD: F:2 MO-DY YR Seq: 1 Site: A RI:
Acrostic: PAYCN:
PO:

1. Smoking h/o 10 packs-year. A.....: 21.[3](63)

igns 22. No documentation [_](64) (Skip to next section)
1=Yes (documented) 2=No (documented) 3=Not mentioned/Uncertain

3. Ankle edema 2+ or greater A 23.[2](65)
4. Bilateral ankle edema F 24.[2](66)
5. Tachycardia 120+ A,F 25 [2](67)
6. Jungular venous distention A,F 26 [2](68)
7a Increased venous pressure (> 8 and <= 16 cm h2o).....: 27a[2](69)
7b (> 16cm h2o)....F.....: 27b[2](70)
8. Heptatojugular reflux F 28.[3](71)
9. Rales A F 29.[2](72)
0. S3 gallop A F 30.[3](73)
1. Hepatomegaly F 31.[3](74)
2. Decrease in vital cap[acity by 1/3 F 32.[3](75)
3. Circulation time > 25s arm-tongue F 33.[3](76)
4. I.V. Therapy for CHF A 34.[2](77)
5. Weight loss on CHF RX 10 lbs/5days F 35.[2](78)
6. Diuresis of 10lbs or 5kg in response to diuretic treatment. F.....: 36.[2](79)

ALLHAT CHF REVIEW OF CODER 1

ID: Form: 023 Ver 1 EF:

DE REC: VF FMDT: Seq: 1 Site: A RI:

MOD: F:2 MO-DY YR Acrostic: PAYCN:

PO:

7. Chest X-Ray (1=No documentation 2=Done but no result provided) 37. [_] (80)
8. Cardiomegaly F,A 38. [1] (81) 1=Yes 2=No 3=Not mentioned
9. Acute pulmonary edema F 39. [2] (82) 1=Yes 2=No 3=Not mentioned
0. Pleural effusion F 40. [2] (83) 1=Yes 2=No 3=Not mentioned
1. Pulmonary vascular egorgement 41. [1] (84) 1=Yes 2=No 3=Not mentioned
2. Pulmonary Vascular re-distribution 42. [3] (85) 1=Yes 2=No 3=Not mentioned
3. Char. of CHF A a. Conc. of Reviewer: 43a. [3] (86) 1=Yes 2=No 3=Not mentioned
A b. Conc. of Radiology 43b. [1] (87) 1=Yes 2=No 3=Not mentioned
4. Characteristic of lung disease
a. Conclusion of reviewer A 44a. [2] (88) 1=Yes 2=No 3=Not mentioned
b. Conclusion on radiology report A 44b. [2] (89) 1=Yes 2=No 3=Not mentioned
5.a.Ecocardiogram? 1=Yes 2=No 3=DN..... 45a. [2] (90)
b. If yes, give ejection fraction 45b. [__%] (91) c. Range: [__%] (92) to [__%] (93)
d. Description of left ventrical 45d. [_] (94) 1=Normal 2=Border 3=Below 4=No
easurments: e. LV Post: [ ] (95) mm or [_].[_]cm (96) f. LV Sep: [___] (97) mm or [_].[_] (98) cm
g. LV Atrial: [ ] (99) mm or [_].[_]cm (100)
h. Doppler Flow: .....[_] (101) i. Clinical Significant Valvular 45i. [_] (102)
j. Moderate/greater...[_] (103) k. Aortic Valve: [_] (104) l. Estimate PA: 45l [__] (105) mmHg

ALLHAT CHF REVIEW OF CODER 1 EF:

ID: Form: 023 Ver 1 RI:

DE:__ REC VF:__ FMDT: Seq: 1 Site: A PAYCN:

MOD: F:2 MO-DY YR Acrostic: PO:

mpressions: Cons. Pericardial m. Report: [_](106) n. Reviewer: [_](107)
Echocardiographic: o. Report: [_](108) p. Reviewer: [_](109) q. Report: [_](110) r:Review[_](111)
6.a. Radionuclide done?..... 46a.[2](112) 1=Yes 2=No 3=DK
b. If yes, give ejection fraction res 46b.[__%](113) c.Range: [__%](114) to [__%](115)
d. Description of left ventricular fun 46d.(116) 1=Normal 2=Border 3=Below 4=No
7.a. Cardiac catheterization done?..... 47a.[2](117) 1=Yes 2=No 3=DK
b. If yes, give ejection fraction res 47b.[__%](118) c.Range: [__%](119) to [__%](120)
or, if ejection fraction not specifically provided -
d. Description of left ventricular 47d.(121) 1=Normal 2=Border 3=Below 4=No
e. Coronary angiography - significant 47e.(122) (1=Yes; 2=No; 3=DK)
f. PCW Pressure (99 if not available) 47f.(123) mmHg
g. Cardiac index (9.9 if not avialable).47g.[_._](124)

oncurrent Conditions/Precipitating Factors
8. No Documentation 48. [_](125)
9. Pneumonia A 49. [3](126) 1=Yes 2=No 3=Not Mentioned
0. Infective endocarditis 50. [3](127) 1=Yes 2=No 3=Not Mentioned

ALLHAT CHF REVIEW OF CODER 1

ID: Form: 023 Ver 1 EF:

DE REC VF FMDT Seq: 1 Site: A RI:

MOD: F:2 MO-DY YR Acrostic: PAYCN:

PO:

oncurrent Conditions/Precipitating Factors		1=Yes 2=No 3=Not Mentioned
1. Other infections	51.	[3](128)
2. Anemia/blood loss	52.	[3](129)
3. Hemodynamically significant arrhythmias		
a. New onset or new episode of recurrent	53a.	[2](130)
b. Other sustained supraventricular	53b.	[2](131)
c. Sustained ventricular tachycardia	53c.	[2](132)
d. Sustained bradycardia	53d.	[1](133)
4. Thyrotoxicosis	54.	[3](134)
5. Rheumatic and other forms of myocarditis	55.	[3](135)
6. Mycardial infarction		
a. Prior to CHF	56a.	[3](136)
b. Associated with onset of CHF	56b.	[3](137)
7. Pulmonary embolism	57.	[3](138)
8. Acute renal failure		
a. Prior to CHF	58a.	[3](139)
b. Associated with onset of CHF	58b.	[3](140)

ALLHAT CHF REVIEW OF CODER 1 EF:

ID: Form: 023 Ver 1 RI:

E REC VF FMDT: Seq: 1 Site: A PAYCN:

IOD F:2 MO-DY YR Acrostic: PO:

ncurrent Conditions/Precipitating Factors 1=Yes 2=No 3=Not Mentioned

. Uncontrolled Hypertension	59.	[3](141)
. Perioperative Onset		
a. Cardiac Surgery	60a.	[2](142)
b. Non-cardiac surgery	60b.	[2](143)
. Iatrogenic fluid overload:		
a. in context of surgery	61a.	[2](144)
b. transfusion	61b.	[2](145)
c. hydration	61c.	[2](146)
d. other (e.g. excessive heat,..)	61d.	[2](147)
. New Medications or dosage increase for heart failure at discharge		
a. Loop diuretics	62a.	[2](148)
b. ACE inhibitors or ARBs	62b.	[2](149)
c. Digoxin	62c.	[2](150)
d. Beta-blocker	62d.	[2](151)
e. Aldosterone antagonists	62e.	[2](152)
f. Vaspdilators	62f.	[2](153)
g. Other	62g.	[2](154)

ALLHAT CHF REVIEW OF CODER 1 EF:
ID: ___ Form: 023 Ver 1 RI: _____
DE: REC: _____ VF ___ FMD? Seq: 1 Site: A PAYCN: ___
MOD ___ F: MO-DY YR Acrostic: PO: _____

utopsy 63. [2] (155) 1=Not applicable 2=No documentation
1=Yes (documented) 2=No (documented) 3=Not mentioned/Uncertain
4. Pulmonary edema or visceral congestion..: F 64. [_] (156)
ase Summary
5. The reviewer suspects Non-Cardiact Etiology: 65. [1] (157) 1=Yes 2=No 3=DK
6. Given all of the information.....: 66. [2] (158) 1=Yes 2=No 3=DK

7. Signature Flag 67. [1] (159)

```
AL023 1 001I    1-  2 F23KPCOD         1         9 2
AL023 1 002IDR  3-  8 F23BATDT         1         9 2
AL023 1 003A    9- 10 F23VFDAT         1         9 0
AL023 1 004IDR 11- 16 F23DTMOD         1         9 2
AL023 1 005I   17- 20 F23TMMOD         1         9 2
AL023 1 006I   21- 21 F23MDFLG         1         9 2
AL023 1 007I   22- 24 F23TCN           1         9 2       Y$
AL023 1 008I   25- 27 F23PNO           1       900 1       Y$
AL023 1 009I   28- 30 F23RCN           1       400 1       Y$
AL023 1 010I   35- 42 F23DATE8         1  99999999 1       Y$
AL023 1 011I   34- 34 F23VS            1         9 2       Y$
AL023 1 012I   35- 36 F23CENT          1         9 2       Y$
AL023 1 013IDR 37- 42 F23KEYDT         1         9 2       Y$
AL023 1 014I   43- 43 F23SEQ           1         9 2       Y$
AL023 1 015A   44- 44 F23SITE          1         9 0       Y$
AL023 1 016A   45- 50 F23ACR           1         9 0       Y$
AL023 1 017A   51- 52 F23EDIT          1         9 0       Y$
AL023 1 018A   53- 63 F23RINO          1         9 0       Y$
AL023 1 019A   64- 66 F23PAYCN         1         9 0       Y$
AL023 1 020A   67- 69 DUMMY           1         9 0       Y$
AL023 1 021A   70- 80 F23CKNO          1         9 0
AL023 1 022ID  81- 86 F23Q5YY          1         9 2
AL023 1 023I   87- 87 F23Q6A           1         9 2
AL023 1 024I   88- 88 F23Q6B           0         1 2
AL023 1 025I   89- 89 F23Q7A           0         1 2
AL023 1 026I   90- 90 F23Q7B           0         1 2
AL023 1 027I   91- 91 F23Q7C           0         1 2
AL023 1 028I   92- 92 F23Q7D           0         1 2
AL023 1 029I   93- 93 F23Q7E           0         1 2
AL023 1 030I   94- 94 F23Q7F           0         1 2
AL023 1 031I   95- 95 F23Q7G           0         1 2
AL023 1 032I   96- 96 F23Q7H           0         1 2
AL023 1 033I   97- 97 F23Q7I           0         1 2
AL023 1 034I   98- 98 F23Q7J           0         1 2
AL023 1 035I   99- 99 F23Q7K           0         1 2
AL023 1 036I  100-100 F23Q7L           0         1 2
AL023 1 037I  101-101 F23Q8            0         1 2
AL023 1 038A  102-104 F23Q9            1         9 0
AL023 1 039I  105-105 F23Q10           0         1 2
AL023 1 040ID 106-113 F23Q11CN         1         9 0
AL023 1 041ID 114-121 f23Q11Yb         1         9 0
AL023 1 042ID 122-129 F23Q12YR         1         9 0
AL023 1 043I  130-130 F23CCCT          0         1 2
AL023 1 044A  131-133 F23Q13           1         9 0
AL023 1 045I  134-134 F23Q14           0         1 2
AL023 1 046A  135-137 F23C1Q4          1         9 0
AL023 1 047ID 138-145 F23C1Q5Y         1         9 0
AL023 1 048I  146-146 F23C1Q6          1         9 2
AL023 1 049I  147-147 F23C1Q7          0         3 2
AL023 1 050I  148-148 F23C1Q8          0         3 2
AL023 1 051I  149-149 F23C1Q9          0         3 2
AL023 1 052I  150-150 F23C1Q10         0         3 2
AL023 1 053I  151-151 F23C1Q11         0         3 2
AL023 1 054I  152-152 F23C1Q12         0         3 2
AL023 1 055I  153-153 F23C1Q13         1         9 2
AL023 1 056I  154-154 F23C1Q14         0         3 2
AL023 1 057I  155-155 F23Q15           0         3 2
AL023 1 058I  156-156 F23Q16           0         3 2
AL023 1 059I  157-157 F23C1Q16         0         3 2
AL023 1 060I  158-158 F23C1Q17         0         3 2
```

```
AL023 1 061I  159-159 F23C1Q18         0         3 2
AL023 1 062I  160-160 F23C1Q19         0         3 2
AL023 1 063I  161-161 F23Q21           0         3 2
AL023 1 064I  162-162 F23C1Q21         1         9 2
AL023 1 065I  163-163 F23F             0         3 2
AL023 1 066I  164-164 F23Q23           0         3 2
AL023 1 067I  165-165 F23Q1C24         0         3 2
AL023 1 068I  166-166 F23C1Q25         0         3 2
AL023 1 069I  167-167 F23C126A         0         3 2
AL023 1 070I  168-168 F23C126B         0         3 2
AL023 1 071I  169-169 F23C1Q27         0         3 2
AL023 1 072I  170-170 F23C1Q28         0         3 2
AL023 1 073I  171-171 F23C1Q29         0         3 2
AL023 1 074I  172-172 F23C1Q30         0         3 2
AL023 1 075I  173-173 F23C1Q31         0         3 2
AL023 1 076I  174-174 F23C1Q32         0         3 2
AL023 1 077I  175-175 F23C1Q33         0         3 2
AL023 1 078I  176-176 F23C1Q34         0         3 2
AL023 1 079I  177-177 F23FD079         1         9 2
AL023 1 080I  178-178 F23Q37C1         1        99 1
AL023 1 081I  179-179 F23C1Q36         0         3 2
AL023 1 082I  180-180 F23C1Q37         0         3 2
AL023 1 083I  181-181 F23C1Q38         0         3 2
AL023 1 084I  182-182 F23C1Q39         0         3 2
AL023 1 085I  183-183 F23Q42           0         3 2
AL023 1 086I  184-184 F23C140A         0         3 2
AL023 1 087I  185-185 F23C140B         0         3 2
AL023 1 088I  186-186 F23C141A         0         3 2
AL023 1 089I  187-187 F23C141B         0         3 2
AL023 1 090I  188-188 F23C142A         1        99 1
AL023 1 091I  189-190 F23C142B         1        99 1
AL023 1 092I  191-192 F45Q45Ca         1        99 1
AL023 1 093I  193-194 F23FD093         1        99 1
AL023 1 094I  195-195 F23C142C         0         4 2
AL023 1 095I  196-198 F23FD095         0       999 1
AL023 1 096A  199-200 F23FD097         1        99 0
AL023 1 097I  201-203 F23FD098         0       999 1
AL023 1 098A  204-205 F23FD099         1        99 0
AL023 1 099I  206-208 F23FD101         0       999 1
AL023 1 100A  209-210 F23FD102         1        99 0
AL023 1 101I  211-211 F23FD104         0         3 2
AL023 1 102I  212-212 F23FD105         0         3 2
AL023 1 103I  213-213 F23C142F         0         3 2
AL023 1 104I  214-214 F23FD107         0         3 2
AL023 1 105A  215-216 F23FD108         1        99 0
AL023 1 106I  217-217 F23FD109         1         9 2
AL023 1 107I  218-218 F23FD110         1         9 2
AL023 1 108I  219-219 F23FD111         1         9 2
AL023 1 109I  220-220 F23FD112         1         9 2
AL023 1 110I  221-221 F23FD113         1         9 2
AL023 1 111I  222-222 F23FD114         1         9 2
AL023 1 112I  223-223 F23C143A         1         9 2
AL023 1 113I  224-225 F23C143B         1         9 2
AL023 1 114I  226-227 F23FD117         1         9 2
AL023 1 115I  228-229 F23FD118         1         9 2
AL023 1 116I  230-230 F23C143C         0         4 2
AL023 1 117I  231-231 F23C144A         0         3 2
AL023 1 118I  232-233 F23C144B         1         9 2
AL023 1 119I  234-235 F23FD122         1         9 2
AL023 1 120I  236-237 F23FD123         1         9 2
```

```
AL023 1 121I  238-238 F23C144C         0         3 2
AL023 1 122I  239-239 F23C144D         1         9 2
AL023 1 123I  240-241 F23C144E         1         9 2
AL023 1 124I  242-243 F23C144F         1         9 2
AL023 1 125I  244-244 F23C1Q45         0         1 2
AL023 1 126I  245-245 F23C1Q46         0         3 2
AL023 1 127I  246-246 F23C1Q47         0         3 2
AL023 1 128I  247-247 F23C1Q48         0         3 2
AL023 1 129I  248-248 F23C1Q49         0         3 2
AL023 1 130I  249-249 F23C150A         0         3 2
AL023 1 131I  250-250 F23C150B         0         3 2
AL023 1 132I  251-251 F23C150C         0         3 2
AL023 1 133I  252-252 F23C150D         0         3 2
AL023 1 134I  253-253 F23C1Q51         0         3 2
AL023 1 135I  254-254 F23C1Q52         0         3 2
AL023 1 136I  255-255 F23C153A         0         3 2
AL023 1 137I  256-256 F23C153B         0         1 2
AL023 1 138I  257-257 F23C1Q54         0         3 2
AL023 1 139I  258-258 F23C155A         0         3 2
AL023 1 140I  259-259 F23C155B         0         3 2
AL023 1 141I  260-260 F23C1Q56         0         3 2
AL023 1 142I  261-261 F23C157A         0         3 2
AL023 1 143I  262-262 F23C157B         0         3 2
AL023 1 144I  263-263 F23C158A         0         3 2
AL023 1 145I  264-264 F23C158B         0         3 2
AL023 1 146I  265-265 F23C158C         0         3 2
AL023 1 147I  266-266 F23C158D         0         3 2
AL023 1 148I  267-267 F23C159A         0         3 2
AL023 1 149I  268-268 F23C159B         0         1 2
AL023 1 150I  269-269 F23C159C         0         3 2
AL023 1 151I  270-270 F23C159D         0         3 2
AL023 1 152I  271-271 F23C159E         0         3 2
AL023 1 153I  272-272 F23C159F         0         3 2
AL023 1 154I  273-273 F23C159G         0         3 2
AL023 1 155I  274-274 F23C1Q60         0         2 2
AL023 1 156I  275-275 F23C1Q61         0         3 2
AL023 1 157I  276-276 F23FD161         0         3 2
AL023 1 158I  277-277 F23C1Q63         0         3 2
AL023 1 159I  278-278 F23C1Q64         0         1 2
AL023 1 160A  279-281 F23FD164         1         9 0
AL023 1 161ID 282-289 F23FD165         1         9 0
AL023 1 162I  290-290 F24QC26          1         9 2
AL023 1 163I  291-291 F23FD167         0         3 2
AL023 1 164I  292-292 F23FD168         0         3 2
AL023 1 165I  293-293 F23FD169         0         3 2
AL023 1 166I  294-294 F23FD170         0         3 2
AL023 1 167I  295-295 F23FD171         0         3 2
AL023 1 168I  296-296 F23FD172         0         3 2
AL023 1 169I  297-297 F23FD173         1         9 2
AL023 1 170I  298-298 F23FD174         0         3 2
AL023 1 171I  299-299 F23FD175         0         3 2
AL023 1 172I  300-300 F23FD176         0         3 2
AL023 1 173I  301-301 F23FD177         0         3 2
AL023 1 174I  302-302 F23FD178         0         3 2
AL023 1 175I  303-303 F23FD179         0         3 2
AL023 1 176I  304-304 F23FD180         0         3 2
AL023 1 177I  305-305 F23FD181         0         3 2
AL023 1 178I  306-306 F23FD182         1         9 2
AL023 1 179I  307-307 F23FD183         0         3 2
AL023 1 180I  308-308 F23FD184         0         3 2
```

```
AL023 1 181I  309-309 F23FD185         0         3 2
AL023 1 182I  310-310 F23FD186         0         3 2
AL023 1 183I  311-311 F23FD187         0         3 2
AL023 1 184I  312-312 F23FD188         0         3 2
AL023 1 185I  313-313 F23FD189         0         3 2
AL023 1 186I  314-314 F23FD190         0         3 2
AL023 1 187I  315-315 F23FD191         0         3 2
AL023 1 188I  316-316 F23FD192         0         3 2
AL023 1 189I  317-317 F23FD193         0         3 2
AL023 1 190I  318-318 F23FD194         0         3 2
AL023 1 191I  319-319 F23FD195         0         3 2
AL023 1 192I  320-320 F23FD196         0         3 2
AL023 1 193I  321-321 F23FD197         1         9 2
AL023 1 194I  322-322 F23FD198         1        99 1
AL023 1 195I  323-323 F23FD199         0         3 2
AL023 1 196I  324-324 F23FD200         0         3 2
AL023 1 197I  325-325 F23FD201         0         3 2
AL023 1 198I  326-326 F23FD202         0         3 2
AL023 1 199I  327-327 F23FD203         0         3 2
AL023 1 200I  328-328 F23FD204         0         3 2
AL023 1 201I  329-329 F23FD205         0         3 2
AL023 1 202I  330-330 F23FD206         0         3 2
AL023 1 203I  331-331 F23FD207         0         3 2
AL023 1 204I  332-332 F23FD208         1        99 1
AL023 1 205I  333-334 F23FD209         1        99 1
AL023 1 206I  335-336 F23FD210         1        99 1
AL023 1 207I  337-338 F23FD211         1        99 1
AL023 1 208I  339-339 F23FD212         0         4 2
AL023 1 209I  340-342 F23FD213         0       999 1
AL023 1 210A  343-344 F23FD214         1        99 0
AL023 1 211I  345-347 F23FD216         0       999 1
AL023 1 212A  348-349 F23FD217         1        99 0
AL023 1 213I  350-352 F23FD219         0       999 1
AL023 1 214A  353-354 F23FD220         1        99 0
AL023 1 215I  355-355 F23FD222         0         3 2
AL023 1 216I  356-356 F23FD223         0         3 2
AL023 1 217I  357-357 F23FD224         0         3 2
AL023 1 218I  358-358 F23FD225         0         3 2
AL023 1 219A  359-360 F23FD226         1        99 0
AL023 1 220I  361-361 F23FD227         1         9 2
AL023 1 221I  362-362 F23FD228         1         9 2
AL023 1 222I  363-363 F23FD229         1         9 2
AL023 1 223I  364-364 F23FD230         1         9 2
AL023 1 224I  365-365 F23FD231         1         9 2
AL023 1 225I  366-366 F23FD232         1         9 2
AL023 1 226I  367-367 F23FD233         1         9 2
AL023 1 227I  368-369 F23FD234         1         9 2
AL023 1 228I  370-371 F23FD235         1         9 2
AL023 1 229I  372-373 F23FD236         1         9 2
AL023 1 230I  374-374 F23FD237         0         4 2
AL023 1 231I  375-375 F23FD238         0         3 2
AL023 1 232I  376-377 F23FD239         1         9 2
AL023 1 233I  378-379 F23FD240         1         9 2
AL023 1 234I  380-381 F23FD241         1         9 2
AL023 1 235I  382-382 F23FD242         0         3 2
AL023 1 236I  383-383 F23FD243         1         9 2
AL023 1 237I  384-385 F23FD244         1         9 2
AL023 1 238I  386-387 F23FD245         1         9 2
AL023 1 239I  388-388 F23FD247         0         1 2
AL023 1 240I  389-389 F23FD248         0         3 2
```

```
AL023 1 241I  390-390 F23FD249         0         3 2
AL023 1 242I  391-391 F23FD250         0         3 2
AL023 1 243I  392-392 F23FD251         0         3 2
AL023 1 244I  393-393 F23FD252         0         3 2
AL023 1 245I  394-394 F23FD253         0         3 2
AL023 1 246I  395-395 F23FD254         0         3 2
AL023 1 247I  396-396 F23FD255         0         3 2
AL023 1 248I  397-397 F23FD256         0         3 2
AL023 1 249I  398-398 F23FD257         0         3 2
AL023 1 250I  399-399 F23FD258         0         3 2
AL023 1 251I  400-400 F23FD259         0         1 2
AL023 1 252I  401-401 F23FD260         0         3 2
AL023 1 253I  402-402 F23FD261         0         3 2
AL023 1 254I  403-403 F23FD262         0         3 2
AL023 1 255I  404-404 F23FD263         0         3 2
AL023 1 256I  405-405 F23FD264         0         3 2
AL023 1 257I  406-406 F23FD265         0         3 2
AL023 1 258I  407-407 F23FD266         0         3 2
AL023 1 259I  408-408 F23FD267         0         3 2
AL023 1 260I  409-409 F23FD268         0         3 2
AL023 1 261I  410-410 F23FD269         0         3 2
AL023 1 262I  411-411 F23FD270         0         3 2
AL023 1 263I  412-412 F23FD271         0         1 2
AL023 1 264I  413-413 F23FD272         0         3 2
AL023 1 265I  414-414 F23FD273         0         3 2
AL023 1 266I  415-415 F23FD274         0         3 2
AL023 1 267I  416-416 F23FD275         0         3 2
AL023 1 268I  417-417 F23FD276         0         3 2
AL023 1 269I  418-418 F23FD277         0         2 2
AL023 1 270I  419-419 F23FD278         0         3 2
AL023 1 271I  420-420 F23FD279         0         3 2
AL023 1 272I  421-421 F23FD280         0         3 2
AL023 1 273I  422-422 F23FD281         0         1 2
AL023 1 274A  423-425 F23Q4C3          1         9 0
AL023 1 275ID 426-433 F23FD283         1         9 0
AL023 1 276I  434-434 F23FD284         1         9 2
AL023 1 277I  435-435 F23FD285         0         3 2
AL023 1 278I  436-436 F23FD286         0         3 2
AL023 1 279I  437-437 F23FD287         0         3 2
AL023 1 280I  438-438 F23FD288         0         3 2
AL023 1 281I  439-439 F23FD289         0         3 2
AL023 1 282I  440-440 F23FD290         0         3 2
AL023 1 283I  441-441 F23FD291         1         9 2
AL023 1 284I  442-442 F23FD292         0         3 2
AL023 1 285I  443-443 F23FD293         0         3 2
AL023 1 286I  444-444 F23FD294         0         3 2
AL023 1 287I  445-445 F23FD295         0         3 2
AL023 1 288I  446-446 F23FD296         0         3 2
AL023 1 289I  447-447 F23FD297         0         3 2
AL023 1 290I  448-448 F23FD298         0         3 2
AL023 1 291I  449-449 F23FD299         0         3 2
AL023 1 292I  450-450 F23FD300         1         9 2
AL023 1 293I  451-451 F23FD301         0         3 2
AL023 1 294I  452-452 F23FD302         0         3 2
AL023 1 295I  453-453 F23FD303         0         3 2
AL023 1 296I  454-454 F23FD304         0         3 2
AL023 1 297I  455-455 F23FD305         0         3 2
AL023 1 298I  456-456 F23FD306         0         3 2
AL023 1 299I  457-457 F23FD307         0         3 2
AL023 1 300I  458-458 F23FD308         0         3 2
```

```
AL023 1 301I  459-459 F23FD309         0         3 2
AL023 1 302I  460-460 F23FD310         0         3 2
AL023 1 303I  461-461 F23FD311         0         3 2
AL023 1 304I  462-462 F23FD312         0         3 2
AL023 1 305I  463-463 F23FD313         0         3 2
AL023 1 306I  464-464 F23FD314         0         3 2
AL023 1 307I  465-465 F23FD315         1         9 2
AL023 1 308I  466-466 F23FD316         1        99 1
AL023 1 309I  467-467 F23FD317         0         3 2
AL023 1 310I  468-468 F23FD318         0         3 2
AL023 1 311I  469-469 F23FD319         0         3 2
AL023 1 312I  470-470 F23FD320         0         3 2
AL023 1 313I  471-471 F23FD321         0         3 2
AL023 1 314I  472-472 F23FD322         0         3 2
AL023 1 315I  473-473 F23FD323         0         3 2
AL023 1 316I  474-474 F23FD324         0         3 2
AL023 1 317I  475-475 F23FD325         0         3 2
AL023 1 318I  476-476 F23FD326         1        99 1
AL023 1 319I  477-478 F23FD327         1        99 1
AL023 1 320I  479-480 F23FD328         1        99 1
AL023 1 321I  481-482 F23FD329         1        99 1
AL023 1 322I  483-483 F23FD330         0         4 2
AL023 1 323I  484-486 F23FD331         0       999 1
AL023 1 324A  487-488 F23FD332         1        99 0
AL023 1 325I  489-491 F23FD334         0       999 1
AL023 1 326A  492-493 F23FD335         1        99 0
AL023 1 327I  494-496 F23FD337         0       999 1
AL023 1 328A  497-498 F23FD338         1        99 0
AL023 1 329I  499-499 F23FD340         0         3 2
AL023 1 330I  500-500 F23FD341         0         3 2
AL023 1 331I  501-501 F23FD342         0         3 2
AL023 1 332I  502-502 F23FD343         0         3 2
AL023 1 333A  503-504 F23FD344         1        99 0
AL023 1 334I  505-505 F23FD345         1         9 2
AL023 1 335I  506-506 F23FD346         1         9 2
AL023 1 336I  507-507 F23FD347         1         9 2
AL023 1 337I  508-508 F23FD348         1         9 2
AL023 1 338I  509-509 F23FD349         1         9 2
AL023 1 339I  510-510 F23FD350         1         9 2
AL023 1 340I  511-511 F23FD351         1         9 2
AL023 1 341I  512-513 F23FD352         1         9 2
AL023 1 342I  514-515 F23FD353         1         9 2
AL023 1 343I  516-517 F23FD354         1         9 2
AL023 1 344I  518-518 F23FD355         0         4 2
AL023 1 345I  519-519 F23FD356         0         3 2
AL023 1 346I  520-521 F23FD357         1         9 2
AL023 1 347I  522-523 F23FD358         1         9 2
AL023 1 348I  524-525 F23FD359         1         9 2
AL023 1 349I  526-526 F23FD360         0         3 2
AL023 1 350I  527-527 F23FD361         1         9 2
AL023 1 351I  528-529 F23FD362         1         9 2
AL023 1 352I  530-531 F23FD363         1         9 2
AL023 1 353I  532-532 F23FD365         0         1 2
AL023 1 354I  533-533 F23FD366         0         3 2
AL023 1 355I  534-534 F23FD367         0         3 2
AL023 1 356I  535-535 F23FD368         0         3 2
AL023 1 357I  536-536 F23FD369         0         3 2
AL023 1 358I  537-537 F23FD370         0         3 2
AL023 1 359I  538-538 F23FD371         0         3 2
AL023 1 360I  539-539 F23FD372         0         3 2
```

```
AL023 1 361I  540-540 F23FD373         0         3 2
AL023 1 362I  541-541 F23FD374         0         3 2
AL023 1 363I  542-542 F23FD375         0         3 2
AL023 1 364I  543-543 F23FD376         0         3 2
AL023 1 365I  544-544 F23FD377         0         1 2
AL023 1 366I  545-545 F23FD378         0         3 2
AL023 1 367I  546-546 F23FD379         0         3 2
AL023 1 368I  547-547 F23FD380         0         3 2
AL023 1 369I  548-548 F23FD381         0         3 2
AL023 1 370I  549-549 F23FD382         0         3 2
AL023 1 371I  550-550 F23FD383         0         3 2
AL023 1 372I  551-551 F23FD384         0         3 2
AL023 1 373I  552-552 F23FD385         0         3 2
AL023 1 374I  553-553 F23FD386         0         3 2
AL023 1 375I  554-554 F23FD387         0         3 2
AL023 1 376I  555-555 F23FD388         0         3 2
AL023 1 377I  556-556 F23FD389         0         1 2
AL023 1 378I  557-557 F23FD390         0         3 2
AL023 1 379I  558-558 F23FD391         0         3 2
AL023 1 380I  559-559 F23FD392         0         3 2
AL023 1 381I  560-560 F23FD393         0         3 2
AL023 1 382I  561-561 F23FD394         0         3 2
AL023 1 383I  562-562 F23FD395         0         2 2
AL023 1 384I  563-563 F23FD396         0         3 2
AL023 1 385I  564-564 F23FD397         0         3 2
AL023 1 386I  565-565 F23FD398         0         3 2
AL023 1 387I  566-566 F23FD399         0         1 2
```

AL024 - ALLHAT Closeout Postcard Form

Postcard sent to participants who did not come in for their final visit.

Version 1 - 06/2001 (only version)

Coding details:
F24018 - 'How would you rate your health today?' Range: 0-10, 0=worse, 10=best, 99=DN

F24021 to F24041 (Question 5) - Reasons for not taking medicine: check all that apply.

AL024 Version 1

ALLHAT

Dear _____:

Your health is very important to us, and we want to make sure you are well. We value you as our patient and thank you for participating in the ***ALLHAT*** program. The information you provide about your health is very important, not only to us, but to other patients with high blood pressure. Please take a few minutes and fill out the information on this card and drop it in the mail to us.

Thank you for your cooperation.

Name: _____ ALLHAT ID: __ __ __ - __ __ __ - __ __ __

Since we last contacted you on _____:

1. How many times have you made a visit to a doctor's office or clinic? __ __
2. How many times have you been in the hospital overnight? __ __
3. Have you been hospitalized for:

Heart attack?	☐ Yes ☐ No ☐ Don't know	Cancer?	☐ Yes ☐ No ☐ Don't know
Stroke?	☐ Yes ☐ No ☐ Don't know	Accident?	☐ Yes ☐ No ☐ Don't know
Heart failure?	☐ Yes ☐ No ☐ Don't know	Kidney dialysis?	☐ Yes ☐ No ☐ Don't know
Chest pain?	☐ Yes ☐ No ☐ Don't know	Kidney transplant?	☐ Yes ☐ No ☐ Don't know
Have you had an operation on your heart or blood vessels?			☐ Yes ☐ No ☐ Don't know
Have you had an operation on the blood vessels in your legs?			☐ Yes ☐ No ☐ Don't know

If you answered Yes to any of the health problems in Question 3, please tell us where you were in the hospital and the dates you were in the hospital:

4. Are you still taking the ALLHAT blood pressure medicine that we gave you? ☐ Yes ☐ No
5. What other medicines are you taking for your blood pressure or cholesterol (including the ALLHAT cholesterol medicine)?

6. We may need to contact you for more information. What is your current address and telephone number, and when is the best time of day to reach you?

7. Your next scheduled contact: _____

Thank you!

Clinic Address: _____ Telephone: __ __ __ - __ __ __ __ ext. __ __ __ __

Return address: _____

_____

_____

Affix

Postage

Here

Fold and tape
Do not staple

Fields-Marked Version

ALLHAT CLOSEOUT POSTCARD

ID: (7) _ _ - (8) _ _ _ - (9) _ _ _ FMDT: _ _ - (10) _ _ - _ _ _ _ Seq: (14) _ Site: (15) _
MO - DAY - YEAR

Acrostic: _ _ (16) _ _ _ _

2. How would you rate your health today? [(18) _ _] (0-10, 0:worst, 10:best 99=DN)

3. In general, would you say your health is [(19) _] 1=poor, 2=Fair, 3=Good, 4=Very good, 5=Excellent 9=Don't know

4. Take medicine for blood pressure now? [(20) _] 1=Yes 2=No 3=Don't know

5. Reasons for not taking medicine: check all that apply.
Problem with Medicine:

a. Size or taste of pills a problem [_] (21)

b. Too many pills [_] (22)

c. Didn't like not knowing what it was [_] (23)

d. Hard to remember to take medicine [_] (24)

e. Didn't think I needed it [_] (25)

f. Didn't understand how to take medicine [_] (26)

g. Had a bad reaction to medicine [_] (27)

h. Worried about health effects of medicine [_] (28)

i. Didn't want to be in study [_] (29)

j. Didn't want to come to clinic [_] (30)

k. Not convenient to attend clinic [_] (31)

l. Didn't like the clinic [_] (32)

m. Didn't like the visits [_] (33)

n. Transportation problems [_] (34)

Other reasons, including financial

o. Living in nursing home [_] (35)

p. Lack of support from family/friends [_] (36)

q. Another doctor told me to stop [_] (37)

r. My insurance changed [_] (38)

s. Other reason (39) [_] Specify flag [_] (40)

t. No reason [_] (41)

6. Comment flag: [_] (42)

7. Signature of person completing flag: [_] (43)

AL24

6/20/2002

```
AL024 1 001I    1-  2 F24KPCOD         1         9 2
AL024 1 002IDR  3-  8 F24BATDT         1         9 2
AL024 1 003A    9- 10 F24VFDAT         1         9 0
AL024 1 004IDR 11- 16 F24DTMOD         1         9 2
AL024 1 005I   17- 20 F24TMMOD         1         9 2
AL024 1 006I   21- 21 F24MDFLG         1         9 2
AL024 1 007I   22- 24 F24TCN           1         9 2       Y$
AL024 1 008I   25- 27 F24PNO           1       900 1       Y$
AL024 1 009I   28- 30 F24RCN           1       400 1       Y$
AL024 1 010IR  35- 42 F24FMDT8         1  99999999 1       Y$
AL024 1 011I   34- 34 F24VS            1         9 2       Y$
AL024 1 012I   35- 36 F24CENT          1         9 2       Y$
AL024 1 013IDR 37- 42 F24KEYDT         1         9 2       Y$
AL024 1 014I   43- 43 F24SEQ           1         9 2       Y$
AL024 1 015A   44- 44 F24SITE          1         9 0       Y$
AL024 1 016A   45- 50 F24ACR           1         9 0       Y$
AL024 1 017A   51- 52 F24EDIT          1         9 0
AL024 1 018I   53- 54 F24V1Q2          0        10 1
AL024 1 019I   55- 55 F24V1Q3          0         5 2
AL024 1 020I   56- 56 F24V1Q4          0         3 2
AL024 1 021I   57- 57 F24V1Q5A         0         1 2
AL024 1 022I   58- 58 F24V1F5B         0         1 2
AL024 1 023I   59- 59 F24V1Q5C         0         1 2
AL024 1 024I   60- 60 F24V1Q5D         0         1 2
AL024 1 025I   61- 61 F24V1Q5E         0         1 2
AL024 1 026I   62- 62 F24V1Q5F         0         1 2
AL024 1 027I   63- 63 F24V1Q5G         0         1 2
AL024 1 028I   64- 64 F24V1Q5H         0         1 2
AL024 1 029I   65- 65 F24V1Q5I         0         1 2
AL024 1 030I   66- 66 F24V1Q5J         0         1 2
AL024 1 031I   67- 67 F24V1Q5K         0         1 2
AL024 1 032I   68- 68 F24V1Q5L         0         1 2
AL024 1 033I   69- 69 F24V1Q5M         0         1 2
AL024 1 034I   70- 70 F24V1Q5N         0         1 2
AL024 1 035I   71- 71 F24V1Q5O         0         1 2
AL024 1 036I   72- 72 F24V1Q5P         0         1 2
AL024 1 037I   73- 73 F24V1Q5Q         0         1 2
AL024 1 038I   74- 74 F24V1Q5R         0         1 2
AL024 1 039I   75- 75 F24V1Q5S         0         1 2
AL024 1 040I   76- 76 F24V1SPF         0         1 2
AL024 1 041I   77- 77 F24V1Q5T         0         1 2
AL024 1 042I   78- 78 F24V1Q6          0         1 2
AL024 1 043I   79- 79 F24V1Q7          0         1 2
```

AL025 – ALLHAT Blood Pressure Medication at Study Entry Form

Ancillary form completed on a sample of hospitalized heart failure cases only to obtain baseline medication status not otherwise obtained at time of randomization.

Version 1 – 05/2002 (only version)

Modified Fields for LADS Master File:
Blanked:
F25038

AL025 Version 1

COPY

Region «REGION»

ALLHAT BLOOD PRESSURE MEDICATION AT STUDY ENTRY

Please fill out the information below regarding BP medication history. Complete the items as best as you can. If the patient was taking a medication **at study entry**, please put a check mark in the "yes" box and then specify the drug name and daily dose. *Use the blue laminated medication card to help you decide what class of medication to check. If a medication fits into more than one of the categories listed below, check both categories and list the drug in both places.*

305A

305- -305

1. **Date this form is completed:** ..... __ __ - __ __ - __ __ __ __ (mm-dd-yyyy)

2. **Where did you obtain the BP medication information for this participant?**
   a. ALLHAT records at randomization ..... Yes ☐1 No ☐2
   b. Other medical chart of patient ..... Yes ☐1 No ☐2
   c. Asked patient ..... Yes ☐1 No ☐2
   d. Other (specify _____) ..... Yes ☐1 No ☐2

Medication Class		Drug Name (Trade or Generic)	Daily Dose
3. **Diuretics**	Yes ☐1 →	_____	_____
	No ☐2	_____	_____
4. **Beta-blocker**	Yes ☐1 →	_____	_____
	No ☐2	_____	_____
5. **Calcium-channel blocker (CCB)**	Yes ☐1 →	_____	_____
	No ☐2	_____	_____
6. **ACE inhibitor**	Yes ☐1 →	_____	_____
	No ☐2	_____	_____
7. **ARB (angiotensin II receptor antagonist)**	Yes ☐1 →	_____	_____
	No ☐2	_____	_____
8. **Alpha blocker**	Yes ☐1 →	_____	_____
	No ☐2	_____	_____

If a medication does not fit into one of the above classes OR you DO NOT know the class of blood pressure medication OR if there is a drug you are not sure was taken for blood pressure, please provide it here:

9. **Other**	Yes ☐1 →	_____	_____
	No ☐2	_____	_____

10. **Signature and initials of person completing this form:** _____ __ __ __

Fields-Marked Version

ALLHAT BLOOD PRESSURE MEDICATION AT STUDY ENTRY

Please fill out the information below regarding BP medication history. Complete the items as best as you can. If the patient was taking a medication **at study entry**, please put a check mark in the "yes" box and then specify the drug name and daily dose. *Use the blue laminated medication card to help you decide what class of medication to check. If a medication fits into more than one of the categories listed below, check both categories and list the drug in both places.*

«ID»

«ACROSTIC» (16)

1. **Date this form is completed:** ..... (10) (YYYYMMDD) or (13) (MMDDYY) _ _ - _ _ - _ _ _ _
(mm-dd-yyyy)

2. **Where did you obtain the BP medication information for this participant?**
   a. ALLHAT records at randomization ..... Yes ☐1 No ☐2 (18)
   b. Other medical chart of patient ..... Yes ☐1 No ☐2 (19)
   c. Asked patient ..... Yes ☐1 No ☐2 (20)
   d. Other (specify _____ (22) ▷ _____) ..... Yes ☐1 No ☐2 (21)

Medication Class		Drug Name (Trade or Generic)	Daily Dose
3. **Diuretics**	(23) Yes ☐1 → No ☐2	(24) ▷	
4. **Beta-blocker**	(25) Yes ☐1 → No ☐2	(26) ▷	
5. **Calcium-channel blocker (CCB)**	(27) Yes ☐1 → No ☐2	(28) ▷	
6. **ACE inhibitor**	(29) Yes ☐1 → No ☐2	(30) ▷	
7. **ARB (angiotensin II receptor antagonist)**	(31) Yes ☐1 → No ☐2	(32) ▷	
8. **Alpha blocker**	(33) Yes ☐1 → No ☐2	(34) ▷	

If a medication does not fit into one of the above classes OR you DO NOT know the class of blood pressure medication OR if there is a drug you are not sure was taken for blood pressure, please provide it here:

9. **Other**	(35) Yes ☐1 → No ☐2	(36) ▷	

10. **Signature and initials of person completing this form:** (37) ▷ _____ (38) _ _ _

```
AL025 1 001I    1-  2 F25DE           1         9 2
AL025 1 002IDR  3-  8 F25BDAT         1         9 2
AL025 1 003A    9- 10 F25VERF         1         9 0
AL025 1 004IDR 11- 16 F25MODDT        1         9 2
AL025 1 005I   17- 20 F25MODTM        1         9 2
AL025 1 006I   21- 21 F25MODFG        1         9 2
AL025 1 007I   22- 24 F25TCN          1       700 1       Y$
AL025 1 008I   25- 27 F25PNUM         1       900 1       Y$
AL025 1 009I   28- 30 F25RCN          1       700 1       Y$
AL025 1 010I   35- 42 F25DATE8        1  99999999 1       Y$
AL025 1 011I   34- 34 F25VERSN        1         9 2       Y$
AL025 1 012I   35- 36 F25CENT         1         9 2       Y$
AL025 1 013IDR 37- 42 F25KEYDT        1         9 2       Y$
AL025 1 014I   43- 43 F25SEQ          1         9 2       Y$
AL025 1 015A   44- 44 F25SITE         1         9 0       Y$
AL025 1 016A   45- 50 F25ACOS         1         9 0       Y$
AL025 1 017I   51- 52 F25EDTFG        0         3 2       Y$
AL025 1 018I   53- 53 F25Q2A          1         2 2
AL025 1 019I   54- 54 F25Q2B          1         2 2
AL025 1 020I   55- 55 F25Q2C          1         2 2
AL025 1 021I   56- 56 F25Q2DYN        1         2 2
AL025 1 022I   57- 57 F25Q2DFG        0         1 2
AL025 1 023I   58- 58 F25Q3YN         1         2 2
AL025 1 024I   59- 59 F25Q3FG         0         1 2
AL025 1 025I   60- 60 F25Q4YN         1         2 2
AL025 1 026I   61- 61 F25Q4FG         0         1 2
AL025 1 027I   62- 62 F25Q5YN         1         2 2
AL025 1 028I   63- 63 F25Q5FG         0         1 2
AL025 1 029I   64- 64 F25Q6YN         1         2 2
AL025 1 030I   65- 65 F25Q6FG         0         1 2
AL025 1 031I   66- 66 F25Q7YN         1         2 2
AL025 1 032I   67- 67 F25Q7FG         0         1 2
AL025 1 033I   68- 68 F25Q8YN         1         2 2
AL025 1 034I   69- 69 F25Q8FG         0         1 2
AL025 1 035I   70- 70 F25Q9YN         1         2 2
AL025 1 036I   71- 71 F25Q9FG         0         1 2
AL025 1 037I   72- 72 F25Q10FG        0         1 2
AL025 1 038A   73- 75 F25Q10IN        0         0 0
```

AL030 – ALLHAT Lab Record (Computer Record Only)

This form represents laboratory data transmitted from the ALLHAT Central Laboratory.

Version 1 – Final modification 10/98 (only version)

Modified Fields for LADS Master File:

Blanked:
F30019

Changed reverse date (yymmdd) to days since randomization:
F30021
F30031
F30040
F30049
F30058
F30067
F30076
F30085
F30094
F30103
F30112

AL030 Version 1

ALLHAT LAB RECORD

ID: ___-___-___ Acrostic: (16)

FMDT: (13) -19__ Seq: (14) Site: (15)
MO-DY YR

Visit Number: (18) Specm # (19) Ctime: (20)

Vfdate (21) Vftime (22) Hours Since last ate: (23)

	Potassium First K	Potassium K	ALT	Creatinine	Glucose
Lvalue	(24)	(33)	(42)	(51)	(60)
TPC	(25)	(34)	(43)	(52)	(61)
TRC	(26)	(35)	(44)	(53)	(62)
Rlevel	(27)	(36)	(45)	(54)	(63)
Tstatus	(28)	(37)	(46)	(55)	(64)
Rtype	(29)	(38)	(47)	(56)	(65)
Panel OTcode	(30)	(39)	(48)	(57)	(66)
SRdate	(31)	(40)	(49)	(58)	(67)
SRtime	(32)	(41)	(50)	(59)	(68)

	Cholesterol	HDLC	LDL-Calc	Triglycer	Beta Quant
Lvalue	(69)	(78)	(87)	(96)	(105)
TPC	(70)	(79)	(88)	(97)	(106)
TRC	(71)	(80)	(89)	(98)	(107)
Rlevel	(72)	(81)	(90)	(99)	(108)
Tstatus	(73)	(82)	(91)	(100)	(109)
Rtype	(74)	(83)	(92)	(101)	(110)
OTcode	(75)	(84)	(93)	(102)	(111)
SRdate	(76)	(85)	(94)	(103)	(112)
SRtime	(77)	(86)	(95)	(104)	(113)

```
AL030 1 001I    1-  2 F30KPCOD         1        99 1
AL030 1 002IDR  3-  8 F30BATDT         1        99 1
AL030 1 003A    9- 10 F30VFCOD         1        99 0
AL030 1 004IDR 11- 16 F30DTMOD         1        99 1
AL030 1 005I   17- 20 F30TMMOD         1        99 1
AL030 1 006I   21- 21 F30MDFLG         1        99 1
AL030 1 007I   22- 24 F30TCN           1       662 1       Y$
AL030 1 008I   25- 27 F30PNO           1       700 1       Y$
AL030 1 009I   28- 30 F30RCN           1       662 1       Y$
AL030 1 010I   35- 42 F30DATE8         1  99999999 1       Y$
AL030 1 011I   34- 34 F30VS            1        99 1       Y$
AL030 1 012I   35- 36 F30CENT          1        99 2       Y$
AL030 1 013IDR 37- 42 F30KEYDT         1        99 1       Y$
AL030 1 014I   43- 43 F30SEQ           1        99 1       Y$
AL030 1 015A   44- 44 F30SITE          1        99 0       Y$
AL030 1 016A   45- 50 F30ACR           1        99 0       Y$
AL030 1 017I   51- 52 F30EDIT          1        99 0
AL030 1 018I   53- 54 F30VNUM          1        99 0
AL030 1 019A   55- 64 F30SPEC          1        99 0
AL030 1 020I   65- 68 F30CTIME         1        99 1
AL030 1 021A   69- 76 F30VDATE         1        99 0
AL030 1 022A   77- 80 F30VTIME         1        99 0
AL030 1 023F   81- 86 F30FD023         1        99 1
AL030 1 024F   87- 92 F30FD024         1        99 1
AL030 1 025A   93-102 F30FD025         1        99 0
AL030 1 026A  103-112 F30FD026         1        99 0
AL030 1 027I  113-116 F30FD027         1        99 1
AL030 1 028I  117-117 F30FD028         1        99 1
AL030 1 029A  118-118 F30FD029         1        99 0
AL030 1 030A  119-128 F30FD030         1        99 0
AL030 1 031I  129-136 F30FD031         1        99 1
AL030 1 032I  137-140 F30FD032         1        99 1
AL030 1 033F  141-146 F30FD033         1        99 1
AL030 1 034A  147-156 F30FD034         1        99 0
AL030 1 035A  157-166 F30FD035         1        99 0
AL030 1 036I  167-170 F30FD036         1        99 1
AL030 1 037A  171-171 F30FD037         1        99 1
AL030 1 038A  172-172 F30FD038         1        99 0
AL030 1 039A  173-182 F30FD039         1        99 0
AL030 1 040I  183-190 F30FD040         1        99 1
AL030 1 041I  191-194 F30FD041         1        99 1
AL030 1 042F  195-200 F30FD042         1        99 1
AL030 1 043A  201-210 F30FD043         1        99 0
AL030 1 044A  211-220 F30FD044         1        99 0
AL030 1 045I  221-224 F30FD045         1        99 1
AL030 1 046A  225-225 F30FD046         1        99 1
AL030 1 047A  226-226 F30FD047         1        99 0
AL030 1 048A  227-236 F30FD048         1        99 0
AL030 1 049I  237-244 F30FD049         1        99 1
AL030 1 050I  245-248 F30FD050         1        99 1
AL030 1 051F  249-254 F30FD051         1        99 1
AL030 1 052A  255-264 F30FD052         1        99 0
AL030 1 053A  265-274 F30FD053         1        99 0
AL030 1 054I  275-278 F30FD054         1        99 1
AL030 1 055A  279-279 F30FD055         1        99 1
AL030 1 056A  280-280 F30FD056         1        99 0
AL030 1 057A  281-290 F30FD057         1        99 0
AL030 1 058I  291-298 F30FD058         1        99 1
```

```
AL030 1 059I  299-302 F30FD059         1        99 1
AL030 1 060F  303-308 F30FD060         1        99 1
AL030 1 061A  309-318 F30FD061         1        99 0
AL030 1 062A  319-328 F30FD062         1        99 0
AL030 1 063I  329-332 F30FD063         1        99 1
AL030 1 064A  333-333 F30FD064         1        99 1
AL030 1 065A  334-334 F30FD065         1        99 0
AL030 1 066A  335-344 F30FD066         1        99 0
AL030 1 067I  345-352 F30FD067         1        99 1
AL030 1 068I  353-356 F30FD068         1        99 1
AL030 1 069F  357-362 F30FD069         1        99 1
AL030 1 070A  363-372 F30FD070         1        99 0
AL030 1 071A  373-382 F30FD071         1        99 0
AL030 1 072I  383-386 F30FD072         1        99 1
AL030 1 073A  387-387 F30FD073         1        99 1
AL030 1 074A  388-388 F30FD074         1        99 0
AL030 1 075A  389-398 F30FD075         1        99 0
AL030 1 076I  399-406 F30FD076         1        99 1
AL030 1 077I  407-410 F30FD077         1        99 1
AL030 1 078F  411-416 F30FD078         1        99 1
AL030 1 079A  417-426 F30FD079         1        99 0
AL030 1 080A  427-436 F30FD080         1        99 0
AL030 1 081I  437-440 F30FD081         1        99 1
AL030 1 082A  441-441 F30FD082         1        99 1
AL030 1 083A  442-442 F30FD083         1        99 0
AL030 1 084A  443-452 F30FD084         1        99 0
AL030 1 085I  453-460 F30FD085         1        99 1
AL030 1 086I  461-464 F30FD086         1        99 1
AL030 1 087F  465-470 F30FD087         1        99 1
AL030 1 088A  471-480 F30FD088         1        99 0
AL030 1 089A  481-490 F30FD089         1        99 0
AL030 1 090I  491-494 F30FD090         1        99 1
AL030 1 091A  495-495 F30FD091         1        99 1
AL030 1 092A  496-496 F30FD092         1        99 0
AL030 1 093A  497-506 F30FD093         1        99 0
AL030 1 094I  507-514 F30FD094         1        99 1
AL030 1 095I  515-518 F30FD095         1        99 1
AL030 1 096F  519-524 F30FD096         1        99 1
AL030 1 097A  525-534 F30FD097         1        99 0
AL030 1 098A  535-544 F30FD098         1        99 0
AL030 1 099I  545-548 F30FD099         1        99 1
AL030 1 100A  549-549 F30FD100         1        99 1
AL030 1 101A  550-550 F30FD101         1        99 0
AL030 1 102A  551-560 F30FD102         1        99 0
AL030 1 103I  561-568 F30FD103         1        99 1
AL030 1 104I  569-572 F30FD104         1        99 1
AL030 1 105F  573-578 F30FD105         1        99 1
AL030 1 106A  579-588 F30FD106         1        99 0
AL030 1 107A  589-598 F30FD107         1        99 0
AL030 1 108I  599-602 F30FD108         1        99 1
AL030 1 109I  603-603 F30FD109         1        99 1
AL030 1 110A  604-604 F30FD110         1        99 0
AL030 1 111A  605-614 F30FD111         1        99 0
AL030 1 112I  615-622 F30FD112         1        99 1
AL030 1 113I  623-626 F30FD113         1        99 1
```

AL031 – ALLHAT ECG Record (Computer Record Only)

This form represents baseline ECG data transmitted from the Minnesota Coding Center.

Version 1 – Final modification 10/98 (only version)

Modified Fields for LADS Master File:
Blanked:
F31021
F31022
F31025

Changed date (mmddyy) to days since randomization:
F31024
F31046

Definitions:
Major ST segment depression – "4 codes" (F031034, F031036, F031038). 4-3 through 4-1-x: 2, 3, 11 or 12 in one or more of the three fields.

T wave inversion – (F031035, F031037, F031039). 5-3 through 5-1: 1, 2 or 3 in one or more of the three fields.

Tall R wave – "3 code" (F031043). 3-1 or 3-3: 1 or 3 in this field.

LVH – Tall R plus [Major ST or T wave]

AL031 Version 1

ALLHAT ECG RECORD

ID: ___-___-___ Acrostic: (16) _____

FMDT: (13) __-__-19__ Seq: (14) _ Site: (15) _

MO-DY YR

(18) [___]	Visit Number (ECG)	(34) [__]	4 Code (I,AVL,V6 (anterolater))
(19) [_]	Hospital or Clinic	(35) [_]	5 Code (I,AVL,V6 (anterolater))
(21) [___]	Shipment identifier (SHIP)	(36) [__]	4 Code (II,III,AVF (posterior))
(22) [___]	Shipment identifier (LOT)	(37) [_]	5 Code (II,III,AVF (posterior))
(23) [_]	Worksheet number	(38) [__]	4 Code (V1-V5 (anterior))
[(24) ____]	Date baseline coded	(39) [_]	5 Code (V1-V5 (anterior))
[(25) ___]	ECG coder	(40) [_]	9 Code (I,AVL,V6 (anterolater))
(26) [__]	RHT	(41) [_]	9 Code (II,III,AVF (posterior))
(27) [__]	SV3	(42) [_]	9 Code (V1-V5 (anterior))
(28) [_]	Arrythmia Code	(43) [__]	3 Code
(29) [__]	7 Code	(44) [_]	TP
(30) [__]	6 Code	(45) [_]	Clear
(31) [__]	Q code: I,AVL,V6 (anterolateral)	[(46) ____]	MIDATE
(32) [__]	Q code: II, III, AVF (posterior)	(47) [_]	MINO
(33) [__]	Q code: V1-V5 (anterior)	(48) [_]	MITOT
		(49) [_]	AR8X3 ✓

University of Minnesota
Division of Epidemiology
ECG Coding Laboratory

DATE:
STUDY:
FILE:

Variable Definitions

starting column	variable	length	decimal places
001	STUDY	3	
004	FORM	3	
007	CLINIC	3	
010	ID	6	
016	SITE	1	
017	INITIALS	6	
023	HC	1	
024	VISIT	3	
027	SHIP	3	
030	LOT	3	
033	WS	1	
034	ECGDATE	6	
040	DATECODE	6	
046	CODER	3	
049	RHT	2	
051	SV3	2	
053	SUPP8	1	
054	VCD7XX	2	
056	ACD6XX	2	
058	QS1XX1	2	
060	QS1XX2	2	
062	QS1XX3	2	
064	ST4XX1	2	
066	TW5X1	1	
067	ST4XX2	2	
069	TW5X2	1	
070	ST4XX3	2	
072	TW5X3	1	
073	STV6	1	
074	STF	1	
075	STV5	1	
076	R	2	
078	TP	1	
079	CLEAR	1	
080	MIDATE	6	
086	MINO	1	
087	MITOT	1	
088	AR8X3	1	

Post-it® Fax Note 7671 | Date | # of pages ▶
To Sara Pressel | From Carmen DeMarco II
Co./Dept. | Co.
Phone # | Phone #
Fax # 713 500 9530 | Fax #

```
AL031 1 001I    1-  2 F31KPCOD         1         9 2
AL031 1 002IDR  3-  8 F31BATDT         1         9 2
AL031 1 003A    9- 10 F31VFCOD         1         9 0
AL031 1 004IDR 11- 16 F31DTMOD         1         9 2
AL031 1 005I   17- 20 F31TMMOD         1         9 2
AL031 1 006I   21- 21 F31MDFLG         1         9 2
AL031 1 007I   22- 24 F31TCN           1       662 1       Y$
AL031 1 008I   25- 27 F31PNO           1       700 1       Y$
AL031 1 009I   28- 30 F31RCN           1       662 1       Y$
AL031 1 010I   35- 42 F31DATE8         1  99999999 1       Y$
AL031 1 011I   34- 34 F31VS            1         9 2       Y$
AL031 1 012I   35- 36 F31CENT          1         9 0       Y$
AL031 1 013IDR 37- 42 F31KEYDT         1         9 2       Y$
AL031 1 014I   43- 43 F31SEQ           1         9 2       Y$
AL031 1 015A   44- 44 F31SITE          1         9 0       Y$
AL031 1 016A   45- 50 F31ACR           1         9 0       Y$
AL031 1 017I   51- 52 F31EDIT          1         9 0       Y$
AL031 1 018I   53- 55 F31VNO1          1         9 0
AL031 1 019A   56- 56 F31HOSP          1         9 0
AL031 1 021A   57- 59 F31SHIP          1         9 0
AL031 1 022A   60- 62 F31LOG           1         9 0
AL031 1 023A   63- 63 F31WKSHT         1         9 0
AL031 1 024AD  64- 69 F31DCODE         1         9 0
AL031 1 025A   70- 72 F31CODER         1         9 0
AL031 1 026A   73- 74 F31RHT           1         9 0
AL031 1 027A   75- 76 F31SV3           1         9 0
AL031 1 028A   77- 77 F31SUPP8         1         9 0
AL031 1 029A   78- 79 F31CD7           1         9 0
AL031 1 030A   80- 81 F31FD030         1         9 0
AL031 1 031A   82- 83 F31FD031         1         9 0
AL031 1 032A   84- 85 F31FD032         1         9 0
AL031 1 033A   86- 87 F31FD033         1         9 0
AL031 1 034A   88- 89 F31FD034         1         9 0
AL031 1 035A   90- 90 F31FD035         1         9 0
AL031 1 036A   91- 92 F31FD036         1         9 0
AL031 1 037A   93- 93 F31FD037         1         9 0
AL031 1 038A   94- 95 F31FD038         1         9 0
AL031 1 039A   96- 96 F31FD039         1         9 0
AL031 1 040A   97- 97 F31FD040         1         9 0
AL031 1 041A   98- 98 F31FD041         1         9 0
AL031 1 042A   99- 99 F31FD042         1         9 0
AL031 1 043A  100-101 F31FD043         1         9 0
AL031 1 044A  102-102 F31FD044         1         9 0
AL031 1 045A  103-103 F31FD045         1         9 0
AL031 1 046A  104-109 F31FD046         1         9 0
AL031 1 047A  110-110 F31FD047         1         9 0
AL031 1 048A  111-111 F31FD048         1         9 0
AL031 1 049A  112-112 F31FD049         1         9 0
```

AL032 - ALLHAT Serial Change ECG Record (Computer Record Only)

This form represents follow-up ECG data transmitted from the Minnesota Coding Center.

Version 1 – Final modification 10/98 (only version)

Modified Fields for LADS Master File:

Blanked:
F32020
F32021
F32022
F32023
F32024
F32028
F32050
F32051
F32054
F32076

Changed date (mmddyy) to days since randomization:
F32026
F32027
F32053
F32192
F32197

Changed date (ddmmyy) to days since randomization:
F32075

AL032 Version 1

ALLHAT SERIUM CHANGE ECG RECORD

ID: ___-___-___ Acrostic: (16)

FMDT: (13) __-__-19__ (date of follow-up ECG) Seq: (14) Site: (15)
MO-DY YR

[(18)] Visit Number (ECG) [(19)] Hospital/Clinic [(20)-(21)-(22)] Baseline ID

[(23)] Shipment identifier (SHIP)

[(24)] Shipment identifier (LOT)

(25)[_] Worksheet number

[(26)] Date baseline coded

[(27)] Date baseline coded

(28)[___] ECG coder

(29)[__] RHT

(30)[__] SV3

(31) [_] Arrythmia Code

(32)[__] 7 Code

(33)[__] 6 Code

(34)[__] Q code: I,AVL,V6 (anterolateral)

(35)[__] Q code: II, III, AVF (posterior)

(36) [__] Q code: V1-V5 (anterior)

(37)[__] 4 Code (I,AVL,V6 (anterolater))

(38) [_] 5 Code (I,AVL,V6 (anterolater))

(39)[__] 4 Code (II,III,AVF (posterior))

(40) [_] 5 Code (II,III,AVF (posterior))

(41)[__] 4 Code (V1-V5 (anterior))

(42)[_] 5 Code (V1-V5 (anterior))

(43)[_] 9 Code (I,AVL,V6 (anterolater))

(44)[_] 9 Code (II,III,AVF (posterior))

(45)[_] 9 Code (V1-V5 (anterior))

(46)[__] 3 Code

(47)[_] TP

(48)[_] Clear

(49)

----Follow up part of Serium Change Record---

(49) [___] Visit Number (ECG)
(50) [___] Shipment identifier (SHIP)
(51) [___] Shipment identifier (LOT)
(52) [_] Worksheet number
[(53)] Followup Date coded
(54) [___] ECG coder
(55) [__] RHT
(56) [__] SV3
(57) [_] Arrythmia Code
(58) [__] 7 Code
(59) [__] 6 Code
(60) [__] Q code: I,AVL,V6 (anterolateral)
(61) [__] Q code: II, III, AVF (posterior)
(62) [__] Q code: V1-V5 (anterior)

(63) [__] 4 Code (I,AVL,V6 (anterolater))
(64) [_] 5 Code (I,AVL,V6 (anterolater))
(65) [__] 4 Code (II,III,AVF (posterior))
(66) [_] 5 Code (II,III,AVF (posterior))
(67) [__] 4 Code (V1-V5 (anterior))
(68) [_] 5 Code (V1-V5 (anterior))
(69) [_] 9 Code (I,AVL,V6 (anterolater))
(70) [_] 9 Code (II,III,AVF (posterior))
(71) [_] 9 Code (V1-V5 (anterior))
(72) [__] 3 Code
(73) [_] TP
(74) [_] Clear

[(75)] Serium (Serial ECG) Date coded
(76) [___] ECG coder
(77) [_] Cond1-1
(78) [_] Cond1-2
(79) [_] Cond1-3
(80) [_] Cond2-1
(81) [_] Cond2-2
(82) [_] Cond2-3
(83) [_] Cond3-1
(84) [_] Cond3-2
(85) [_] Cond3-3
(86) [_] Cond4-1
(87) [_] Cond4-2
(88) [_] Cond4-3
(89) [_] Cond7-1
(90) [_] Cond7-2
(91) [_] Cond7-3

(92) [_] Cond8-1
(93) [_] Cond8-2
(94) [_] Cond8-3
(95) [_] Cond9-1
(96) [_] Cond9-2
(97) [_] Cond9-3
(98) [_] Cond10-1
(99) [_] Cond10-2
(100) [_] Cond10-3
(101) [_] Cond11-1
(102) [_] Cond11-2
(103) [_] Cond11-3
(104) [_] Cond12-1
(105) [_] Cond12-2
(106) [_] Cond12-3

(107) [_] Cond13-1
(108) [_] Cond13-2
(109) [_] Cond13-3
(110) [_] Cond14-1
(111) [_] Cond14-2
(112) [_] Cond14-3
(113) [_] Cond15-1
(114) [_] Cond15-2
(115) [_] Cond15-3
(116) [_] Cond16-1
(117) [_] Cond16-2
(118) [_] Cond16-3
(119) [_] Cond17-1
(120) [_] Cond17-2
(121) [_] Cond17-3

(122) [_]Cond18-1
(123) [_]Cond18-2
(124) [_]Cond18-3
(125) [_]Cond19-1
(126) [_]Cond19-2
(127) [_]Cond19-3
(128) [_]Cond20-1
(129) [_]Cond20-2
(130) [_]Cond20-3
(131) [_]Cond21-1
(132) [_]Cond21-2
(133) [_]Cond21-3
(134) [_]Cond22-1
(135) [_]Cond22-2
(136) [_]Cond22-3
(137) [_]Cond23-1
(138) [_]Cond23-2
(139) [_]Cond23-3

(140) [_]Cond24-1
(141) [_]Cond24-2
(142) [_]Cond24-3
(143) [_]Cond25-1
(144) [_]Cond25-2
(145) [_]Cond25-3
(146) [_]Cond26-1
(147) [_]Cond26-2
(148) [_]Cond26-3
(149) [_]Cond27
(150) [_]Cond28
(151) [_]Cond29
(152) [_]Cond30
(153) [_]Cond31
(154) [_]Cond32
(155) [_]Cond33
(156) [_]Cond34

(157) [_]Cond35
(158) [_]Cond36
(159) [_]Cond37

(160) [_]ED1
(161) [_]ED2A
(162) [_]ED2B
(163) [_]ED3A
(164) [_]ED3B
(165) [_]ED4A
(166) [_]ED4B
(167) [_]ED5A
(168) [_]ED5B
(169) [_]ED6A
(170) [_]ED6B
(171) [_]ED7A
(172) [_]ED7B

(173) [_]EV1
(174) [_]EV2
(175) [_]EV3
(176) [_]EV4
(177) [_]EV5
(178) [_]EV6
(179) [_]EV7
(180) [_]EV8
(181) [_]EV9A
(182) [_]EV9B
(183) [_]ELVH1
(184) [_]ELVH2
(185) [_]ELVH3
(186) [_]ELVH4
(187) [_]ELVH5
(188) [_]ELVH6

(189) [_]EBBB1
(190) [_]EBBB2
(191) [_]EBBB3
[(192)_____]MI Date
(193) [_]MINO
(194) [_]MITOT
(195) [_]BAR8X3
(196) [_]FAR8X3
[(197)_____]SECG MI LIST DATE

University of Minnesota
Division of Epidemiology
ECG Coding Laboratory

DATE:
STUDY:
FILE:

Variable Definitions

starting column	variable	length	decimal places
001	STUDY	3	
004	FORM	3	
007	BCLINIC	3	
010	BID	6	
016	FCLINIC	3	
019	FID	6	
025	SITE	1	
026	INITIALS	6	
032	HC	1	
033	BVISIT	3	
036	BSHIP	3	
039	BLOT	3	
042	BWS	1	
043	BECGDATE	6	
049	BDATECOD	6	
055	BCODER	3	
058	BRHT	2	
060	BSV3	2	
062	BSUPP8	1	
063	BVCD7XX	2	
065	BACD6XX	2	
067	BQS1XX1	2	
069	BQS1XX2	2	
071	BQS1XX3	2	
073	BST4XX1	2	
075	BTW5X1	1	
076	BST4XX2	2	
078	BTW5X2	1	
079	BST4XX3	2	
081	BTW5X3	1	
082	BSTV6	1	
083	BSTF	1	
084	BSTV5	1	
085	BR	2	
087	BTP	1	
088	BCLEAR	1	
089	FVISIT	3	
092	FSHIP	3	
095	FLOT	3	
098	FWS	1	
099	FECGDATE	6	
105	FDATECOD	6	
111	FCODER	3	
114	FRHT	2	
116	FSV3	2	
118	FSUPP8	1	
119	FVCD7XX	2	

121	FACD6XX	2
123	FQS1XX1	2
125	FQS1XX2	2
127	FQS1XX3	2
129	FST4XX1	2
131	FTW5X1	1
132	FST4XX2	2
134	FTW5X2	1
135	FST4XX3	2
137	FTW5X3	1
138	FSTV6	1
139	FSTF	1
140	FSTV5	1
141	FR	2
143	FTP	1
144	FCLEAR	1
145	SDATECOD	6
151	SCODER	3
154	COND1_1	1
155	COND1_2	1
156	COND1_3	1
157	COND2_1	1
158	COND2_2	1
159	COND2_3	1
160	COND3_1	1
161	COND3_2	1
162	COND3_3	1
163	COND4_1	1
164	COND4_2	1
165	COND4_3	1
166	COND7_1	1
167	COND7_2	1
168	COND7_3	1
169	COND8_1	1
170	COND8_2	1
171	COND8_3	1
172	COND9_1	1
173	COND9_2	1
174	COND9_3	1
175	COND10_1	1
176	COND10_2	1
177	COND10_3	1
178	COND11_1	1
179	COND11_2	1
180	COND11_3	1
181	COND12_1	1
182	COND12_2	1
183	COND12_3	1
184	COND13_1	1
185	COND13_2	1
186	COND13_3	1
187	COND14_1	1
188	COND14_2	1
189	COND14_3	1
190	COND15_1	1
191	COND15_2	1
192	COND15_3	1
193	COND16_1	1
194	COND16_2	1
195	COND16_3	1

196	COND17_1	1
197	COND17_2	1
198	COND17_3	1
199	COND18_1	1
200	COND18_2	1
201	COND18_3	1
202	COND19_1	1
203	COND19_2	1
204	COND19_3	1
205	COND20_1	1
206	COND20_2	1
207	COND20_3	1
208	COND21_1	1
209	COND21_2	1
210	COND21_3	1
211	COND22_1	1
212	COND22_2	1
213	COND22_3	1
214	COND23_1	1
215	COND23_2	1
216	COND23_3	1
217	COND24_1	1
218	COND24_2	1
219	COND24_3	1
220	COND25_1	1
221	COND25_2	1
222	COND25_3	1
223	COND26_1	1
224	COND26_2	1
225	COND26_3	1
226	COND27	1
227	COND28	1
228	COND29	1
229	COND30	1
230	COND31	1
231	COND32	1
232	COND33	1
233	COND34	1
234	COND35	1
235	COND36	1
236	COND37	1
237	ED1	1
238	ED2A	1
239	ED2B	1
240	ED3A	1
241	ED3B	1
242	ED4A	1
243	ED4B	1
244	ED5A	1
245	ED5B	1
246	ED6A	1
247	ED6B	1
248	ED7A	1
249	ED7B	1
250	EV1	1
251	EV2	1
252	EV3	1
253	EV4	1
254	EV5	1
255	EV6	1

256	EV7	1
257	EV8	1
258	EV9A	1
259	EV9B	1
260	ELVH1	1
261	ELVH2	1
262	ELVH3	1
263	ELVH4	1
264	ELVH5	1
265	ELVH6	1
266	EBBB1	1
267	EBBB2	1
268	EBBB3	1
269	MIDATE	6
275	MINO	1
276	MITOT	1
277	BAR8X3	1
278	FAR8X3	1

Format without RHT & SV3 which were added on 7/12/94

ALLHAT STANDARD VARIABLE DEFINITIONS
BASELINE ECGS

COL	VARIABLE	DEFINITION
001	STUDY	3 digit alphabetic study identifier for the baseline ECGs ***Used Internally by the Coding Center***
004	FORM	Identifies the coding form ***Used Internally by the Coding Center***
007	ID	Unique 9 field identifier for each patient's ECGs
016	VISITID	000=baseline
019	INIT	Patient acrostic
025	HC	Hospital or clinic ECG
026	VISIT	000=baseline
029	SHIP	3 digit shipment identifier for the ECG ***Used Internally by the Coding Center***
032	LOT	3 digit shipment identifier for the ECG ***Used Internally by the Coding Center***
035	WS	Worksheet number for the ECG
036	ECGDATE	Date the baseline was recorded
042	DATECODE	Date the baseline was coded
048	CODER	Coder ID number for the ECG ***Used Internally by the Coding Center***
051	SUPP8	Arrythmia code which suppresses all other codes
052	VCD7XX	7 Code

054	ACD6XX	6 code
056	QS1XX1	Q code in leads I, AVL, V6 (anterolateraL sites)
058	QS1XX2	Q code in II,III, AVF (posterior sites)
060	QS1XX3	Q code in V1-V5 (anterior sites)
062	ST4XX1	4 code in I, AVL, V6 (anterolateral sites)
064	TW5X1	5 code in I, AVL, V6 (anterolateral sites)
065	ST4XX2	4 code in II, III, AVF (posterior sites)
067	TW5X2	5 code in II, III, AVF (posterior sites)
068	ST4XX3	4 code in V1-V5 (anterior sites)
070	TW5X3	5 code in V1-V5 (anterior sites)
071	STV6	9 code in I, AVL, V6 (anterolateraL sites)
072	STF	9 code in II, III, AVF (posterior sites)
073	STV5	9 code in V1-V5 (anterior sites)
074	R	3 code
076	TP	Technical problem
077	CLEAR	No code on the ECG

CONDITION DEFINITIONS

All ED, R-ED, EV, E-LVM, and E-BBB classifications are divided into categories called "conditions". Conditions are used to simplify the code changes which prompt serial change. A condition is defined as a specific combination of Minnesota Code changes from the baseline ECG to the follow-up ECG. Every specific combination of Minnesota Code that is examined for serial change is defined in a condition.

There are two components to every condition. For a condition to be met, it must be present on the set of comparison ECGs, and it must be scored with a specific value.

For the condition to be present on the set of comparison ECGs, it must meet the specified criteria. As an example, Condition 1 requires either no Q-code or a 1-2-6 at baseline and any 1-1-X through a 1-2-5, or a 1-2-7 at follow-up. If the combination of codes is present on the set of comparison ECGs, the condition is said to be present. It is possible for the condition to be present in all three lead groups of the ECGs.

The second component of the condition criteria is the scoring. If a condition is present on the set of comparison ECGs, it must be scored. The following system is used for scoring conditions: 1 = increase, 2 = decrease, 3 = no change, 4 = technical problem. The scoring is determined upon visual comparison. Each condition can be scored in one of three ways, however, there is only one value which will allow the condition to be met. The condition may be present in all three lead groups of the ECGs, but only needs to be met in one of the lead groups to qualify for the ED, EV or R-ED criteria.

The conditions are defined on pages 24 to 26. The format is:

Code at baseline / Code at follow-up lead group(s) Follow-up ECG "type" score

The codes required at baseline and at follow-up will often be indicated by a range. The first digit of the code is never included.

Lead group indicates the lead group in which the condition can occur. Conditions 27-37 are for codes which do not occur in lead groups. ECG type indicates the type of record which qualifies for each condition. There are two types of records, hospital and non-hospital (clinic). Some classifications are only used for certain types of records. For example, Left Ventricular Hypertrophy is only examined in clinic records, and decreases in 4, 5, and 9-2 codes are only examined in hospital records. Score is the required value for the condition to be met. Recall that 1 = increase, 2 = decrease, 3 = no change, 4 = technical problem. Conditions are only met through an increase or decrease.

Page 27 describes which condition combinations are required for each serial change category. The condition must be met to qualify for the category.

SERIAL CHANGE CONDITIONS

Q & QS PATTERN 1XX

Condition	Minnesota Codes	Lead Groups			ECG Type	Score
Condition 1	B, 26 / 11-25, 27	I,L,6 ____	II, III, F ____	Vs ____	Hospital/Clinic	1
Condition 2	28, 3X / 1X	I,L,6 ____	II, III, F ____	Vs ____	Hospital/Clinic	1
Condition 3	28, 3X/ 21-25, 27	I,L,6 ____	II, III, F ____	Vs ____	Hospital/Clinic	1
Condition 4	B, 26 / 28, 3X	I,L,6 ____	II, III, F ____	Vs ____	Hospital/Clinic	1
Condition 5	11-25, 27 / B, 26	I,L,6 ____	II, III, F ____	Vs ____	Hospital/Clinic	2
Condition 6	1X, 28 / 3X	I,L,6 ____	II, III, F ____	Vs ____	Hospital/Clinic	2

ST SEGMENT DEPRESSION 4XX

Condition	Minnesota Codes	Lead Groups			ECG Type	Score
Condition 7	B, 3, 4 / 11, 12, 2	I,L,6 ____	II, III, F ____	Vs ____	Hospital/Clinic	1
Condition 8	11, 12, 2 / B, 3, 4	I,L,6 ____	II, III, F ____	Vs ____	Hospital	2
Condition 9	2 / 12	I,L,6 ____	II, III, F ____	Vs ____	Hospital/Clinic	1
Condition 10	12 / 2	I,L,6 ____	II, III, F ____	Vs ____	Hospital	2
Condition 11	12, 2 / 11	I,L,6 ____	II, III, F ____	Vs ____	Hospital/Clinic	1
Condition 12	11 / 12, 2	I,L,6 ____	II, III, F ____	Vs ____	Hospital	2
Condition 13	11 / 11	I,L,6 ____	II, III, F ____	Vs ____	Hospital/Clinic	1
Condition 14	11 / 11	I,L,6 ____	II, III, F ____	Vs ____	Hospital	2

T WAVE DEPRESSION 5X

Condition	Minnesota Codes	Lead Groups			ECG Type	Score
Condition 15	B, 3, 4 / 1, 2	I,L,6 ____	II, III, F ____	Vs ____	Hospital/Clinic	1
Condition 16	1, 2 / B, 3, 4	I,L,6 ____	II, III, F ____	Vs ____	Hospital	2
Condition 17	2 / 1	I,L,6 ____	II, III, F ____	Vs ____	Hospital/Clinic	1

Condition 18	1/2	I,L,6 ___	II, III, F ___	Vs ___	Hospital	2
Condition 19	1/1	I,L,6 ___	II, III, F ___	Vs ___	Hospital/Clinic	1
Condition 20	1/1	I,L,6 ___	II, III, F ___	Vs ___	Hospital	2
Condition 21	2/2	I,L,6 ___	II, III, F ___	Vs ___	Hospital/Clinic	1
Condition 22	2/2	I,L,6 ___	II, III, F ___	Vs ___	Hospital	2

T WAVE ELEVATION 9X

Condition	Minnesota Codes	Lead Groups			ECG Type	Score
Condition 23	8/2	I,L,6 ___	II, III, F ___	Vs ___	Hospital/Clinic	1
Condition 24	2/2	I,L,6 ___	II, III, F ___	Vs ___	Hospital/Clinic	1
Condition 25	2/2	I,L,6 ___	II, III, F ___	Vs ___	Hospital	2
Condition 26	2/8	I,L,6 ___	II, III, F ___	Vs ___	Hospital	2

VENTRICULAR CONDUCTION DEFECT 7XX

Condition	Minnesota Codes		ECG Type	Score
Condition 27	8/11	VCD ___	Hospital/Clinic	1
Condition 28	8/21	VCD ___	Hospital/Clinic	1
Condition 29	8/4	VCD ___	Hospital/Clinic	1

LEFT VENTRICULAR HYPERTROPHY 3X

Condition	Minnesota Codes		ECG Type	Score
Condition 30	8/1	LVH ___	Clinic	1
Condition 31	8/3	LVH ___	Clinic	1
Condition 32	1/8	LVH ___	Clinic	2
Condition 33	3/8	LVH ___	Clinic	2
Condition 34	1/1	LVH ___	Clinic	1
Condition 35	3/3	LVH ___	Clinic	1

ondition 36	1 / 1	LVH	Clinic	2
Condition 37	3 / 3	LVH	Clinic	2

SERIAL CHANGE CATEGORIES

ED1	Condition 1 or 2
ED2A	Condition 3 & 7
ED2B	Condition 3 & (9 or 11 or 13)
ED3A	Condition 3 & 15
ED3B	Condition 3 & (17 or 19 or 21)
ED4A	Condition 3 & 23
ED4B	Condition 3 & 24
ED5A	Condition 4 & 7
ED5B	Condition 4 & (9 or 11 or 13)
ED6A	Condition 4 & 15
ED6B	Condition 4 & (17 or 19 or 21)
ED7A	Condition 4 & 23
ED7B	Condition 4 & 24

R-ED1	Condition 5 or 6

E-LVH1	Condition 30
E-LVH2	Condition 31
E-LVH3	Condition 32
E-LVH4	Condition 33
E-LVH5	Condition 34 or 35
E-LVH6	Condition 36 or 37

EV1	7 or 8 or 9 or 10
EV2	11 or 12
EV3	15 or 16
EV4	17 or 18
EV5	23 or 24 or 25 or 26
EV6	13 or 14
EV7	19 or 20
EV8	21 or 22
EV9A	Condition 4 & (8 or 10 or 12 or 14 or 16 or 18 or 20 or 22 or 25 or 26)
EV9B	Condition 3 & (8 or 10 or 12 or 14 or 16 or 18 or 20 or 22 or 25 or 26)

***For EV1 - EV 8, Conditions 1-6 can not be met in any lead group**

E-BBB1	Condition 27
E-BBB2	Condition 28
E-BBB3	Condition 29

```
AL032 1 001I    1-  2 F32KPCOD         1         9 2
AL032 1 002IDR  3-  8 F32BATDT         1         9 2
AL032 1 003A    9- 10 F32VFCOD         1         9 0
AL032 1 004IDR 11- 16 F32DTMOD         1         9 2
AL032 1 005I   17- 20 F32TMMOD         1         9 2
AL032 1 006I   21- 21 F32MDFLG         1         9 2
AL032 1 007I   22- 24 F32TCN           1       662 1       Y$
AL032 1 008I   25- 27 F32PNO           1       700 1       Y$
AL032 1 009I   28- 30 F32RCN           1       662 1       Y$
AL032 1 010I   35- 42 F32DATE8         1  99999999 1       Y$
AL032 1 011I   34- 34 F32VS            1         9 2       Y$
AL032 1 012I   35- 36 F32CENT          1         9 0       Y$
AL032 1 013IDR 37- 42 F32KEYDT         1         9 2       Y$
AL032 1 014I   43- 43 F32SEQ           1         9 2       Y$
AL032 1 015A   44- 44 F32SITE          1         9 0       Y$
AL032 1 016A   45- 50 F32ACR           1         9 0       Y$
AL032 1 017A   51- 52 f32EDIT          1         9 0
AL032 1 018I   53- 55 F32VNO1          1         9 0
AL032 1 019A   56- 56 F32HOSP          1         9 0
AL032 1 020I   57- 59 F32BLTCN         1       662 1
AL032 1 021I   60- 62 F32BLPNO         1       700 1
AL032 1 022I   63- 65 F32BLRCN         1       662 1
AL032 1 023I   66- 68 F32SHIP          1         9 0
AL032 1 024I   69- 71 F32LOG           1         9 0
AL032 1 025I   72- 72 F32WKSHT         1         9 0
AL032 1 026ID  73- 78 F32DCODE         1         9 0
AL032 1 027ID  79- 84 F32FD027         1         9 0
AL032 1 028I   85- 87 F32FD028         1         9 0
AL032 1 029I   88- 89 F32FD029         1         9 0
AL032 1 030I   90- 91 F32FD030         1         9 0
AL032 1 031I   92- 92 F32FD031         1         9 0
AL032 1 032I   93- 94 F32FD032         1         9 0
AL032 1 033I   95- 96 F32FD033         1         9 0
AL032 1 034I   97- 98 F32FD034         1         9 0
AL032 1 035I   99-100 F32FD035         1         9 0
AL032 1 036I  101-102 F32FD036         1         9 0
AL032 1 037I  103-104 F32FD037         1         9 0
AL032 1 038I  105-105 F32FD038         1         9 0
AL032 1 039I  106-107 F32FD039         1         9 0
AL032 1 040I  108-108 F32FD040         1         9 0
AL032 1 041I  109-110 F32FD041         1         9 0
AL032 1 042I  111-111 F32FD042         1         9 0
AL032 1 043I  112-112 F32FD043         1         9 0
AL032 1 044I  113-113 F32FD044         1         9 0
AL032 1 045I  114-114 F32FD045         1         9 0
AL032 1 046I  115-116 F32FD046         1         9 0
AL032 1 047I  117-117 F32FD047         1         9 0
AL032 1 048I  118-118 F32FD048         1         9 0
AL032 1 049I  119-121 F32FD049         1         9 0
AL032 1 050I  122-124 F32FD050         1         9 0
AL032 1 051I  125-127 F32FD051         1         9 0
AL032 1 052I  128-128 F32FD052         1         9 0
AL032 1 053ID 129-134 F32FD053         1         9 0
AL032 1 054I  135-137 F32FD054         1         9 0
AL032 1 055I  138-139 F32FD055         1         9 0
AL032 1 056I  140-141 F32FD056         1         9 0
AL032 1 057I  142-142 F32FD057         1         9 0
AL032 1 058I  143-144 F32FD058         1         9 0
```

```
AL032 1 059I  145-146 F32FD059         1         9 0
AL032 1 060I  147-148 F32FD060         1         9 0
AL032 1 061I  149-150 F32FD061         1         9 0
AL032 1 062I  151-152 F32FD062         1         9 0
AL032 1 063I  153-154 F32FD063         1         9 0
AL032 1 064I  155-155 F32FD064         1         9 0
AL032 1 065I  156-157 F32FD065         1         9 0
AL032 1 066I  158-158 F32FD066         1         9 0
AL032 1 067I  159-160 F32FD067         1         9 0
AL032 1 068I  161-161 F32FD068         1         9 0
AL032 1 069I  162-162 F32FD069         1         9 0
AL032 1 070I  163-163 F32FD070         1         9 0
AL032 1 071I  164-164 F32FD071         1         9 0
AL032 1 072I  165-166 F32FD072         1         9 0
AL032 1 073I  167-167 F32FD073         1         9 0
AL032 1 074I  168-168 F32FD074         1         9 0
AL032 1 075ID 169-174 F32FD075         1         9 0
AL032 1 076I  175-177 F32FD076         1         9 0
AL032 1 077I  178-178 F32FD077         1         9 0
AL032 1 078I  179-179 F32FD078         1         9 0
AL032 1 079I  180-180 F32FD079         1         9 0
AL032 1 080I  181-181 F32FD080         1         9 0
AL032 1 081I  182-182 F32FD081         1         9 0
AL032 1 082I  183-183 F32FD082         1         9 0
AL032 1 083I  184-184 F32FD083         1         9 0
AL032 1 084I  185-185 F32FD084         1         9 0
AL032 1 085I  186-186 F32FD085         1         9 0
AL032 1 086I  187-187 F32FD086         1         9 0
AL032 1 087I  188-188 F32FD087         1         9 0
AL032 1 088I  189-189 F32FD088         1         9 0
AL032 1 089I  190-190 F32FD089         1         9 0
AL032 1 090I  191-191 F32FD090         1         9 0
AL032 1 091I  192-192 F32FD091         1         9 0
AL032 1 092I  193-193 F32FD092         1         9 0
AL032 1 093I  194-194 F32FD093         1         9 0
AL032 1 094I  195-195 F32FD094         1         9 0
AL032 1 095I  196-196 F32FD095         1         9 0
AL032 1 096I  197-197 F32FD096         1         9 0
AL032 1 097I  198-198 F32FD097         1         9 0
AL032 1 098I  199-199 F32FD098         1         9 0
AL032 1 099I  200-200 F32FD099         1         9 0
AL032 1 100I  201-201 F32FD100         1         9 0
AL032 1 101I  202-202 F32FD101         1         9 0
AL032 1 102I  203-203 F32FD102         1         9 0
AL032 1 103I  204-204 F32FD103         1         9 0
AL032 1 104I  205-205 F32FD104         1         9 0
AL032 1 105I  206-206 F32FD105         1         9 0
AL032 1 106I  207-207 F32FD106         1         9 0
AL032 1 107I  208-208 F32FD107         1         9 0
AL032 1 108I  209-209 F32FD108         1         9 0
AL032 1 109I  210-210 F32FD109         1         9 0
AL032 1 110I  211-211 F32FD110         1         9 0
AL032 1 111I  212-212 F32FD111         1         9 0
AL032 1 112I  213-213 F32FD112         1         9 0
AL032 1 113I  214-214 F32FD113         1         9 0
AL032 1 114I  215-215 F32FD114         1         9 0
AL032 1 115I  216-216 F32FD115         1         9 0
AL032 1 116I  217-217 F32FD116         1         9 0
```

```
AL032 1 117I  218-218 F32FD117         1         9 0
AL032 1 118I  219-219 F32FD118         1         9 0
AL032 1 119I  220-220 F32FD119         1         9 0
AL032 1 120I  221-221 F32FD120         1         9 0
AL032 1 121I  222-222 F32FD121         1         9 0
AL032 1 122I  223-223 F32FD122         1         9 0
AL032 1 123I  224-224 F32FD123         1         9 0
AL032 1 124I  225-225 F32FD124         1         9 0
AL032 1 125I  226-226 F32FD125         1         9 0
AL032 1 126I  227-227 F32FD126         1         9 0
AL032 1 127I  228-228 F32FD127         1         9 0
AL032 1 128I  229-229 F32FD128         1         9 0
AL032 1 129I  230-230 F32FD129         1         9 0
AL032 1 130I  231-231 F32FD130         1         9 0
AL032 1 131I  232-232 F32FD131         1         9 0
AL032 1 132I  233-233 F32FD132         1         9 0
AL032 1 133I  234-234 F32FD133         1         9 0
AL032 1 134I  235-235 F32FD134         1         9 0
AL032 1 135I  236-236 F32FD135         1         9 0
AL032 1 136I  237-237 F32FD136         1         9 0
AL032 1 137I  238-238 F32FD137         1         9 0
AL032 1 138I  239-239 F32FD138         1         9 0
AL032 1 139I  240-240 F32FD139         1         9 0
AL032 1 140I  241-241 F32FD140         1         9 0
AL032 1 141I  242-242 F32FD141         1         9 0
AL032 1 142I  243-243 F32FD142         1         9 0
AL032 1 143I  244-244 F32FD143         1         9 0
AL032 1 144I  245-245 F32FD144         1         9 0
AL032 1 145I  246-246 F32FD145         1         9 0
AL032 1 146I  247-247 F32FD146         1         9 0
AL032 1 147I  248-248 F32FD147         1         9 0
AL032 1 148I  249-249 F32FD148         1         9 0
AL032 1 149I  250-250 F32FD149         1         9 0
AL032 1 150I  251-251 F32FD150         1         9 0
AL032 1 151I  252-252 F32FD151         1         9 0
AL032 1 152I  253-253 F32FD152         1         9 0
AL032 1 153I  254-254 F32FD153         1         9 0
AL032 1 154I  255-255 F32FD154         1         9 0
AL032 1 155I  256-256 F32FD155         1         9 0
AL032 1 156I  257-257 F32FD156         1         9 0
AL032 1 157I  258-258 F32FD157         1         9 0
AL032 1 158I  259-259 F32FD158         1         9 0
AL032 1 159I  260-260 F32FD159         1         9 0
AL032 1 160I  261-261 F32FD160         1         9 0
AL032 1 161I  262-262 F32FD161         1         9 0
AL032 1 162I  263-263 F32FD162         1         9 0
AL032 1 163I  264-264 F32FD163         1         9 0
AL032 1 164I  265-265 F32FD164         1         9 0
AL032 1 165I  266-266 F32FD165         1         9 0
AL032 1 166I  267-267 F32FD166         1         9 0
AL032 1 167I  268-268 F32FD167         1         9 0
AL032 1 168I  269-269 F32FD168         1         9 0
AL032 1 169I  270-270 F32FD169         1         9 0
AL032 1 170I  271-271 F32FD170         1         9 0
AL032 1 171I  272-272 F32FD171         1         9 0
AL032 1 172I  273-273 F32FD172         1         9 0
AL032 1 173I  274-274 F32FD173         1         9 0
AL032 1 174I  275-275 F32FD174         1         9 0
```

```
AL032 1 175I  276-276 F32FD175         1         9 0
AL032 1 176I  277-277 F32FD176         1         9 0
AL032 1 177I  278-278 F32FD177         1         9 0
AL032 1 178I  279-279 F32FD178         1         9 0
AL032 1 179I  280-280 F32FD179         1         9 0
AL032 1 180I  281-281 F32FD180         1         9 0
AL032 1 181I  282-282 F32FD181         1         9 0
AL032 1 182I  283-283 F32FD182         1         9 0
AL032 1 183I  284-284 F32FD183         1         9 0
AL032 1 184I  285-285 F32FD184         1         9 0
AL032 1 185I  286-286 F32FD185         1         9 0
AL032 1 186I  287-287 F32FD186         1         9 0
AL032 1 187I  288-288 F32FD187         1         9 0
AL032 1 188I  289-289 F32FD188         1         9 0
AL032 1 189I  290-290 F32FD189         1         9 0
AL032 1 190I  291-291 F32FD190         1         9 0
AL032 1 191I  292-292 F32FD191         1         9 0
AL032 1 192ID 293-298 F32FD192         1         9 0
AL032 1 193A  299-299 F32FD193         1         9 0
AL032 1 194A  300-300 F32FD194         1         9 0
AL032 1 195I  301-301 F32FD195         1         9 0
AL032 1 196I  302-302 F32FD196         1         9 0
AL032 1 197I  303-310 F32FD197         0  99999999 0
```

AL040 - ALLHAT Supplemental Death Form

Version 1 – 06/02/06 (only version)

This form represents deaths validated with death certificates based on SSA or NDI sources. ICD codes for cause of death are predominately from NDI source records; NDI records without code or deaths identified solely through SSA were coded by a contract nosologist (with Medical Coding and Consultation Services, Inc.).

Two coding schemes are present in these records. The ICD coding scheme changed in 1999 from the International Classification of Diseases (ICD)– 9th revision to ICD–10th revision. ICD-9 E codes (injury/poisoning) and V (procedure) codes require 4th and 5th digits (i.e. should be four or five digits); ICD-10 codes are 3 digits only for mortality.

Modified Fields for LADS Master File:

Blanked:

F40019
F40020
F40021
F40022
F40023

Changed date (mmddyy) to days since randomization:

F40018
F40026

AL040 Version 1

F40008

ALLHAT Supplemental Death Form

1. **ID:** F40007 _ _ _ - _ _ _ - F40009 _ _ _
2. **Acrostic:** F40016 _ _ _ _ _ _
3. **Site:** F40015 _
4. **Date of Death (mm/dd/yyyy):** _ _ / _ _ / F40010 _ _ _ _
5. **Sequence:** F40014 _
6. **Date of Report of Death (Search Date)(mm/dd/yyyy):** _ _ / _ _ / F40018 _ _ _ _
7. **Source of death:** F40019 _ _ _ _
8. **Search Round:** F40020 _ _
9. **For future expansion (Coordinating Center use only):** F40021 _
10. **NDI Score (01-17):** F40022 _ _
11. **Death certificate number:** F40023 _ _ _ _ _ _ _
12. **Death certificate ICD (ICD9 or ICD10):** F40024 _ _ _ _ _ _
13. **Cause of death:** F40025 _ _

    01) Definite MI
    02) Definite CHD
    03) Possible CHD
    04) Stroke
    05) CHF
    06) Other cardiovascular disease
    07) Cancer
    08) Kidney Disease
    09) Accident, suicide, homicide
    10) Other non-cardiovascular disease
    11) Unknown cause

14. **Date of confirmation (mm/dd/yyyy):** _ _ / _ _ / F40026 _ _ _ _ **(mm/dd/yyyy)**
15. **How used in analysis:** F40027 _

    1) Used as death and cause of death
    2) Used for cause of death only
    3) Not used

16. **Available for Doxazosin Final Papers:** F40028 _

    Blank/0) No
    1) Yes

17. **Available for Antihypertensive Final Papers:** F40029 _

    Blank/0) No
    1) Yes

```
AL040 1 001I    1-  2 F40KPCOD         1        99 1
AL040 1 002IDR  3-  8 F40BTDAT         1    999999 1
AL040 1 003A    9- 10 F40VERF          1         9 0
AL040 1 004IDR 11- 16 F40DTMOD         1    999999 1
AL040 1 005I   17- 20 F40TMMOD         1      9999 1
AL040 1 006I   21- 21 F40MDFLG         1         9 2
AL040 1 007I   22- 24 F40TCN           1       662 1       Y$
AL040 1 008I   25- 27 F40PNO           1       700 1       Y$
AL040 1 009I   28- 30 F40RCN           1       662 1       Y$
AL040 1 010I   35- 42 F40DATE8         1  99999999 1       Y$
AL040 1 011I   34- 34 F40VERS          1         3 2       Y$
AL040 1 012I   35- 36 F40CENT         19        20 2       Y$
AL040 1 013IDR 37- 42 F40KEYDT         1    999999 1       Y$
AL040 1 014I   43- 43 F40SEQ           1         9 2       Y$
AL040 1 015A   44- 44 F40SITE          1         9 0       Y$
AL040 1 016A   45- 50 F40ACROS         1         9 0       Y$
AL040 1 017I   51- 52 F40EDIT          0         3 2       Y$
AL040 1 018ID  53- 60 F40SRCH          0  99999999 1
AL040 1 019A   61- 64 F40SORCE         1         9 0
AL040 1 020I   65- 66 F40ROUND         1        99 1
AL040 1 021A   67- 67 F40UK            1         9 0
AL040 1 022I   68- 69 F40NDISC         1        99 1
AL040 1 023A   70- 76 F40DCNUM         1   9999999 1
AL040 1 024A   77- 82 F40DCICD         1         9 0
AL040 1 025I   83- 84 F40CAUSE         1        99 1
AL040 1 026ID  85- 92 F40CNFDT         1  99999999 1
AL040 1 027I   93- 93 F40USE           1         9 2
AL040 1 028I   94- 94 F40DOXFP         1         9 2
AL040 1 029I   95- 95 F40ANTFP         1         9 2
```

AL041 - ALLHAT Supplemental Event Form

Version 1 – 06/02/06 (only version)

This form represents hospitalized events based on HCFA/CMS or VA sources (electronic record only).

Only ICD-9 CM (Clinical Modification) codes are used in these records.

Modified Fields for LADS Master File:
Blanked:
F41020

Changed date (mmddyy) to days since randomization:
F41018
F41019

Coding details:
F41043 – MI Verification Definition: 1=Confirmed MI, 2=Confirmed as Not MI, 3=Unknown

AL041 Version 1

F41008

F41007 F41009

ALLHAT Supplemental Event Form

1. ID: _ _ _ - _ _ - _ _ _
2. Acrostic: _ _ _ _ _ _ F41016
3. Site: _ F41015
4. Date of Admission (mm/dd/yyyy): _ _ / _ _ / _ _ _ _ F41010
5. Sequence: F41014
6. Date of Discharge (mm/dd/yyyy): _ _ / _ _ / _ _ _ _ F41018
7. Date of Report of Event (Search Date)(mm/dd/yyyy): _ _ / _ _ / _ _ _ _ F41019
8. Source of Report: _ _ _ _ F4102

HCFA) HCFA/CMS
VAE) VA Events
VAP) VA Procedures

9. Primary Code (ICD): _ _ _ _ _ _ F41021
10. Secondary Code 1 (ICD): _ _ _ _ _ _ F41022
11. Secondary Code 2 (ICD): _ _ _ _ _ _ F41023
12. Secondary Code 3 (ICD): _ _ _ _ _ _ F41024
13. Secondary Code 4 (ICD): _ _ _ _ _ _ F41025
14. Secondary Code 5 (ICD): _ _ _ _ _ _ F41026
15. Secondary Code 6 (ICD): _ _ _ _ _ _ F41027
16. Secondary Code 7 (ICD): _ _ _ _ _ _ F41028
17. Secondary Code 8 (ICD): _ _ _ _ _ _ F41029
18. Secondary Code 9 (ICD): _ _ _ _ _ _ F41030
19. Secondary Code 10 (ICD): _ _ _ _ _ _ F41031
20. Procedure Code 1 (ICD): _ _ _ _ _ F41032
21. Procedure Code 2 (ICD): _ _ _ _ _ F41033
22. Procedure Code 3 (ICD): _ _ _ _ _ F41034
23. Procedure Code 4 (ICD): _ _ _ _ _ F41035
24. Procedure Code 5 (ICD): _ _ _ _ _ F41036
25. Procedure Code 6 (ICD): _ _ _ _ _ F41037
26. Procedure Code 7 (ICD): _ _ _ _ _ F41038
27. Procedure Code 8 (ICD): _ _ _ _ _ F41039
28. Procedure Code 9 (ICD): _ _ _ _ _ F41040
29. Procedure Code 10 (ICD): _ _ _ _ _ F41041
30. MI selection: _ F41042

Blank/0) Not selected
1) Selected

31. MI verification: _ F41043

1) Confirmed MI
2) Confirmed no MI or not right person
3) Unconfirmed

32. DRG code: _ _ _ F41044
33. Available for Doxazosin Final Papers: _ F41045 Blank/0) No, 1) Yes
34. Available for Antihypertensive Final Papers: _ F41046 Blank/0) No, 1) Yes

```
AL041 1 001I    1-  2 F41KPCOD         1        99 1
AL041 1 002IDR  3-  8 F41BTDAT         1    999999 1
AL041 1 003A    9- 10 F41VERF          1         9 0
AL041 1 004IDR 11- 16 F41DTMOD         1    999999 1
AL041 1 005I   17- 20 F41TMMOD         1      9999 1
AL041 1 006I   21- 21 F41MDFLG         1         9 2
AL041 1 007I   22- 24 F41TCN           1       662 1       Y$
AL041 1 008I   25- 27 F41PNO           1       700 1       Y$
AL041 1 009I   28- 30 F41RCN           1       662 1       Y$
AL041 1 010I   35- 42 F41DATE8         1  99999999 1       Y$
AL041 1 011I   34- 34 F41VERS          1         3 2       Y$
AL041 1 012I   35- 36 F41CENT         19        20 2       Y$
AL041 1 013IDR 37- 42 F41KEYDT         1    999999 1       Y$
AL041 1 014I   43- 43 F41SEQ           1         9 2       Y$
AL041 1 015A   44- 44 F41SITE          1         9 0       Y$
AL041 1 016A   45- 50 F41ACROS         1         9 0       Y$
AL041 1 017I   51- 52 F41EDIT          0         3 2       Y$
AL041 1 018ID  53- 60 F41DISCH         0  99999999 1
AL041 1 019ID  61- 68 F41SRCH          0  99999999 1
AL041 1 020A   69- 72 F41SORCE         1         9 0
AL041 1 021A   73- 78 F41PRICD         1         9 0
AL041 1 022A   79- 84 F41ICD01         1         9 0
AL041 1 023A   85- 90 F41ICD02         1         9 0
AL041 1 024A   91- 96 F41ICD03         1         9 0
AL041 1 025A   97-102 F41ICD04         1         9 0
AL041 1 026A  103-108 F41ICD05         1         9 0
AL041 1 027A  109-114 F41ICD06         1         9 0
AL041 1 028A  115-120 F41ICD07         1         9 0
AL041 1 029A  121-126 F41ICD08         1         9 0
AL041 1 030A  127-132 F41ICD09         1         9 0
AL041 1 031A  133-138 F41ICD10         1         9 0
AL041 1 032A  139-143 F41PRC01         1         9 0
AL041 1 033A  144-148 F41PRC02         1         9 0
AL041 1 034A  149-153 F41PRC03         1         9 0
AL041 1 035A  154-158 F41PRC04         1         9 0
AL041 1 036A  159-163 F41PRC05         1         9 0
AL041 1 037A  164-168 F41PRC06         1         9 0
AL041 1 038A  169-173 F41PRC07         1         9 0
AL041 1 039A  174-178 F41PRC08         1         9 0
AL041 1 040A  179-183 F41PRC09         1         9 0
AL041 1 041A  184-188 F41PRC10         1         9 0
AL041 1 042I  189-189 F41MISEL         0         9 2
AL041 1 043I  190-190 F41MIVER         0         9 2
AL041 1 044A  191-193 F41DRGCD         1         9 0
AL041 1 045I  194-194 F41DOXFP         1         9 2
AL041 1 046I  195-195 F41ANTFP         1         9 2
```

AL080 - ALLHAT Antihypertensive Randomization Screen (Computer Record Only)

The AL001 is the hard-copy version of the information captured on this form during the Antihypertensive Randomization phone call. The AL080 was never modified, even if there were discrepancies between the AL001 and the AL080. The AL080 was used for obtaining baseline characteristics until the AL001 was received at the CTC, and then the AL001 took precedence in analyses. The AL001 was subject to editing for consistency and logic.

Version 1 – 02/94

Version 2 – 08/94

Version 3 – 04/98

Modified Fields for LADS Master File:

Blanked:
F80018
F80019
F80020
F80039 (may be blank)
F80048 (versions 1,2,3)
F80050 (versions 1,2,3)
F80051 (versions 1,2,3)

Changed date (mmddyy) to days since randomization:
F80029 (versions 1,2,3)
F80037 (versions 1,2,3)
F80038 (versions 1,2,3)
F80039 (if not blanked)

AL080 Version 1

ALLHAT Antihypertensive Randomization Screen

(item numbers used below correspond to the AL01, including the Eligibility Worksheet, Visit 1 and Visit 2)

1. Patient's full name: (18) _____ (12 characters) (First) _ (19) (MI) _____ (20) (14 characters) (Last)

(1) Entry Code (2) Batch Date (3) Verifier
(4) Mod Date (5) Mod Time (6) Mod Flag
(10) Form Num (11) Version (14) Sequence
(17) Edit Code

2b. ID #: (7) _ _ _ - (8) _ _ _ - (9) _ _ _
cen seq cen

c. Site code: (15) _ d. Acrostic: (16) _ _ _ _ _ _ a. Date randomized: _ _ - (13) _ _ - 1 9 _ _
mon day year (century, e.g. 19, = field (12))

Exclusion criteria for antihypertensive trial:

(1=yes,2=no)

4. Factors suggesting a low likelihood of compliance..... _ (21)
5. Any of items 5. through 12. answered "Yes"..... _ (22)

Eligibility criteria for antihypertensive trial:

(1=yes,2=No)

13. Old(>6 months) or age-indeterminate MI or stroke..... _ (23)
14. History of CABG, coronary angio. or other revascularization procedure _ (24)
15. Other documented atherosclerotic cardiovascular disease(ASCVD)..... _ (25)
16. Type II diabetes mellitus..... _ (26)
17. HDL-cholesterol < 35 mg/dl (twice within five years)..... _ (27)
18. Left ventricular hypertrophy(LVH) by ECG..... _ (28)

[Visit 1 Information]

19. Visit 1 date: _ _ - (29) _ _ - _ _
mon day year

20.b. Blood pressures... SBP / DBP
(30) _ _ _ / (31) _ _ _
(32) _ _ _ / (33) _ _ _
Average: (34) _ _ _ / (35) _ _ _

21. Antihypertensive med status: (36) _ (1=on 1-2 drugs 3+ years,
2=on 1-2 drugs 2+ months but < 3 years,
3=on drugs < 2 months,
4=currently untreated)

[Visit 2 Information]

24. Visit 2 date: _ _ - (37) _ _ - _ _
mon day year

25. Birthdate: _ _ - (38) _ _ - _ _ _ _
mon day year

Age: (39) _ _ _
(at Visit 2)

26.c. Blood pressures..... SBP / DBP
(40) _ _ _ / (41) _ _ _
(42) _ _ _ / (43) _ _ _
Average: (44) _ _ _ / (45) _ _ _

29. Consent for antihypertensive trial randomization signed? (46) _ (1=yes,2=no)

35.a. Race: (52) _ (1=White, 2=Black, 3=Amer Indian/Alaskan native, 4=Asian/Pacific Islander, 5=Other)

Coordinating Center operator code: (1) _ _

42. Initials of caller: (48) _ _ _

31. Antihypertensive drug bottle number: (47) _ _

(49) Randomization Group (1-4) (50) Active Site
(51) Active Acrostic

```
AL080 1 001I    1-  2 F80KPCD          1        99 1
AL080 1 002IDR  3-  8 F80BATDT         1    999999 1
AL080 1 003A    9- 10 F80VFCD          1         9 0
AL080 1 004IDR 11- 16 F80DTMOD         1    999999 1
AL080 1 005I   17- 20 F80TMMOD      0000      2359 1
AL080 1 006I   21- 21 F80TPMOD         0         9 2
AL080 1 007I   22- 24 F80TCN           1       662 2       Y$
AL080 1 008I   25- 27 F80PNO           1       700 1       Y$
AL080 1 009I   28- 30 F80RCN           1       662 2       Y$
AL080 1 010I   35- 42 F80DATE8         1  99999999 1       Y$
AL080 1 011I   34- 34 F80VS            1         9 2       Y$
AL080 1 012I   35- 36 F80CENT         19        20 2       Y$
AL080 1 013IDR 37- 42 F80KEYDT         1    999999 1       Y$
AL080 1 014I   43- 43 F80SEQ           1         9 2       Y$
AL080 1 015A   44- 44 F80SITE                     0       Y$
AL080 1 016A   45- 50 F80ACROS         0           0       Y$
AL080 1 017I   51- 52 F80EDIT         0         3 2       Y$
AL080 1 018A   53- 64 F80Q1FN                     0
AL080 1 019A   65- 65 F80Q1MI                     0
AL080 1 020A   66- 79 F80Q1LN                     0
AL080 1 021I   80- 80 F80FD021         1         2 2
AL080 1 022I   81- 81 F80FD022         0         1 2
AL080 1 023I   82- 82 F80FD023         1         2 2
AL080 1 024I   83- 83 F80FD024         1         2 2
AL080 1 025I   84- 84 F80FD025         1         2 2
AL080 1 026I   85- 85 F80FD026         1         2 2
AL080 1 027I   86- 86 F80FD027         1         2 2
AL080 1 028I   87- 87 F80FD028         1         2 2
AL080 1 029ID  88- 93 F80FD029         1    999999 1
AL080 1 030I   94- 96 F80FD030         2       300 1
AL080 1 031I   97- 99 F80FD031         2       200 1
AL080 1 032I  100-102 F80FD032         2       300 1
AL080 1 033I  103-105 F80FD033         2       200 1
AL080 1 034I  106-108 F80FD034         2       300 1
AL080 1 035I  109-111 F80FD035         2       200 1
AL080 1 036I  112-112 F80FD036         1         4 2
AL080 1 037ID 113-118 F80FD037         1    999999 1
AL080 1 038ID 119-126 F80FD038         1  99999999 1
AL080 1 039I  127-129 F80FD039         1       999 1
AL080 1 040I  130-132 F80FD040         2       300 1
AL080 1 041I  133-135 F80FD041         2       200 1
AL080 1 042I  136-138 F80FD042         2       300 1
AL080 1 043I  139-141 F80FD043         2       200 1
AL080 1 044I  142-144 F80FD044         2       300 1
AL080 1 045I  145-147 F80FD045         2       200 1
AL080 1 046I  148-148 F80FD046         1         2 2
AL080 1 052I  149-149 F80FD052         1         5 2
AL080 1 047I  150-151 F80FD047         1        99 1
AL080 1 048A  152-154 F80FD048                   0
AL080 1 049I  155-155 F80FD049         1         4 2
AL080 1 050A  156-156 F80FD050                   0
AL080 1 051A  157-162 F80FD051                   0
```

AL080 Version 2

ALLHAT Antihypertensive Randomization Screen

(item numbers used below correspond to the AL01 ver. 2, including the Eligibility Worksheet, Visit 1 and Visit 2)

Patient's full name: (18) (12 characters) (First) (19) _ (MI) (20) (14 characters) (Last)

(1) Entry Code (2) Batch Date (3) Verifier
(4) Mod Date (5) Mod Time (6) Mod Flag
(10) Form Num (11) Version (14) Sequence
(17) Edit Code

1a. ID #: (7) ___ - (8) ___ - (9) ___
cen seq cen

b. Site code: (15) _ c. Acrostic: (16) _____ d. Date randomized: __ - (13) __ - 19__
mon day year (century, e.g. 19, = field (12))

Exclusion criteria for antihypertensive trial:

(1=yes,2=no)

2. Factors suggesting a low likelihood of compliance..... _ (21)
3. Any of items 3. through 10. answered "Yes"..... _ (22)

Eligibility criteria for antihypertensive trial:

(1=yes,2=No)

11. Old(>6 months) or age-indeterminate MI or stroke..... _ (23)
12. History of CABG, coronary angio. or other revascularization procedure _ (24)
13. Major ST segment depression or T-wave inversion in past two years... _ (53)
14. Other documented atherosclerotic cardiovascular disease(ASCVD)..... _ (25)
15. Type II diabetes mellitus in past two years..... _ (26)
16. HDL-cholesterol < 35 mg/dl (twice within five years)..... _ (27)
17. Left ventricular hypertrophy(LVH) by ECG in past two years..... _ (28)
18. Combined wall thickness 25+ mm in the past two years..... _ (54)

[Visit 1 Information]

19. Visit 1 date: __ - (29) __ - __
mon day year

20.b. Blood pressures... SBP / DBP
(30) ___ / (31) ___
(32) ___ / (33) ___
Average: (34) ___ / (35) ___

21. Antihypertensive med status: (36) _ (1=on 1-2 drugs 2+ months,
2=on drugs < 2 months,
3=currently untreated)

[Visit 2 Information]

24. Visit 2 date: __ - (37) __ - __
mon day year

25. Birthdate: __ - (38) __ - ____
mon day year

Age: (39) ___
(at Visit 2)

26.c. Blood pressures..... SBP / DBP
(40) ___ / (41) ___
(42) ___ / (43) ___
Average: (44) ___ / (45) ___

29. Consent for antihypertensive trial randomization signed? (46) _ (1=yes,2=no)

34.a. Race: (52) _ (1=White, 2=Black, 3=Amer Indian/Alaskan native, 4=Asian/Pacific Islander, 5=Other)

Coordinating Center operator code: (1) __

48. Initials of caller: (48) ___

31. Antihypertensive drug bottle number: (47) __

(49) Randomization Group (1-4) (50) Active Site
(51) Active Acrostic

```
AL080 2 001I    1-  2 F80KPCD          1        99 1
AL080 2 002IDR  3-  8 F80BATDT         1    999999 1
AL080 2 003A    9- 10 F80VFCD          1         9 0
AL080 2 004IDR 11- 16 F80DTMOD         1    999999 1
AL080 2 005I   17- 20 F80TMMOD      0000      2359 1
AL080 2 006I   21- 21 F80TPMOD         0         9 2
AL080 2 007I   22- 24 F80TCN           1       662 1       Y$
AL080 2 008I   25- 27 F80PNO           1       700 1       Y$
AL080 2 009I   28- 30 F80RCN           1       662 1       Y$
AL080 2 010I   35- 42 F80DATE8         1  99999999 1       Y$
AL080 2 011I   34- 34 F80VS            1         3 2       Y$
AL080 2 012I   35- 36 F80CENT         19        20 2       Y$
AL080 2 013IDR 37- 42 F80KEYDT         1    999999 1       Y$
AL080 2 014I   43- 43 F80SEQ           1         9 2       Y$
AL080 2 015A   44- 44 F80SITE                     0       Y$
AL080 2 016A   45- 50 F80ACROS                    0       Y$
AL080 2 017I   51- 52 F80EDIT          0         3 2       Y$
AL080 2 018A   53- 64 F80Q1FN                     0
AL080 2 019A   65- 65 F80Q1MI                     0
AL080 2 020A   66- 79 F80Q1LN                     0
AL080 2 021I   80- 80 F80FD021         1         2 2
AL080 2 022I   81- 81 F80FD022         1         2 2
AL080 2 023I   82- 82 F80FD023         1         2 2
AL080 2 024I   83- 83 F80FD024         1         2 2
AL080 2 025I   84- 84 F80FD025         1         2 2
AL080 2 026I   85- 85 F80FD026         1         2 2
AL080 2 027I   86- 86 F80FD027         1         2 2
AL080 2 028I   87- 87 F80FD028         1         2 2
AL080 2 029ID  88- 93 F80FD029         1    999999 1
AL080 2 030I   94- 96 F80FD030         2       300 1
AL080 2 031I   97- 99 F80FD031         2       200 1
AL080 2 032I  100-102 F80FD032         2       300 1
AL080 2 033I  103-105 F80FD033         2       200 1
AL080 2 034I  106-108 F80FD034         2       300 1
AL080 2 035I  109-111 F80FD035         2       200 1
AL080 2 036I  112-112 F80FD036         1         3 2
AL080 2 037ID 113-118 F80FD037         1    999999 1
AL080 2 038ID 119-126 F80FD038         1  99999999 1
AL080 2 039I  127-129 F80FD039         1       999 1
AL080 2 040I  130-132 F80FD040         2       300 1
AL080 2 041I  133-135 F80FD041         2       200 1
AL080 2 042I  136-138 F80FD042         2       300 1
AL080 2 043I  139-141 F80FD043         2       200 1
AL080 2 044I  142-144 F80FD044         2       300 1
AL080 2 045I  145-147 F80FD045         2       200 1
AL080 2 046I  148-148 F80FD046         1         2 2
AL080 2 052I  149-149 F80FD052         1         5 2
AL080 2 047I  150-151 F80FD047         1        99 1
AL080 2 048A  152-154 F80FD048                    0
AL080 2 049I  155-155 F80FD049         1         4 2
AL080 2 050A  156-156 F80FD050                    0
AL080 2 051A  157-162 F80FD051                    0
AL080 2 053I  163-163 F80FD053         1         2 2
AL080 2 054I  164-164 F80FD054         1         2 2
```

```
AL080 1 051A  157-162 F80FD051                    0
AL080 2 001I    1-  2 F80KPCD          1        99 1
AL080 2 002IDR  3-  8 F80BATDT         1    999999 1
AL080 2 003A    9- 10 F80VFCD          1         9 0
AL080 2 004IDR 11- 16 F80DTMOD         1    999999 1
AL080 2 005I   17- 20 F80TMMOD      0000      2359 1
AL080 2 006I   21- 21 F80TPMOD         0         9 2
AL080 2 007I   22- 24 F80TCN           1       662 1       Y$
AL080 2 008I   25- 27 F80PNO           1       700 1       Y$
AL080 2 009I   28- 30 F80RCN           1       662 1       Y$
AL080 2 010I   35- 42 F80DATE8         1  99999999 1       Y$
AL080 2 011I   34- 34 F80VS            1         3 2       Y$
AL080 2 012I   35- 36 F80CENT         19        20 2       Y$
AL080 2 013IDR 37- 42 F80KEYDT         1    999999 1       Y$
AL080 2 014I   43- 43 F80SEQ           1         9 2       Y$
AL080 2 015A   44- 44 F80SITE                    0       Y$
AL080 2 016A   45- 50 F80ACROS                   0       Y$
AL080 2 017I   51- 52 F80EDIT          0         3 2       Y$
AL080 2 018A   53- 64 F80Q1FN                    0
AL080 2 019A   65- 65 F80Q1MI                    0
AL080 2 020A   66- 79 F80Q1LN                    0
AL080 2 021I   80- 80 F80FD021         1         2 2
AL080 2 022I   81- 81 F80FD022         1         2 2
AL080 2 023I   82- 82 F80FD023         1         2 2
AL080 2 024I   83- 83 F80FD024         1         2 2
AL080 2 025I   84- 84 F80FD025         1         2 2
AL080 2 026I   85- 85 F80FD026         1         2 2
AL080 2 027I   86- 86 F80FD027         1         2 2
AL080 2 028I   87- 87 F80FD028         1         2 2
AL080 2 029ID  88- 93 F80FD029         1    999999 1
AL080 2 030I   94- 96 F80FD030         2       300 1
AL080 2 031I   97- 99 F80FD031         2       200 1
AL080 2 032I  100-102 F80FD032         2       300 1
AL080 2 033I  103-105 F80FD033         2       200 1
AL080 2 034I  106-108 F80FD034         2       300 1
AL080 2 035I  109-111 F80FD035         2       200 1
AL080 2 036I  112-112 F80FD036         1         3 2
AL080 2 037ID 113-118 F80FD037         1    999999 1
AL080 2 038ID 119-126 F80FD038         1  99999999 1
AL080 2 039I  127-129 F80FD039         1       999 1
AL080 2 040I  130-132 F80FD040         2       300 1
AL080 2 041I  133-135 F80FD041         2       200 1
AL080 2 042I  136-138 F80FD042         2       300 1
AL080 2 043I  139-141 F80FD043         2       200 1
AL080 2 044I  142-144 F80FD044         2       300 1
AL080 2 045I  145-147 F80FD045         2       200 1
AL080 2 046I  148-148 F80FD046         1         2 2
AL080 2 052I  149-149 F80FD052         1         5 2
AL080 2 047I  150-151 F80FD047         1        99 1
AL080 2 048A  152-154 F80FD048                   0
AL080 2 049I  155-155 F80FD049         1         4 2
AL080 2 050A  156-156 F80FD050                   0
AL080 2 051A  157-162 F80FD051                   0
AL080 2 053I  163-163 F80FD053         1         2 2
AL080 2 054I  164-164 F80FD054         1         2 2
```

AL080 Version 3

AS Form:AL80V3 SHOWMODE: Your in DISPLAY Mode Page 1 of 1

ALLHAT ANTIHYPERTENSIVE RANDOMIZATION RECORD

DE:_ REC:_ VF__ ID: ___ ___ ___ Form: 080 Ver 3 F: __
MOD:_____ ____ F:2 RZ Date: 02-07-1996 Seq: 1 Site: A
MO-DY-YR Acrostic: _____

Name.....First [##########] MI [#] Last [##########]

[Chart Review/Local Determination]
2.Factors suggest low compliance...[2]
Any medical items 3 through 11...[2]
[Eligibility criteria]
12.MI,stroke...[2] 18.LVH.....[2]
13.CABG,etc....[2] 19.Wall thickness[2]
14.ST or T-wave[2] 20.Cig. smoker...[2]
15.Other ASCVD.[2]
16.Diabetes....[1]
17.HDL<35mg/dl.[2]
[Visit 1 Information]
21.Visit date.....[__ __ __]
22.b.Blood Pressures.....[155]/[075]
[160]/[075]
Average[157]/[075]
2? Antihypertensive med status.....[1]

[Visit 2 Information]
26.Visit date.....[__ __ __]
27.Birthdate [11/07/1929] Age...[066]
28.c.Blood Pressures.....[160]/[070]
[140]/[065]
Average[150]/[067]
31.Consent signed.....[1]
36.a.Race.....[2]
[Randomization]
33.Drug bottle number.....[36]
51.Initials of caller.....[___]
Above item numbers refer to AL01,
related via phone Randomization.
Coordinating Center Use Only
RZ group[3]
Active Site[A] Active Acrostic[_____]

```
AL080 3 001I    1-  2 F80KPCD          1        99 1
AL080 3 002IDR  3-  8 F80BATDT         1    999999 1
AL080 3 003A    9- 10 F80VFCD          1         9 0
AL080 3 004IDR 11- 16 F80DTMOD         1    999999 1
AL080 3 005I   17- 20 F80TMMOD      0000      2359 1
AL080 3 006I   21- 21 F80TPMOD         0         9 2
AL080 3 007I   22- 24 F80TCN           1       662 1       Y$
AL080 3 008I   25- 27 F80PNO           1       700 1       Y$
AL080 3 009I   28- 30 F80RCN           1       662 1       Y$
AL080 3 010I   35- 42 F80DATE8         1  99999999 1       Y$
AL080 3 011I   34- 34 F80VS            1         3 2       Y$
AL080 3 012I   35- 36 F80CENT         19        20 2       Y$
AL080 3 013IDR 37- 42 F80KEYDT         1    999999 1       Y$
AL080 3 014I   43- 43 F80SEQ           1         9 2       Y$
AL080 3 015A   44- 44 F80SITE                     0       Y$
AL080 3 016A   45- 50 F80ACROS                    0       Y$
AL080 3 017I   51- 52 F80EDIT          0         3 2       Y$
AL080 3 018A   53- 64 F80Q1FN                     0
AL080 3 019A   65- 65 F80Q1MI                     0
AL080 3 020A   66- 79 F80Q1LN                     0
AL080 3 021I   80- 80 F80FD021         1         2 2
AL080 3 022I   81- 81 F80FD022         1         2 2
AL080 3 023I   82- 82 F80FD023         1         2 2
AL080 3 024I   83- 83 F80FD024         1         2 2
AL080 3 025I   84- 84 F80FD025         1         2 2
AL080 3 026I   85- 85 F80FD026         1         2 2
AL080 3 027I   86- 86 F80FD027         1         2 2
AL080 3 028I   87- 87 F80FD028         1         2 2
AL080 3 029ID  88- 93 F80FD029         1    999999 1
AL080 3 030I   94- 96 F80FD030         2       300 1
AL080 3 031I   97- 99 F80FD031         2       200 1
AL080 3 032I  100-102 F80FD032         2       300 1
AL080 3 033I  103-105 F80FD033         2       200 1
AL080 3 034I  106-108 F80FD034         2       300 1
AL080 3 035I  109-111 F80FD035         2       200 1
AL080 3 036I  112-112 F80FD036         1         3 2
AL080 3 037ID 113-118 F80FD037         1    999999 1
AL080 3 038ID 119-126 F80FD038         1  99999999 1
AL080 3 039I  127-129 F80FD039         1       999 1
AL080 3 040I  130-132 F80FD040         2       300 1
AL080 3 041I  133-135 F80FD041         2       200 1
AL080 3 042I  136-138 F80FD042         2       300 1
AL080 3 043I  139-141 F80FD043         2       200 1
AL080 3 044I  142-144 F80FD044         2       300 1
AL080 3 045I  145-147 F80FD045         2       200 1
AL080 3 046I  148-148 F80FD046         1         2 2
AL080 3 052I  149-149 F80FD052         1         5 2
AL080 3 047I  150-151 F80FD047         1        99 1
AL080 3 048A  152-154 F80FD048                    0
AL080 3 049I  155-155 F80FD049         1         4 2
AL080 3 050A  156-156 F80FD050                    0
AL080 3 051A  157-162 F80FD051                    0
AL080 3 053I  163-163 F80FD053         1         2 2
AL080 3 054I  164-164 F80FD054         1         2 2
AL080 3 055I  165-165 F80FD055         1         2 2
```

AL081 - ALLHAT Lipid-lowering Randomization Screen (Computer Record Only)

The AL002 is the hard-copy version of the information captured on this form during the Lipid-Lowering Randomization phone call.

Version 1 – 02/94

Version 2 – 08/94

Version 3 – 04/98
Unique fields to version 3: F81031, F81032.

Fields unique to version 2 and version 3: F81029.

Modified Fields for LADS Master File:
Blanked:
F81026 (versions 1,2,3)
F81030 (versions 1,2,3)

Changed date (mmddyy) to days since randomization:
F81032 (version 3)

AL081 Version 1

ALLHAT LIPID-LOWERING RANDOMIZATION RECORD

DE:__ REC:_____ VF:__
MOD:_____ ____ F:5

ID: ____ ____ Form: 081 Ver 1 F: __
RZ Date: __ __ ____ Seq: 1 Site: A
MO-DY-YR Acrostic: _____

3. Does patient have evidence of CHD? [2] (18)

Exclusion criteria for lipid-lowering trial

4. Current use of lipid-lowering agents, niacin, probucol.....[2] (19)
5. Contraindications to HMG CoA reductase inhibitors.....[2] (20)
6. Known untreated secondary cause of hypercholesterolemia....[2] (21)

Central laboratory results from Visit 2

7. LDL cholesterol at Visit 2 (from central lab).....[0132] (22)
8. Triglycerides at Visit 2 (from central lab).....[0066] (23)
9. ALT value from central lab confirmed as rwice upper limit? [2] (24)

10. Lipid-lowering trial informed consent signed? [1] (025)
12. Initials of caller.....[___] (26)

11. RZ group assignment:[1] 1=Pravastatin, 2=Usual Care (027)

(28)
Sample:[1] 1=include 2=exclude

Lipid RZ cen:[002]

Above item numbers refer to AL02, related via phone randomization.

```
AL081 1 001I    1-  2 F81KPCOD         1        99 1
AL081 1 002IDR  3-  8 F81BATDT         1    999999 1
AL081 1 003A    9- 10 F81VFCOD         1        99 0
AL081 1 004IDR 11- 16 F81DTMOD         1    999999 1
AL081 1 005I   17- 20 F81TMMOD      0000      2359 1
AL081 1 006I   21- 21 F81TPMOD         0         9 2
AL081 1 007I   22- 24 F81TCN           1       662 2       Y$
AL081 1 008I   25- 27 F81PNO           1       700 1       Y$
AL081 1 009I   28- 30 F81RCN           1       662 2       Y$
AL081 1 010I   35- 42 F81DATE8         1  99999999 1       Y$
AL081 1 011I   34- 34 F81VS            1         9 2       Y$
AL081 1 012I   35- 36 F81CENT         19        20 2       Y$
AL081 1 013IDR 37- 42 F81KEYDT         1    999999 1       Y$
AL081 1 014I   43- 43 F81SEQ           1         9 2       Y$
AL081 1 015A   44- 44 F81SITE                     0       Y$
AL081 1 016A   45- 50 F81ACROS                    0       Y$
AL081 1 017I   51- 52 F81EDIT          0         3 2       Y$
AL081 1 018I   53- 53 F81FD018         1         2 2
AL081 1 019I   54- 54 F81FD019         1         2 2
AL081 1 020I   55- 55 F81FD020         1         2 2
AL081 1 021I   56- 56 F81FD021         1         2 2
AL081 1 022I   57- 60 F81FD022         1       999 1
AL081 1 023I   61- 64 F81FD023         1       999 1
AL081 1 024I   65- 65 F81FD024         1         2 2
AL081 1 025I   66- 66 F81FD025         1         2 2
AL081 1 026A   67- 69 F81FD026                   0
AL081 1 027I   70- 70 F81FD027         1         2 2
AL081 1 028I   71- 71 F81FD028         1         2 2
AL081 1 030I   76- 78 F81FD030         1       750 2
```

AL081 Version 2

JF AS Form:AL81V2 SHOWMODE: Your in DISPLAY Mode Page 1 of 1

ALLHAT LIPID-LOWERING RANDOMIZATION RECORD

ID: ___ Form: 081 Ver 2 EF: __

!DE:__ REC . . VF __!RZ Date: __ __ ____ Seq: 1 Site: A

!MOD:[ ] ____ F:5 ! MO-DY-YR Acrostic: ____

10 Does patient have evidence of CHD? [1]

Exclusion criteria for lipid-lowering trial

11. Current use of lipid-lowering agents, niacin, probucol.....[2]
12. Contraindications to HMG CoA reductase inhibitors.....[2]
13. Known untreated secondary cause of hypercholesterolemia....[2]

Above item numbers refer to AL01, ver.2, related via phone Randomization

Central laboratory results from Visit 2

2. LDL cholesterol at Visit 2 (from central lab).....[0137]
3. Triglycerides at Visit 2 (from central lab).....[0078]
4. Confirmed ALT value (from central lab).....[0066]

ALT value from central lab confirmed as twice upper limit? [2]

5. Lipid-lowering trial informed consent signed? [1]
7. Initials of caller.....[ ]

!Sample:[2] 1=include!
! 2=exclude!

6. RZ group assignment:[2] 1=Pravastatin, 2=Usual Care

Above item numbers refer to AL02, ver.2, related via phone Randomization

```
AL081 2 001I    1-  2 F81KPCOD         1        99 1
AL081 2 002IDR  3-  8 F81BATDT         1    999999 1
AL081 2 003A    9- 10 F81VFCOD         1        99 0
AL081 2 004IDR 11- 16 F81DTMOD         1    999999 1
AL081 2 005I   17- 20 F81TMMOD      0000      2359 1
AL081 2 006I   21- 21 F81TPMOD         0         9 2
AL081 2 007I   22- 24 F81TCN           1       662 2       Y$
AL081 2 008I   25- 27 F81PNO           1       700 1       Y$
AL081 2 009I   28- 30 F81RCN           1       662 2       Y$
AL081 2 010I   35- 42 F81DATE8         1  99999999 1       Y$
AL081 2 011I   34- 34 F81VS            1         9 2       Y$
AL081 2 012I   35- 36 F81CENT         19        20 2       Y$
AL081 2 013IDR 37- 42 F81KEYDT         1    999999 1       Y$
AL081 2 014I   43- 43 F81SEQ           1         9 2       Y$
AL081 2 015A   44- 44 F81SITE                     0       Y$
AL081 2 016A   45- 50 F81ACROS                    0       Y$
AL081 2 017I   51- 52 F81EDIT          0         3 2       Y$
AL081 2 018I   53- 53 F81FD018         1         2 2
AL081 2 019I   54- 54 F81FD019         1         2 2
AL081 2 020I   55- 55 F81FD020         1         2 2
AL081 2 021I   56- 56 F81FD021         1         2 2
AL081 2 022I   57- 60 F81FD022         1       999 1
AL081 2 023I   61- 64 F81FD023         1       999 1
AL081 2 024I   65- 65 F81FD024         1         2 2
AL081 2 025I   66- 66 F81FD025         1         2 2
AL081 2 026A   67- 69 F81FD026                   0
AL081 2 027I   70- 70 F81FD027         1         2 2
AL081 2 028I   71- 71 F81FD028         1         2 2
AL081 2 029I   72- 75 F81FD029         1       999 1
AL081 2 030I   76- 78 F81FD030         1       750 2
```

AL081 Version 3

ALLHAT Lipid-lowering Randomization Record

ID : (7) ___ - (8) ___ - (9) ___ Site Code: (15) __

Acrostic: (16) ___ ___ ___ ___ ___ ___

Date of Lipid Randomization: (13) ___ ___ ___ ___ ___ ___ (mm – dd – yy)

Century: (12) ___ ___ (19 or 20)

Entry Code (1) Batch Date (2) Verifier (3)

Mod Date (4) Mod Time (5) Mod Flag (6)

Version (11) Sequence (14) Edit Code (17)

Lipid RZ Date(yyyymmdd) (10)

Does patient have evidence of CHD? [_] (1=yes, 2=no) (18)

Exclusion criteria for lipid-lowering trial

Current use of lipid-lowering agents, niacin, probucol.....[_] (1=yes, 2=no) (19)

Contraindications to HMG CoA reductase inhibitors.....[_] (1=yes, 2=no) (20)

Known untreated secondary cause of hypercholesterolemia....[_] (1=yes, 2=no) (21)

Central laboratory results from Visit 2

LDL cholesterol at Visit 2 (from central lab).....[___ ___ ___ ___] (22)

Triglycerides at Visit 2 (from central lab).....[___ ___ ___ ___] (23)

Confirmed ALT value (from central lab).....[___ ___ ___ ___] (29) ***not on ver. 1***

ALT value from central lab confirmed as twice upper limit?.....[_] (1=yes, 2=no) (24)

Blood Redrawn? [_] (1=yes, 2=no) (31) Date redrawn: [___ ___ ___ ___ ___ ___ ___ ___] (32) (mmddyyyy)

redraw information not on ver. 1 or ver. 2

Lipid-lowering trial informed consent signed? [_] (25)

Initials of caller.....[___ ___ ___] (26)

Sample:[_] 1=include 2=exclude (28)

RZ group assignment:[_] 1=Pravastatin 2=Usual Care (27)

Lipid RZ center:[___ ___ ___] (30)

J[redacted].S Form:AL81V3 SHOWMODE: Your in DISPLAY Mode

ALLHAT LIPID-LOWERING RANDOMIZATION RECORD

ID: ___ - _____ Form: 081 Ver 3 EF: __

DE: __ REC _____ VF: __ RZ Date: __-__ _____ Seq: 1 Site: A

MOD: [redacted] F:5 MO-DY-YR Acrostic:

40. Does patient have evidence of CHD? [2] 8/0/8 Blood Redrawn? [_]
Exclusion criteria for lipid-lowering trial Date:[_____]
41. Current use of lipid-lowering agents, niacin, probucol.....[2]
42. Contraindications to HMG CoA reductase inhibitors.....[2]
43. Known untreated secondary cause of hypercholesterolemia....[2]
Above item numbers refer to AL01, ver.2, related via phone Randomization

Central laboratory results from Visit 2
2. LDL cholesterol at Visit 2 (from central lab).....[0130]
3. Triglycerides at Visit 2 (from central lab).....[0071]
4. Confirmed ALT value (from central lab).....[0021]
ALT value from central lab confirmed as twice upper limit? [2]

5. Lipid-lowering trial informed consent signed? [1]
7. Initials of caller..... _

Sample:[2] 1=include 2=exclude

6. RZ group assignment:[2] 1=Pravastatin, 2=Usual Care 8/027 Lipid RZ cen:[001]
Above item numbers refer to AL02, ver.2, related via phone randomization

```
AL081 3 001I    1-  2 F81KPCOD         1        99 1
AL081 3 002IDR  3-  8 F81BATDT         1    999999 1
AL081 3 003A    9- 10 F81VFCOD         1        99 0
AL081 3 004IDR 11- 16 F81DTMOD         1    999999 1
AL081 3 005I   17- 20 F81TMMOD      0000      2359 1
AL081 3 006I   21- 21 F81TPMOD         0         9 2
AL081 3 007I   22- 24 F81TCN           1       662 2       Y$
AL081 3 008I   25- 27 F81PNO           1       700 1       Y$
AL081 3 009I   28- 30 F81RCN           1       662 2       Y$
AL081 3 010I   35- 42 F81DATE8         1  99999999 1       Y$
AL081 3 011I   34- 34 F81VS            1         9 2       Y$
AL081 3 012I   35- 36 F81CENT         19        20 2       Y$
AL081 3 013IDR 37- 42 F81KEYDT         1    999999 1       Y$
AL081 3 014I   43- 43 F81SEQ           1         9 2       Y$
AL081 3 015A   44- 44 F81SITE                     0       Y$
AL081 3 016A   45- 50 F81ACROS                    0       Y$
AL081 3 017I   51- 52 F81EDIT          0         3 2       Y$
AL081 3 018I   53- 53 F81FD018         1         2 2
AL081 3 019I   54- 54 F81FD019         1         2 2
AL081 3 020I   55- 55 F81FD020         1         2 2
AL081 3 021I   56- 56 F81FD021         1         2 2
AL081 3 022I   57- 60 F81FD022         1       999 1
AL081 3 023I   61- 64 F81FD023         1       999 1
AL081 3 024I   65- 65 F81FD024         1         2 2
AL081 3 025I   66- 66 F81FD025         1         2 2
AL081 3 026A   67- 69 F81FD026                   0
AL081 3 027I   70- 70 F81FD027         1         2 2
AL081 3 028I   71- 71 F81FD028         1         2 2
AL081 3 029I   72- 75 F81FD029         1       999 1
AL081 3 030I   76- 78 F81FD030         1       750 2
AL081 3 031I   79- 79 F81FD031         0         2 2
AL081 3 032I   80- 87 F81FD032         0  12311999 1
```

AL084 - ALLHAT ECG Inventory Log Form

Inventory log completed at the CTC.

Version 1 – 02/99 (only version)

Modified Fields for LADS Master File:
Blanked:
F84019 (version 1)

Coding details:
ECG Type - F84018 has valid values of 0, 2, 4 and 6; all other values (1, 3, 5, 8 and 9) are invalid.

Date mailed to ECG Center - F84019 is coded as "99999999" for missing/invalid values.

AL084 Version 1

ALLHAT ECG Inventory Log Form

ID: ___ - ___ - ___ Acrostic: _____ (16)

ECG Recording Dt: __ - __ (13) - ____ Seq: _ (14) Site: _ (15)
MO DY YR

1. ECG Type (0=BL; 2=2YR; 4=4YR; 6=6YR): _ (18)

2. Date mailed to ECG Center: _____ (19)
YYYYMMDD

```
AL084 1 001I    1-  2 F84KPCOD         1        99 1
AL084 1 002IDR  3-  8 F84BATDT         1    999999 1
AL084 1 003A    9- 10 F84VFCOD         1        99 0
AL084 1 004IDR 11- 16 F84DTMOD         1    999999 1
AL084 1 005I   17- 20 F84TMMOD      0000      2359 1
AL084 1 006I   21- 21 F84TPMOD         0         9 2
AL084 1 007I   22- 24 F84TCN           1       662 2       Y$
AL084 1 008I   25- 27 F84PNO           1       700 1       Y$
AL084 1 009I   28- 30 F84RCN           1       662 2       Y$
AL084 1 010I   35- 42 F84DATE8         1  99999999 1       Y$
AL084 1 011I   34- 34 F84VS            1         9 2       Y$
AL084 1 012I   35- 36 F84CENT         19        20 2       Y$
AL084 1 013IDR 37- 42 F84KEYDT         1    999999 1       Y$
AL084 1 014I   43- 43 F84SEQ           1         9 2       Y$
AL084 1 015A   44- 44 F84SITE                     0       Y$
AL084 1 016A   45- 50 F84ACROS                    0       Y$
AL084 1 017I   51- 52 F84EDIT          0         3 2       Y$
AL084 1 018I   53- 53 F84VSTCD         1         8 2
AL084 1 019I   54- 61 F84SHIPD         1  99999999 1
```

Antihypertensive Summary File – Appendix 1

Results

For all tables and figures, RZGROUP is used for treatment assignment. With upper and lower range-recoding, slight variations will now exist between the final manuscript and the current file.

Patient Characteristics

Table 1	SAS Variable	Comment
Age	AGE	Same variable used to calculate dichotomous age variable
Ethnicity	RACE by HISPANIC	
Gender	SEX	
Education	EDUCAT	
Receiving antihypertensive treatment	BLMEDS2	
Blood pressure	BV2SBP, BV2DBP	
Smoking	CURSMOKE	
Atherosclerotic CVD		Union of following 4 variables: MISTROKE, HXCABG, STDEPR, OASCVD
History of MI or stroke	MISTROKE	
History of coronary revascularization	HXCABG	
Other atherosclerotic CVD	OASCVD	
Major ST depression or T wave inversion	STDEPR	
Type 2 Diabetes	DIABETES	
HDL-C<35	HDLLT35	
LVH by electrocardiogram	LVHECG	
LVH by echocardiogram	WALL25	
History of CHD	LCHD	
BMI	BLBMI	
Aspirin use	ASPIRIN	
Estrogen use	ESTROGEN	
Lipid RZ group	LLT	

Antihypertensive Summary File – Appendix 1 (continued)

Visit and Medication Adherence

Figure 1	SAS Variable	Comment
Year 1		
Completed visit	VFNDY1	
Discontinued study drug	ONST1Y1	
Year 5		
Completed visit	VFNDY5	
Discontinued study Drug	ONST1Y5	
•unspecified refusal	REFUSEY5	
•symptomatic adverse event	SYMPAEY5	
•blood pressure elevation	BPHIY5	
•blood pressure too low	BPLOWY5	
•morbid event	MORBIDY5	
•other adverse effects	OTHAEY5	
•other nonmedical reasons	NONMEDY5	
•other	OTHRSY5	
Status at closeout	VITSTAT2, VITSTAT for computation of deaths pending confirmation	Deaths pending confirmation: VITSTAT2 confirmed deaths – VITSTAT confirmed deaths

Antihypertensive Summary File – Appendix 1 (continued)

Table 2	SAS Variable	Comment
Expected visits	VEXPY**n** (**n** =1 through 5)	
Completed visits	VFNDY**n** (**n** =1 through 5)	
Receiving blinded study drug	ONST1Y**n** (**n** =1 through 5)	
Receiving blinded study drug or same class	ONST1Y**n,** SAMCLY**n** (**n** =1 through 5)	union of both variables
Full and partial crossovers	CROSSY**n** (**n** =1 through 5)	
Receiving step 2 or 3	ONS23Y**n** (**n** =1 through 5)	
Other antihypertensive medication	ONOHYY**n** (**n** =1 through 5)	Subset of ONOHYY**n** excluding ONST1Y**n,** SAMCLY**n,** CROSSY**n** (if not a crossover)
No. of antihypertensive medications	NHYPRY**n** (**n** =1 through 5)	

Additional data in text for 'Visit and Medication Adherence': ONACEY**n,** ONCCBY**n**, ONDIUY**n** (**n**=1-5) to obtain numbers assigned to one class taking a different class.

Intermediate Outcomes

Table 3	SAS Variable	Comment
SBP		
Baseline	BV2SBP	
Years 1-5	SBP6M**n** (**n** = 12, 24, 36, 48, 60)	
DBP		
Baseline	BV2DBP	
Years 1-5	DBP6M**n** (**n** = 12, 24, 36, 48, 60)	
Achieved BP Goal		Calculated from SBP and DBP variables (above)
SBP Change		Calculated from SBP variables (above)
DBP Change		Calculated from DBP variables (above)

Figure 2 uses data from above table plus SBP6M72, DBP6M72.

Antihypertensive Summary File – Appendix 1 (continued)

Table 4	**SAS Variable**	**Comment**
Cholesterol		
Baseline	ACHOL	
Years 2, 4	CHOLM**n** (**n** = 24, 48)	
Cholesterol ≥240 mg/dL		Subset of cholesterol variables above
Potassium		
Baseline	APOTAS	
Years 2, 4	POTASM**n** (**n** = 24, 48)	
Potassium <3.5 mEq/L		Subset of potassium variables above
Fasting Glucose		
Baseline	AFGLUC	
Years 2, 4	FGLUCM**n** (**n** = 24, 48)	
Fasting glucose≥ 126 mg/dL		Subset of fasting glucose variables above
Fasting glucose among non-diabetics		Subset of fasting glucose using DIABETES
Fasting glucose among non-diabetics ≥ 126 mg/dL		Subset of nondiabetic fasting glucose subset above
Estimated Glomerular Filtration Rate		
Baseline	BLGFR	
Years 2, 4	GFRM**n** (**n** = 24, 48)	

Antihypertensive Summary File – Appendix 1 (continued)

Primary and Secondary Outcomes

Table 5	SAS Variable (event flag, days to event)	Comment
Primary outcome		
CHD	EP_CHD, DYCHD	
Secondary outcomes		Union of seven following categories
All-cause mortality	DEATH, DYDEATH	
Combined CHD	CCHD, DYCCHD	
Stroke	STROKE, DYSTROKE	
Combined CVD	CCVD, DYCCVD	
End-stage renal disease	REND, DYREND	
Cancer	CANCER, DYCANC	
Hospitalized for GI bleed	GIBLEED, DYGIBLD	
Components of secondary Outcomes		
Heart failure	CHF, DYCHF	
Hospitalized/fatal heart failure	OCHF, DYOCHF	
Angina (hospitalized or treated)	ANG, DYANG	
Angina (hospitalized)	HANG, DYHANG	
Coronary revascularizations	CRVSC, DYCRVSC	
Peripheral arterial disease (hospitalized or treated)	LEXT, DYLEXT	

Figures 3 and 4 use the same outcome variables as Table 5.

Figures 5 and 6 use the same outcome variables as Table 5 subset by variables from Table 1.

Table 6 uses DEATH and DYDEATH subset by DTHCAUSE.

Primary Safety Outcomes

Data provided in text only for angioedema uses ANGIOED.

Lipid-Lowering Summary File – Appendix 2

Results

For all tables and figures, LRZGRP is used for treatment assignment. With upper and lower range-recoding, slight variations will now exist between the final manuscript and the current file.

Baseline Characteristics

Table 1	SAS Variable	Comment
Age	AGE	Same variable used to calculate dichotomous age variable
Gender	SEX	
Ethnicity	RACE by HISPANIC	
Education	EDUCAT	
Estrogen use	ESTROGEN	
Aspirin use	ASPIRIN	
Receiving antihypertensive treatment	BLMEDS2	
Smoking	CURSMOKE	
History of CHD	LCHD	
Type 2 Diabetes	DIABETES	
BMI	BLBMI	Same variable used to calculate dichotomous BMI variable
Blood pressure	BV1SBP, BV1DBP	
Fasting glucose	CFGLUC	
Lipid Values (with and without CHD at baseline)		Following lipid variables subset by LCHD
Serum cholesterol	CCHOL	
LDL cholesterol	CLDL	Same variable used to calculate dichotomous LDL variable
HDL cholesterol	CHDL	
Fasting triglycerides	CFTRIG	
Antihypertensive randomization	RZGROUP	

Visit and Medication Adherence

Figure 1	SAS Variable	Comment
Status at closeout	VITSTAT2, VITSTAT for computation of deaths pending confirmation	Deaths pending confirmation: VITSTAT2 confirmed deaths – VITSTAT confirmed deaths

Lipid-Lowering Summary File – Appendix 2 (continued)

Table 2	SAS Variable	Comment
Pravastatin		
Expected visits	VEXPY**n** (**n** =2, 4, 6)	
Actual visits	VFNDY**n** (**n** =2, 4, 6)	
Receiving study drug	ONPRAY**n** (**n**=2, 4, 6)	
Not receiving study drug	OFFPRAY**n** (**n**=2, 4, 6)	
Usual Care		
Expected visits	VEXPY**n** (**n** =2, 4, 6)	
Actual visits	VFNDY**n** (**n** =2, 4, 6)	
Receiving medication	OFFPRAY**n** (**n**=2, 4, 6)	

Data provided in text for ALT elevation uses ALT150. Data provided in text for preceding CHD event use LLMDAYS (if <9999 was started on a lipid-lowering drug), LDYNFMI and LNFMI (the preceding CHD event type), and LCHD.

Lipid Levels

Table 3	SAS Variable	Comment
Cholesterol		
Baseline	CCHOL	
Years 2, 4, 6	CHOLY**n** (**n**=2, 4, 6)	
LDL cholesterol		
Baseline	CLDL	
Years 2, 4, 6	LDLY**n** (**n**=2, 4, 6)	
HDL Cholesterol		
Baseline	CHDL	
Years 2, 4, 6	HDLY**n** (**n**=2, 4, 6)	
Fasting triglyceride		
Baseline	CFTRIG	
Years 2, 4	FTRIGY**n** (**n**=2, 4, 6)	

Figure 2 uses same variables as Table 3.

Lipid-Lowering Summary File – Appendix 2 (continued)

Clinical Outcomes

Table 4	SAS Variable (event flag, days to event)	Comment
All-cause mortality	LDEATH, LDYDEATH	
CVD deaths	DTHCAUSE, LDEATH, LDYDEATH	
CHD	"	
Stroke	"	
Other CVD	"	
Non-CVD deaths	"	
Cancer	"	
Other medical	"	
Unintentional injury/suicide /homicide	"	
Cause unknown	"	
Fatal CHD and nonfatal MI	LEP_CHD, LDYCHD	
Stroke (fatal and nonfatal)	LSTROKE, LDYSTROK	
Heart failure (hospitalized Or fatal)	LOCHF, LDYOCHF	
Cancer	LCANCER, LDYCANC	

Figures 3 and 4 use the same outcome variables as Table 4; Figure 4 outcomes subset by variables from Table 1.

Doxazosin Final Summary File – Appendix 3

Results

For all tables and figures, RZGROUP is used for treatment assignment. With upper and lower range-recoding, slight variations will now exist between the final manuscript and the current file.

Participant Characteristics

Figure 1	SAS Variable	Comment
As of Feb. 15, 2000	VITSTAT	

Table 1	SAS Variable	Comment
Age	AGE	Same variable used to calculate four-category age variable
Ethnicity	RACE by HISPANIC	
Gender	SEX	
Education	EDUCAT	
Smoking	CURSMOKE	
Receiving antihypertensive treatment	BLMEDS2	
Atherosclerotic CVD		Union of following 3 variables: MISTROKE, HXCABG, OASCVD
Major ST depression or T wave inversion	STDEPR	
Type 2 Diabetes	DIABETES	
HDL-C<35	HDLLT35	
LVH by electrocardiogram	LVHECG	
LVH by echocardiogram	WALL25	
Blood pressure	BV2SBP, BV2DBP	
Serum potassium	APOTAS	
Fasting serum glucose	AFGLUC	
Serum creatinine	ACREAT	
Total cholesterol	ACHOL	
LDL-cholesterol	ALDL	
HDL-cholesterol	AHDL	
Fasting triglycerides	AFTRIG	

Medication Adherence and Course in Treatment

Text only. Variables used are: VFNDY4, NHYPRY4, ONST1Y4, REFUSEY5, BPHIY5, BPLOWY5, MORBIDY5, NONMEDY5, OTHAEY5, OTHRSY5, SYMPAEY5.

Intermediate Outcomes

Table 2	**SAS Variable**	**Comment**
SBP		
baseline	BV2SBP	
years 1-4	SBP6M**n** (**n** = 12, 24, 36, 48)	
DBP		
baseline	BV2DBP	
years 1-4	DBP6M**n** (**n** = 12, 24, 36, 48)	
%<140/90		calculated from SBP and DBP variables (above)
SBP/DBP change		calculated from SBP and DBP variables (above)

Other variables discussed in text are: year 4 cholesterol (CHOLM48), participation in the lipid-lowering trial (LLT), year 4 potassium (POTASM48), year 4 glucose (FGLUCM48), year 4 creatinine (CREATM48), creatinine elevations (MXFUPCR compared to ACREAT), baseline and years two and four (HLTHBL, HLTHY2, HLTHY4), and baseline and year four continuous health status (VQOLBL, VQOLY4).

Primary and Secondary Endpoints

table 3

Table 3	SAS Variable (event flag, days to event)	Comment
Primary outcome		
CHD	EP_CHD, DYCHD	
All-cause mortality	DEATH, DYDEATH	
Cardiovascular	DTHCAUSE, DYDEATH	DTHCAUSE=1-6
Myocardial infarction	"	DTHCAUSE=1
Definite CHD	"	DTHCAUSE=2
Possible CHD	"	DTHCAUSE=3
Stroke	"	DTHCAUSE=4
CHF	"	DTHCAUSE=5
Other cardiovascular	"	DTHCAUSE=6
Non-cardiovascular	"	DTHCAUSE=7-10
Cancer	"	DTHCAUSE=7
Kidney disease	"	DTHCAUSE=8
Accident/suicide/homicide	"	DTHCAUSE=9
Other non-cardiovascular	"	DTHCAUSE=10
Unknown	"	DTHCAUSE=11
Combined CHD	CCHD, DYCCHD	
Stroke	STROKE, DYSTROKE	
Combined CVD	CCVD, DYCCVD	
CHF (fatal, hospitalized, treated)	CHF, DYCHF	
CHF (fatal, hospitalized)	OCHF, DYOCHF	
Coronary revascularizations	CRVSC, DYCRVSC	
Angina (hospitalized or treated)	ANG, DYANG	
Peripheral arterial disease (hospitalized or treated)	LEXT, DYLEXT	
Cancer	CANCER, DYCANC	
End-stage renal disease	REND, DYREND	

Figure 2 uses the same outcome variables as Table 3.

Figures 3 uses the same outcome variables as Table 3 subset by variables from Table 1, with the addition of CHD at baseline (ACHD).