For Coor. Center Use Only

B-Prop	M	D	Y

Form 008 (1) 1, 2, 3

BASELINE INTERVIEW AND EXAMINATION

Do not start this form until all eligibility criteria have been checked and Holter Monitoring is completed. Send this form only for randomized patients. Send this form the Coordination Center no later than 8th day after randomization.

(6) EDIT STATUS 19,20 (7) BATCH NUMBER 21-28

1. Patient ID (2) 4, 5 (3) 6, 7, 8, 9, 10 (4) 11, 12

2. Acrostic 13, 14, 15, 16, 17, 18 (5)

3. Date of Interview (11) 44, 45 (month) 46, 47 (day) 48, 49 (year)

(8) DATE RECEIVED 29-34
(9) UPDATE NUMBER 35-37
(10) DATE LAST PROCESSED 38-43

Use blood pressure and heart rate recorded on Determination of Eligibility form to complete the following.

4. Average of 3 blood pressure readings on BH06 (12) 50, 51, 52 (systolic) / (13) 53, 54, 55 (diastolic)

5. Average of 3 heart rate readings on BH06 56, 57, 58 (beats / minute) (14)

To be completed by BHAT personnel from hospital records:

6. Did any of the following occur during this hospitalization prior to randomization:

		1 YES	2 NO	3 DK
a. Cardiogenic shock (oliguria and systolic BP < 90 mm Hg)?	(15)	☐	☐ 59	☐
b. Persistent hypotension (systolic < 90 mm Hg for one hour or more)?	(16)	☐	☐ 60	☐
c. Incomplete A-V block?	(17)	☐	☐ 61	☐
d. Complete A-V block?	(18)	☐	☐ 62	☐
e. Ventricular tachycardia (3 or more successive VPB's)?	(19)	☐	☐ 63	☐
f. Ventricular fibrillation?	(20)	☐	☐ 64	☐
g. Pulmonary edema?	(21)	☐	☐ 65	☐
h. Atrial fibrillation or flutter?	(22)	☐	☐ 66	☐
i. Signs and symptoms of C.H.F. (new or recurrent) requiring therapy with digitalis or diuretics?	(23)	☐	☐ 67	☐
j. Use of propranolol or other beta-blockers?	(24)	☐	☐ 68	☐
k. Use of nitroglycerine or long-acting coronary vasodilators?	(25)	☐	☐ 69	☐
l. Use of other antiarrhythmics?	(26)	☐	☐ 70	☐
m. Use of nitroprusside?	(27)	☐	☐ 71	☐

BASELINE INTERVIEW

PRIOR HISTORY OF CHEST PAIN

Interviewer should say to patient: "We are interested in learning about troubles you may have had with your heart in the past year. For these questions I would like you to think back to the time from ________ to ________ which includes the time from one year ago up to one month before this hospitalization." (interviewer inserts dates)

7. a. During this time period did you have any pain or discomfort in your chest?
(28) 1 ☐ Yes 72   2 ☐ No

b. Did you have any pressure or heaviness in your chest?
(29) 1 ☐ Yes 73   2 ☐ No → SKIP to 19

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If patient said "yes" to pressure or heaviness, use appropriate term instead of pain or discomfort for the following questions.

8. Did you get this pain or discomfort when you walked uphill or hurried?
(30) 1 ☐Yes 2 ☐No → SKIP to 19 3 ☐Never walks uphill or hurries
74

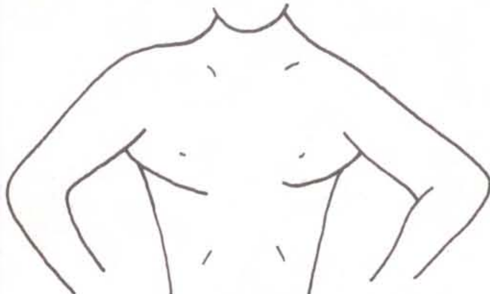
9. Did you get this pain or discomfort when you walked at an ordinary pace on level ground?
(31) 1 ☐Yes 2 ☐No 3 ☐Uncertain
75 **If the answer to question 8 is 3 and the answer to question 9 is 2 SKIP to 19.**

10. What did you do if you got this pain or discomfort while you were walking?
(32) 1 ☐Took nitroglycerine 2 ☐Stopped or slowed down, did not take nitroglygerine
76 3 ☐ **Continued at same pace, did not take nitroglycerine → SKIP to 19.**

11. If you stood still, what happended to the pain or discomfort?
(33) 1 ☐Relieved 2 ☐Not relieved → SKIP to 19
77

12. How soon was the pain or discomfort relieved?
(34) 1 ☐10 minutes or less 2 ☐More than 10 minutes → SKIP to 19
78

13. Will you show me where the pain or discomfort was?



		1 YES		2 NO		3 DK
a. Sternum (middle or upper)	(35)	☐		☐	79	☐
b. Sternum (lower)		☐	(36)	☐	80	☐
c. Left anterior chest	(37)	☐		☐	81	☐
d. Left arm		☐	(38)	☐	82	☐
e. Jaw	(39)	☐		☐	83	☐
f. Other; specify 85 (41) 8 0/1		☐	(40)	☐	84	☐

14. How many days per week did you usually have this pain or discomfort?
(42) 1 ☐Every day 2 ☐One or more days per week but not daily 3 ☐Does not occur every week
86

15. On the days that you had this pain or discomfort, how many times per day did you usually have it? .... (43) [87 | 88] number

16. When you had this pain or discomfort, how long did it usually last?
(44) 1 ☐One minute or less 2 ☐More than one minute up to 5 minutes 3 ☐More than 5 minutes
89

17. Did this pain or discomfort ever occur:

		1 YES		2 NO		3 DK
a. At rest?	(45)	☐		☐	90	☐
b. After meals?		☐	(46)	☐	91	☐

18. In the month prior to this hospitalization, would you say these symptoms:
(47) 1 ☐Increased 2 ☐Decreased 3 ☐Stayed the same
92

OTHER PRIOR HISTORY

19. a. Prior to the start of your present illness, did a doctor ever tell you that you had a heart attack or coronary (myocardial infarction, coronary thrombosis or coronary occlusion)?
(48) 1 ☐Yes 93 2 ☐No → SKIP to 20
↓
b. In what year were you first told by your doctor that you had a heart attack? .... (49) [94 | 95] year

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c. For how many of these attacks were you hospitalized? (Include only attacks which your doctor called "heart attack" or "coronary, myocardial infarction, coronary thrombosis, or coronary occlusion.") .... (50) [96 | 97] number of hospitalizations

20. a. Prior to this hospitalization, have you ever had shortness of breath which your doctor said was due to heart trouble?

(51) 1 ☐Yes 98 2 ☐No → SKIP to 21

b. Were you treated with:

		1 YES	2 NO	3 DK
(1) Digitalis?	(52)	☐	☐ 99	☐
(2) Diuretics (water pills)?	(53)	☐	☐ 100	☐

21. a. Prior to this hospitalization, were you ever told by a doctor that you had high blood pressure or hypertension?

(54) 1 ☐Yes 101 2 ☐No → SKIP to 22

b. Were you treated with:

		1 YES	2 NO	3 DK
(1) Diuretics (water pills)?	(55)	☐	☐ 102	☐
(2) Other antihypertensives?	(56)	☐	☐ 103	☐

22. Prior to this hospitalization, did you ever get pain in either leg while walking?

(57) 1 ☐Yes 104 2 ☐No → SKIP to 30

23. Did that pain ever begin when you were standing still or sitting?

(58) 1 ☐Yes 105 2 ☐No
↓ SKIP to 30

24. In what part of your leg did you feel the pain?

If calves not mentioned, ask, "Anywhere else?" If calves still not mentioned, indicate "Pain did not include calf."

(59) 1 ☐Pain includes calf/calves 106 2 ☐Pain did not include calf → SKIP to 30

25. Did you get this pain when you walked uphill or hurried?

(60) 1 ☐Yes 107 2 ☐No 3 ☐Never walks uphill or hurries
↓ SKIP to 30 (from No)

26. Did the pain ever disappear while you were walking?

(61) 1 ☐Yes 108 2 ☐No
↓ SKIP to 30

27. What did you do if you got this pain while you were walking?

(62) 1 ☐Stopped or slackened pace 109 2 ☐Continued at same pace → SKIP to 30

28. What happened to the pain if you stood still?

(63) 1 ☐Relieved 110 2 ☐Not relieved → SKIP to 30

29. How soon was the pain relieved?

(64) 1 ☐10 minutes 111 2 ☐More than 10 minutes

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"Now I would like to ask you about some medical conditions. They are routine questions that we ask everyone."

30. Prior to this hospitalization have you ever been told by a doctor that you had:

		1 YES		2 NO		3 DK
a. diabetes (high sugar in blood or urine)?	65	☐		☐	112	☐
b. cirrhosis or other liver disease?		☐	66	☐	113	☐
c. bronchial asthma or emphysema?	67	☐		☐	114	☐
d. stroke?		☐	68	☐	115	☐
e. valvular heart disease (damage to the valves inside the heart)?	69	☐		☐	116	☐
f. cancer?		☐	70	☐	117	☐

31. Just prior to this hospitalization, were you taking:

		1 YES		2 NO		3 DK
a. Inderal (propranolol)?	71	☐		☐	118	☐
b. Other beta-blockers? INTERVIEWER: See M.O.P. for list		☐	72	☐	119	☐

32. Within the past 3 months, but prior to this hospitalization, have you experienced any of the following:

		1 YES		2 NO		3 DK
a. Faintness or light-headedness when you stood up quickly?	73	☐		☐	120	☐
b. Problem with heart beating fast or skipping beats?		☐	74	☐	121	☐
c. Blacking out or losing consciousness?	75	☐		☐	122	☐
d. Frequent depression that interferred with work, recreation or sleep?		☐	76	☐	123	☐
e. Unusual tiredness or fatigue during ordinary activities?	77	☐		☐	124	☐
f. Frequent nightmares or vivid dreams?		☐	78	☐	125	☐
g. Hallucinations?	79	☐		☐	126	☐
h. Blurred vision?		☐	80	☐	127	☐
i. Recurrent insomnia or problems with waking up too early?	81	☐		☐	128	☐
j. Recurrent nausea and vomiting?		☐	82	☐	129	☐
k. Recurrent abdominal pain or cramping?	83	☐		☐	130	☐
l. Recurrent diarrhea?		☐	84	☐	131	☐
m. Recurrent constipation?	85	☐		☐	132	☐
n. Recurrent bronchospasm (wheezing in the chest)?		☐	86	☐	133	☐
o. Recurrent muscle cramps?	7	☐		☐	134	☐
p. Dryness of eyes?		☐	88	☐	135	☐
q. Problems with hands or feet being extremely cold?	89	☐		☐	136	☐
r. Problems with burning, prickling, or tingling in hands?		☐	90	☐	137	☐
s. Problems with flushing?	91	☐		☐	138	☐
t. Problems with dry mouth?		☐	92	☐	139	☐
u. Sudden loss of hair?	93	☐		☐	140	☐
v. Rash?		☐	94	☐	141	☐
w. Decrease in sexual activity?	95	☐		☐	142	☐

LIFE STYLE IN THE YEAR PRIOR TO THIS HOSPITALIZATION

33. a. Are you currently employed or were you employed just prior to this hospitalization?

Students, housewives, self-employed persons are considered employed. Check one box only.

96
143

(1) Yes, full-time ≥ 35 hours . . . . . 1 ☐
(2) Yes, part-time < 35 hours . . . . . 2 ☐
(3) No, retired . . . . . 3 ☐
(4) No, temporarily unemployed . . . . . 4 ☐
(5) No . . . . . 5 ☐

b. Is this for medical reasons?

144 (97) 1 ☐Yes   2 ☐No

c. Explain: 145 (98) 8 0/1

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BH08/4

For questions 34 and 35 use the following as a guide to code patient's activity level:

1. ***Almost none**: The sedentary person spends most waking hours in activities such as working at a desk, reading, watching television, or other quiet pursuits.*
2. ***Light physical activity**: This person walks about one mile a day, leisurely rides a bicycle, fishes, bowls, golfs, or engages in light carpentry, light gardening, light industrial work, teaching, or light housework.*
3. ***Moderate physical activity**: This person participates in recreational tennis, swimming, or jogging; or works in occupations such as mail carrier, telephone repair, light building and construction; or engages in full housework and home repairs.*
4. ***Heavy physical activity**: This person does the equivalent of active training in sports such as soccer, handball, ice hockey, or basketball; or engages in very heavy activities such as ditch digging, carrying heavy weights, very heavy farm work, mining, or working as a lumberjack.*

If the patient is not working, SKIP to question 35.

34. Thinking about the things you usually did at work (or housework) in the year prior to this hospitalization, how would you describe the kind of physical activity you got?

(99) 146 1 ☐ Almost none 2 ☐ Light physical activity 3 ☐ Moderate physical activity 4 ☐ Heavy physical activity

35. Now, thinking about the things you did other than work (or housework) in the year prior to this hospitalization, how would you describe the kind of physical activity you got?

(100) 147 1 ☐ Almost none 2 ☐ Light physical activity 3 ☐ Moderate physical activity 4 ☐ Heavy physical activity

36. Prior to this hospitalization, were you forced to change to a less strenuous life style with reduced physical activity because of your health?

(101) 148 1 ☐ Yes 2 ☐ No

37. Have you ever smoked cigarettes? 149 (102) 1 ☐ Yes 2 ☐ No → *SKIP to 42*

38. Approximately how many years have you smoked cigarettes? *If <1 year, code 01* .... (103) [150 | 151] years

39. During those years, on an average, how many cigarettes did you smoke per day?

(104) 152 2 ☐ Less than a half pack 3 ☐ Half pack to less than a pack 4 ☐ Pack to less than 1½ packs 5 ☐ 1½ packs to less than 2 packs 6 ☐ 2 or more packs

40. Just prior to this hospitalization, did you still smoke cigarettes?

(105) 153 1 ☐ Yes → *SKIP to 42* 2 ☐ No

41. How long ago did you stop smoking cigarettes?

(106) 154 1 ☐ Less than 6 months ago 2 ☐ 6 months to less than 12 months ago 3 ☐ 12 months to less than 5 years ago 4 ☐ 5 or more years ago

42. In the year prior to this hospitalization did you usually smoke either of the following:

155 a. pipe? .... 1 ☐ Yes (107) 2 ☐ No
156 b. cigars? .... 1 ☐ Yes (108) 2 ☐ No

43. In the year prior to this hospitalization, on the average, how many days per week did you usually have a drink of beer, wine or liquor? .... (109) [157] days

Code 0 if less than 1 day per week

If unknown, code 9

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BH08/5

FAMILY HISTORY

44. a. Is your mother alive? ...... (110) 1 ☐Yes 2 ☐No 3 ☐DK 158

b. Age of mother at death ...... (111) [159 | 160 | 161] years

CODE 999 if unknown

c. Cause of death: 162 (112) 1 ☐Heart attack 2 ☐Stroke 3 ☐Other 4 ☐Unknown

45. a. Is your father alive? .... (113) 1 ☐Yes 2 ☐No 3 ☐DK 163

b. Age of father at death .... (114) [164 | 165 | 166] years

CODE 999 if unknown

c. Cause of death: 167 (115) 1 ☐Heart attack 2 ☐Stroke 3 ☐Other 4 ☐Unknown

EDUCATION

46. What is the highest grade or year of school that you completed?

(116) 168
1 ☐Less than 7 years 2 ☐7-9 years 3 ☐10-11 years 4 ☐High school graduate
5 ☐Some college, but no degree 6 ☐College graduate 7 ☐Degree beyond college graduation 8 ☐Don't know

MARITAL STATUS

47. What is your current marital status?

(117) 169
1 ☐Never married 2 ☐Married 3 ☐Widowed 4 ☐Separated 5 ☐Divorced

48. Person conducting interview ______________________ (118) [170 | 171] BHAT code

COMMENTS:

Patient ID [ ] [ ] [ ] Acrostic [ ]

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BH08/6

BASELINE PHYSICAL EXAMINATION

*This examination **must** be completed by a BHAT physician*

49. Date examination completed (119) [172 | 173] month [174 | 175] day [176 | 177] year

50. Height: [178 | 179] inches (120)
If unknown, code 99

51. Weight: [180 | 181 | 182] pounds (121)
If unknown, code 999

		1 YES	2 NO
52. Rash	(122)	☐	☐ 183
53. Expiratory wheezes	(123)	☐ *	☐ 184
54. Abnormal neck venous distension present (above the clavical when the patient is at a 45 degree angle)	(124)	☐ **	☐ 185
55. Basilar rales	(125)	☐ **	☐ 186
56. S3 gallop	(126)	☐ **	☐ 187
57. Other findings related to the heart; specify 189 (128) 8 0/1 ______	(127)	☐	☐ 188
58. Hepatomegaly	(129)	☐ **	☐ 190
59. Peripheral edema	(130)	☐ **	☐ 191

60. Examination of pulses:

For the questions below:
N = Normal *D = Diminished* *A = Absent* *L = Limb missing*

			1 N	2 D	3 A	4 L
a. Right carotid	192	(131)	☐	☐	☐	
b. Left carotid	193	(132)	☐	☐	☐	
c. **Right femoral**	194	(133)	☐	☐	☐	☐
d. **Left femoral**	195	(134)	☐	☐	☐	☐
e. Right dorsal pedis	196	(135)	☐	☐	☐	☐
f. Left dorsal pedis	197	(136)	☐	☐	☐	☐
g. **Right posterior tibial**	198	(137)	☐	☐	☐	☐
h. **Left posterior tibial**	199	(138)	☐	☐	☐	☐

61. a. Hemiplegia 200 (139) 1 ☐ Right 2 ☐ Left 3 ☐ Both 4 ☐ None
b. Gross hemiparesis 201 (140) 1 ☐ Right 2 ☐ Left 3 ☐ Both 4 ☐ None

62. In your opinion, has the patient ever experienced:

		1 YES	2 NO	3 DK
a. angina pectoris?	(141)	☐ 202	☐	☐
b. congestive heart failure?	(142)	☐ 203	☐	☐
c. intermittent claudication?	(143)	☐ 204	☐	☐

* *Consider exclusion criteria for asthma*
** *Consider exclusion criteria for CHF*

Patient ID [|] [| | | |] [|] Acrostic [| | | | |]

Item 63 to be completed by the physician. Record information on all drugs currently being taken by the patient as of the date of this baseline interview with the exception of BHAT medication. Information regarding BHAT medication is recorded by the coordinator on Baseline Drug Section.

63. Is the patient taking any of the following categories of drugs:

	1 YES	2 NO	3 DK
a. antiarrhythmics? (144)	☐	☐ 205	☐
b. anticoagulants? (145)	☐	☐ 206	☐
c. antihypertensives excluding diuretics? (146)	☐	☐ 207	☐
d. aspirin prescribed on a continuing basis? (147)	☐	☐ 208	☐
e. digitalis? (148)	☐	☐ 209	☐
f. dipyridamole? (149)	☐	☐ 210	☐
g. diuretics? (150)	☐	☐ 211	☐
h. insulin? (151)	☐	☐ 212	☐
i. lipid-lowering agents? (152)	☐	☐ 213	☐
j. long-acting coronary vasodilators? (153)	☐	☐ 214	☐
k. oral hypoglycemics? (154)	☐	☐ 215	☐
l. sulfinpyrazone? (155)	☐	☐ 216	☐
m. other cardiovascular preparations not previously mentioned? (156)	☐	☐ 217	☐

PHYSICIAN'S COMMENTS (other physical findings, specific drugs of importance, etc.)

218 (157) ? 0/1

64. Physician Completing Examination 219 (158) ? 0/1 (159) [220|221] BHAT code

PROCEDURES COMPLETED *NOTE: a "no response indicates either blood was not drawn, or blood was drawn but lost.

A. Evaluated Centrally

	1 YES	2 NO	3 N/A
1. Holter Monitoring completed and sent to Coordinating Center 222 (160)	☐	☐	
2. ECG completed and sent to Coordinating Center 223 (161)	☐	☐	
*3. Blood drawn at baseline (10 ml) for determination of potassium, cholesteral, SGOT and creatinine, serum (4.5 ml) sent to Central Lab 224 (162)	☐	☐	
*4. Blood drawn (10 ml) for lipid ancillary study 225 (163)	☐	☐	☐

*5. Blood (6 ml) for propranolol determination drawn and serum sent (2.5 ml) to Central Lab 226 (164) 1 ☐Yes, drawn in hospital 2 ☐Yes, drawn at home 3 ☐No → SKIP to B.

a. Time from last BHAT medication to time blood was drawn for propranolol determination (165) [227|228] hours [229|230] minutes

If time more than 24 hrs., code 8888.

Code 9999 if unknown

	1 YES	2 NO
b. Was the patient on 40 mg every 8 hours for at least 48 hours before the blood was drawn? (166)	☐	☐ 231
*c. Was the blood drawn on Day 7 (from randomization) or earlier? (167)	☐	☐ 232

B. Evaluated at Clinical Center:

	1 YES	2 NO
1. X-ray completed (168)	☐	☐ 233
*2. Blood drawn for hematocrit and WBC determinations (169)	☐	☐ 234
3. Urinalysis completed (170)	☐	☐ 235

For any items checked "no," explain: 236 (171) ? 0/1

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Revised 8-9-82

Drug Codes:

01 Inderal
02 Betaloc
03 Blocadrin
04 Lopressor
77 BHAT medication

Entry Codes:

01 Drug started
02 Prescription changed
03 Drug stopped
04 No prescription change

Reason Codes for Prescription (Dose Change) and Sign or Symptoms Codes:

001 Faintness or light-headedness when patient stood up quickly
002 Problem with heart beating fast or skipping beats
003 Blacking out or losing consciousness
004 Frequent depression that interferred with work, recreation, or sleep
005 Unusual tiredness or fatigue during ordinary activities
006 Frequent nightmares or vivid dreams
007 Hallucinations
008 Blurred vision
009 Recurrent insomnia or problems with waking up too early
010 Recurrent nausea and vomiting
011 Recurrent abdominal pain or cramping
012 Recurrent diarrhea
013 Recurrent constipation
014 Recurrent bronchospasm (wheezing in the chest)
015 Recurrent muscle cramps
016 Disorientation to time and space
017 Frequent or severe intermittent claudication
018 Bronchial asthma or chronic lung disease requiring therapy
019 "Brittle" insulin-dependent diabetes mellitus
020 Wolff-Parkinson-White syndrome
021 Mobitz type II or complete A-V block
022 On MAO-inhibitors or amphetamines
023 Congestive heart failure
024 Cardiogenic shock
025 Valvular heart disease
026 Significant angina pectoris
027 Has undergone cardiac surgery
028 Has permanent pacemaker
029 Chest wall trauma
030 Has life-threatening illness other than CHD
031 Scheduled for or very likely to undergo cardiac surgery
032 Adherence to the study protocol has proved to be especially difficult
033 Unable (physically or psychologically) to cooperate with study
034 Hypertension
035 Hypotension
036 Stroke
037 Undergoing procedure likely to lead to unblinding
038 Scheduled for surgery (other than cardiovascular)
039 Dryness of eyes
040 Private physician requested medication change
041 Sign/symptom decreased in severity or disappeared
042 First degree heart block or Mobitz I
043 Significant sinus bradycardia
044 Death
* 071 Patient refused some or all medication
* 072 Hospital personnel forgot to administer
* 073 Physician withheld some or all of medication
* 074 Left hospital before receiving total prescribed dose
* 075 Not all prescribed medication was available to be given to the patient
* 076 Order written incorrectly
077 Hospital personnel gave too much medication
088 Following protocol

If other codes are needed, check manual of procedures or call the Coordinating Center

**Reasons exact prescription was not received in hospital*