

1. Program Number: 34 5.6.7.8.9 10.11

1

006813 2

2. Name: (PRINT IN BLOCK CAPITALS) 12.13.14.15.16.17. BATCH NO. 18.19.20.21.22.23.24.25

(Mr., Miss, Mrs.) Last First Middle

3. Date: 3 Month 26.27 Day 28.29 Year 30.31 (-2)

4. Time arrived: 4 Hour 32.33 : 5 Minute 34.35 6 a.m. 12.01 p.m. 59.00 36

5. Changes required in identifying information: 7 None 37 HP11A attached

COMPLETE THE SECTION BELOW AT TERMINATION OF VISIT BEFORE PARTICIPANT LEAVES

6. Are special procedures indicated as of this visit?

	Yes	No
Special Tests	<input type="checkbox"/>	<input type="checkbox"/>
Notification of Non-Fatal Event	<input type="checkbox"/>	<input type="checkbox"/>
Toxic Reaction Report	<input type="checkbox"/>	<input type="checkbox"/>

7. Review of completed HPO5:

- Every item on each page is complete and legible.
- Name and Program Number are correct.
- HPO5A, Consent Form for Hypertension Treatment Program, is fully executed and entered in Clinic Record.
- HPO5B, Release of Medical Information, signed and entered in Clinic Record.
- HPO5C, Flow Sheet for Blood Pressure, Weight and Medications initiated.
- Antihypertensive medication was received (or none prescribed).
- Exit Interview completed by Health Counselor.
- Appointment slip given:

Clinic Revisit schedule is:

- Step-Up Schedule (2 weeks)
- Maintenance Schedule A (4 weeks)
- Individualized Therapy (specify interval: _____)

(-2) 8 Date of next visit: 38.39 Month 40.41 Day 42.43 Year 44.45 Hour 46.47 Minute 10.11 a.m. 67 31 38 67 58 48

8. Time visit completed: 12 Hour 49.50 : 13 Minute 51.52 14 a.m. 12.01 p.m. 59.00 53

15 54.55 99 0

This section completed by: _____

9. Blood Pressure Measurements:

a. Pulse: Beats in 30 seconds 16 x 2 = 56 57 58 beats/minute. $\frac{200}{30}$

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I will be taking six blood pressure readings, four of them while you are seated and two of them just after you stand up.

b. Blood pressure readings:

		Systolic	Diastolic (5th phase)	
Reading 1 (Std)	$\frac{300}{60}$	(17) 59, 60, 61	(18) 62, 63, 64	$\frac{200}{0}$
Reading 2 (R-Z)	$\frac{301}{60}$	(19) 65, 66, 67	(20) 68, 69, 70	$\frac{299}{0}$
Zero	$\frac{99}{0}$	(21) 71, 72	(22) 73, 74	$\frac{99}{0}$
Corrected	$\frac{300}{60}$	(23) 75, 76, 77	(24) 78, 79, 80	$\frac{200}{0}$ →
Reading 3 (Std)	$\frac{300}{60}$	(25) 81, 82, 83	(26) 84, 85, 86	$\frac{200}{0}$
Reading 4 (R-Z)	$\frac{301}{60}$	(27) 87, 88, 89	(28) 90, 91, 92	$\frac{299}{0}$
Zero	$\frac{99}{0}$	(29) 93, 94	(30) 95, 96	$\frac{99}{0}$
Corrected	$\frac{300}{60}$	(31) 97, 98, 99	(32) 100, 101, 102	$\frac{200}{0}$ →
			(33) 103, 104, 105	SUM $\frac{400}{0}$
Average of Readings 2 and 4		<i>W</i>	<i>A</i>	
Reading 5 (Std) (One minute after standing)	$\frac{300}{60}$	(34) 106, 107, 108	(35) 109, 110, 111	$\frac{200}{0}$
Reading 6 (R-Z) (One minute after standing)	$\frac{301}{60}$	(36) 112, 113, 114	(37) 115, 116, 117	$\frac{299}{0}$
Zero	$\frac{99}{0}$	(38) 118, 119	(39) 120, 121	$\frac{99}{0}$
Corrected	$\frac{300}{60}$	(40) 122, 123, 124	(41) 125, 126, 127	$\frac{200}{0}$

c. Is SUM less than 180? No Yes

(42) 128 Participant is at goal blood pressure.

d. Is the corrected systolic value of Reading 6 lower than the corrected systolic value of Reading 4, by 20, or more?

(43) No Yes
129 Is the participant dizzy or faint after standing?

(44) No Yes
130 Findings are suggestive of postural hypotension.

e. Remarks:

(45) 131

46 Pounds. 132, 133, 134 $\frac{500}{50}$

47 Percent of ideal weight: 135, 136, 137 $\frac{152}{72}$

Observer: _____

(48) 138, 139

11. Interval medical history (to be completed by physician):

Comments: 000013

a. How have you been feeling since your last visit?
(Enter comments as necessary.)

49 140

b. Have you started any new medicines, or have you stopped taking any medicines since your last visit?

50 No Yes
141 Describe:

FOR MEN SKIP TO 12.

c. Have you had a menstrual period within the past six weeks?

51 Yes No
142 What is the reason?
52 Post-menopause, natural
 Post-menopause, other → SKIP TO 12.
143 Known pregnancy
 Possible pregnancy → Order pregnancy test at this visit.
 Other, specify: _____
Are you currently taking birth control pills?

54 145

53 No Yes
144 Discuss at this visit.

12. Interval Clinical Findings of Importance (to be completed by physician):

55 146

56 147

Does the participant have a private physician?

57
 No Yes
 148

Has the physician been advised of the participant's interest in this Program?

58
 149
 Yes, and private physician accepts this person's participation.
 Yes, but private physician refused this person's participation.
 Yes, but result is not known.
 No, but participant will contact physician.
 No, but Clinic physician will contact private physician.
 No, and participant does not wish private physician to be contacted.

Describe details:

59 150

60 151

14. Is the participant already on antihypertensive therapy?

61
 No Yes
 152

Describe:

62 153

63 154

15. Contraindications and Precautions for Drug Therapy:

	<u>Yes</u>	<u>No</u>
a. Chlorthalidone		
-Is the participant a lactating female?	64 <input type="checkbox"/>	<input checked="" type="checkbox"/> 155
-Is either of the two serum K+ determinations less than 3.5 mEq/L while the participant is not on diuretics?	65 <input type="checkbox"/>	<input checked="" type="checkbox"/> 156
-Is either of the two serum K+ determinations less than 3.5 mEq/L, and the participant on digitalis?	66 <input type="checkbox"/>	<input checked="" type="checkbox"/> 157
-Is either serum uric acid determination greater than 9 mg/dl?	67 <input type="checkbox"/>	<input checked="" type="checkbox"/> 158
-Is the fasting glucose greater than 150 mg/dl?	68 <input type="checkbox"/>	<input checked="" type="checkbox"/> 159
-Is the one-hour post-load glucose greater than 180 mg/dl?	69 <input type="checkbox"/>	<input checked="" type="checkbox"/> 160
b. Spironolactone		
-Is the creatinine greater than 2.0 mg/dl?	70 <input type="checkbox"/>	<input checked="" type="checkbox"/> 161
-Are both serum K+ determinations greater than 5.0 mEq/L?	71 <input type="checkbox"/>	<input checked="" type="checkbox"/> 162

72 163

(Continue on next page)

Yes

No

Comments:

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c. Antiadrenergic drugs (Reserpine, methyldopa)

- Is there a positive history of peptic ulcer, repeated epigastric distress, or gastrointestinal bleeding? (73) 164
- Is there a positive history of asthma? (74) 165
- Is there a positive history of depression that interferes with work, recreation, or sleep? (75) 166
- Is any liver function test abnormal? (76) 167

d. Hydralazine

- Is there any evidence of ischemic heart disease? (77) 168

Physician's Summary of Precautions and Contraindications:

	<u>Approved</u>	<u>Conditionally Approved</u>	<u>Contra-indicated</u>
1. Chlorthalidone	(78) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> 169
2. Spironolactone	(79) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> 170
3. Reserpine	(80) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> 171
4. Methyldopa	(81) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> 172
5. Hydralazine	(82) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> 173
6. Guanethidine	(83) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> 174
7. ^{Other, specify:} (84) 175, 176 _{01 00}	(85) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> 177
8. (86) 178, 179 _{01 00}	(87) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> 180
9. (88) 181, 182 _{01 00}	(89) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> 183

(90) 184

Check the following when completed:

- Information pertaining to contraindicated drugs, if any, has been transferred to the Flow Sheet (HPO5C).
- Information indicated in Item 15 above has been reviewed by the physician, and appropriate items have been verified by discussion with the participant.

16. Initial Therapeutic Regimen:

Comments: 006813

Is the participant to begin, continue or stop any antihypertensive medication as of this visit?

(91) No Yes
185 ↓

	Continue	Start	Number of pills given at this visit.	Pill size (mg/pill).	Number of pills/dose.	Number of doses/day.	Stop
Chlorthalidone	(92) <input type="checkbox"/>	(93) <input type="checkbox"/>	280 187, 188, 189	(94) 100/50 190, 191, 192	(95) 1 (96) 1	3	<input type="checkbox"/>
	186		(98) 280 196, 197, 198	(99) 25/25 199, 200, 201	(100) 4 (101) 4		<input type="checkbox"/>
Spironolactone	(97) <input type="checkbox"/>	(98) <input type="checkbox"/>	280 196, 197, 198	(99) 25/25 199, 200, 201	(100) 4 (101) 4		<input type="checkbox"/>
	195		(102) 280 205, 206, 207	(103) 25/12 208, 209	(104) 4 (105) 4		<input type="checkbox"/>
Reserpine	(102) <input type="checkbox"/>	(103) <input type="checkbox"/>	280 205, 206, 207	(104) 25/12 208, 209	(105) 4 (106) 4		<input type="checkbox"/>
	204		(107) 280 213, 214, 215	(108) 50/50 216, 217, 218	(109) 4 (110) 4		<input type="checkbox"/>
Regroton [®]	(107) <input type="checkbox"/>	(108) <input type="checkbox"/>	280 213, 214, 215	(109) 50/50 216, 217, 218	(110) 4 (111) 4		<input type="checkbox"/>
	212		(112) 280 219, 220, 221	(113) 50/50 222, 223, 224	(114) 4 (115) 4		<input type="checkbox"/>
Methyldopa	(111) <input type="checkbox"/>	(112) <input type="checkbox"/>	280 219, 220, 221	(113) 50/50 222, 223, 224	(114) 4 (115) 4		<input type="checkbox"/>
	218		(117) 280 228, 229, 230	(118) 50/10 231, 232, 233	(119) 4 (120) 4		<input type="checkbox"/>
Hydralazine	(116) <input type="checkbox"/>	(117) <input type="checkbox"/>	280 228, 229, 230	(118) 50/10 231, 232, 233	(119) 4 (120) 4		<input type="checkbox"/>
	227		(122) 280 237, 238, 239	(123) 25/10 240, 241	(124) 4 (125) 4		<input type="checkbox"/>
Guanethidine	(121) <input type="checkbox"/>	(122) <input type="checkbox"/>	280 237, 238, 239	(123) 25/10 240, 241	(124) 4 (125) 4		<input type="checkbox"/>
	236		(126) 280 244, 245	(127) 999 250, 251, 252	(128) 4 (129) 4		<input type="checkbox"/>
	246		(131) 280 258, 259, 260	(132) 999 261, 262, 263	(133) 4 (134) 4		<input type="checkbox"/>
	257		(138) <input type="checkbox"/>				<input type="checkbox"/>

(139) 267

17. Has the Consent Form for Hypertension Treatment Program (HPO5A) been fully executed?

(140) Yes No
268 Explain:

(141) 269

(142) 270

18. On the basis of all information available at this time, does this participant have:

a. A new indication for any Special Test?

(143) Yes, entered on Special Tests form (HP10)
271 No

(144) 272

18. b. A new condition requiring notification of non-fatal event (myocardial infarction, stroke, or hospitalization)?

- Yes, Notification of Non-Fatal Event (HPO8) initiated
- No

c. A new condition suggesting a critical toxic reaction, due to therapy from non-HDFP sources?

- Yes, Toxic Reaction Report (HPO9) attached
- No

19. The Clinic Revisit schedule is:

- Step-Up Schedule (2 weeks)
- Maintenance Schedule A (4 weeks)
- Individualized Therapy (specify interval: 276, 277)

149 278

20. Remarks on further management plans, diagnostic evaluation or other matters:

150 279

151 Century Date
282 286

151

Physician _____

280281 99
0

Consent Form for Hypertension Treatment Program

The Special Hypertension Treatment Program at the _____ has been explained to me, and I understand that I am invited to take part in it.

The purpose of the Program, the procedures to be followed, the attendant possible discomforts and risks, and expected benefits have been described to me. In addition, it has been explained to me that high blood pressure (hypertension) is a common condition which results in increased risk of heart disease and stroke. I further understand that:

- 1) My high blood pressure and its effect on my body will be judged by the use of standard medical tests and measurements. As long as my blood pressure remains higher than is considered normal, medications will be given to lower it.
- 2) There are several oral medications which are generally effective in reducing high blood pressure in most cases and that treatment with these medicines is likely to be beneficial in reducing the risk of heart disease and stroke.
- 3) Several different medications may be used, either singly or in combination, in order to lower my blood pressure to a satisfactory level. All medications used will be standard medications which are commonly used by doctors who have special experience in treating high blood pressure patients. No new or "experimental" medications will be used in this Program.
- 4) There may be side effects with respect to the use of these medicines, such as rashes, stomach upset, other allergic reactions, and other side effects. The possible side effects that may occur with the medicines that I will be put on at this time have been explained to me as well as the fact that I can ask any questions about these possible side effects and any other aspect of the procedures that I do not understand. Furthermore, the doctor, therapist, nurses and others involved in my treatment under this Program will watch closely for such side effects and when necessary will stop the medication which appears to be responsible if such side effects occur and will give me new medication.
- 5) Should I require different or stronger medications to lower my blood pressure than I receive at first, my doctor will inform me of any different side effects that these different medications may produce. Furthermore, if a specific cause for my high blood pressure is found by the standard medical tests that I have taken, alternative procedures which may be advantageous to me will be explained.

I understand that I am free to withdraw my consent and to discontinue participation in this Program at any time. These foregoing points have all been explained to me to my satisfaction and, understanding them fully, I hereby give my consent to enter this treatment Program.

Date

Signature of Participant

Printed Name of Participant

Address of Participant

Witness (recommended)

I have fully explained to the participant, _____, the nature and purpose of the procedures described above and such risks as are involved in their performance.

Date

Signature of Physician

RELEASE OF MEDICAL INFORMATION

I, the undersigned, authorize the sources listed below to provide clinical records to the _____
_____ Center of the Hypertension Detection and Follow-up Program.

(a) Dr. _____
Address _____

(b) Institution (s):
Name _____
Address _____

Name _____
Address _____

Signature of Participant

Printed Name of Participant

Date