TREATMENT OF MILD HYPERTENSION STUDY **ELIGIBILITY** VISIT 1 (EV01)

Attac	ch ID Label I	Here
-		-
Month	Day	Year

INSTRUCTIONS: Complete this form for each participant for whom blood pressure is measured to

Date of Visit:

determine eligibility at Eligibility Visit 1.

Complete the examination in the same order as the form. All items should be

completed even if the participant is found to be ineligible.

CONSENT FORM FOR PARTICIPATION IN THE TREATMENT OF MILD HYPERTENSION STUDY ELIGIBILITY VISIT 1 SCREENING PROCEDURES

I volunteer for the first eligibility visit of the Treatment of Mild Hypertension Study (TOMHS). I understand that this visit will involve two sitting blood pressure measurements and some questions regarding my health.

date signed	articipant	
The participant has be rocedures answered	een given the opportunity to have his/her q	uestions about the screening
-	signature of aud	ditor/witness
. Participant's name	and address:	
First Name	Middle Name Last I	Name
House and Street A	Address	Apt. No.
City or Town	State	Zip Code
. Home Phone:	Work phone.	:
(area	•	·

BRT	HDATE				_		_					
6.	Date of Birth:	Month] - ['	Day] -	Year				pible if age < 4 f today's date.		
7.	Do you plan to away from this						ice mo	re than 50 mile	es	1 🔲 yes	2 🔲 no	
8.	Will you travel of time each ye								riods	1 🔲 yes	2 🔲 no	
9.	Do you take m	edicine p	prescri	bed by	a do	octor fo	r diab	etes?		1 ☐ yes	2 🔲 no	
10. Have you ever been hospitalized for a week or more for a heart attack?												
11.	Have you ever	been ho	spitaliz	zed for	a we	ek or r	nore fo	or a stroke?		1 🔲 yes	2 🔲 no	
12.	Blood Pressur	re Measu	ireme	nts (St	anda	ırd Sph	ygmor	nanometer):				
	Arm circumfer	ence: _		cm								
	Cuff size (che	ck one):	p	ediatric	(<24	4.5 cm)		regular adult (2	24.5-33 cm)	large ac	lult (>33 cm)	
	Pulse obliterat	tion		+ 30) = _		Pe	eak inflation lev	/el			
	Reading Systolic Diastolic (5th Phase)											
	After applying cuff, the partici)		1st			mm Hg		mm Hg	
	seated without for 5 minutes b 2 readings. Wa	legs cro efore tak	ssed king th	e		2nd			mm Hg		mm Hg	
	after the 1st re taking the 2nd	ading be			Average mm Hg m				mm Hg			
					В	lood pr	ressure	e observer's co	ode:			
13.	Are you current	ly taking	blood (pressu	re me	edicatio	n?					•
1 [☐ yes —											
2 [] no 1-	4. When	did yo	ou first	begi	n takin	g bloo	d pressure med	dication?	Month	Year	
	1			rently t edication		g more	than c	ne class of blo		1 □ yes	2 🔲 no	
	1							is defined as a combination				
1	,	6. Is the p		e ere e erere contrata aracana			P (item	ı 12) ≥ 95 mmŀ	lg?	1 🔲 yes	2 🔲 no	
17.	Is the participa						or > 99	mmHg?		1 □ yes	2	

21. Have you been troubled in the **past three months** with any of the following specific conditions? (If a participant has been troubled, ask him/her to indicate the severity of the condition (mild, moderate, severe). For those conditions volunteered by the participant which are not listed below, please write them in item 22.)

Definitions of severity:

Mild - bothersome, but does not interfere with usual daily activities Moderate - interferes with usual daily activities Severe - so bad that you cannot perform usual daily activities

		No, not troubled	Yes, mildiy	Yes, moderately	Yes, severely
a.	Fever?	1 🔲	2 🔲	з 🔲	4 🔲
b.	Unexpected sweating?	1 🔲	2 🔲	3 🔲	4 🔲
c.	Drowsiness or sleepiness? SEBL_1	1 🗆	2 🔲	3 🔲	4 🔲
d.	Tiredness or fatigue? SEBL_2	1 🗆	2 🗆	3 🗆	4 🗆
e.	Weakness?	1 🔲	2 🔲	3 □	4 🔲
f.	Faintness or dizziness when arising in the morning, or o hot days or after exercise? SEBL_3	n 1 🔲	2 🗆	3 🗆	4 🗆
g. h.	Blacking out or losing consciousness? Faintness or lightheadedness when you stand up quick	1 🔲	2 🔲 2 🔲	3 🗆 3 🗖	4 🗆 4 🗖
i.	Hair loss?	1 🔲	2 🔲	3 □	4 🗆
j.	Abnormal hair growth?	1 🔲	2 🔲	з 🗖	4 🔲
k.	Flushed face? Itchy skin (urticaria, hives)? SEBL 4	1 🔲 1 🔲	2 🗌 2 🔲	3 🗆 3 🗆	4 🗆 4 🗖
m.		1 🔲	2 🔲	3 🗆	4 🗆
n.	Unusual bruises?	1 🔲	2 🔲	3 🗖	4 🔲
0.	Abnormal bleeding?	1 🗆	2 🔲	3 🗆	4 🗆
p.	Headaches? SEBL_6	1 🔲	2 🗆	3 🗆	4 🗆
q.	Ringing in the ears? SEBL_7	1 🔲	2 🔲	3 🗆	4 🔲
r.	Stuffy nose? SEBL_8	1 🔲	2 🔲	3 🗖	4 🔲
s.	Change in taste perception?	1 🗆	2 🔲	3 🔲	4 🗆
t.	Blurring of vision?	1 🔲	2 🗆	3 🔲	4 🗆
u.	Excessive thirst?	1 🔲	2 🔲	3 🗖	4 🔲
V.	Dry mouth? SEBL_9	1 🔲	2 🔲	3 🔲	4 🔲

		No, not troubled	Yes, mildly	Yes, moderately	Yes, severely
w.	Wheezing?	1 🔲	2 🔲	3 □	4 🔲
χ.	Cough? SEBL_10	1 🔲	2 🔲	3 🔲	4 🔲
у.	Shortness of breath?	1 🗆	2 🔲	3 🔲	4 🔲
z.	SEBL_11 Heart beating unusually fast or skipping beats?	1 🗆	2 🗆	3 □	4 🔲
aa.	SEBL Episodes of chest pain, pressure or heaviness in the ch	_12 est?1 □	2 🔲	3 🗆	4 🔲
bb.	Swelling or tenderness of the breasts?	1 🗆	2 🗆	з 🗖	4 🗆
	Lack of appetite? Diarrhea?	1 🗆 1 🗀	2 🗆	3 🗆 3 🗀	4 🗆 4 🗖
ee.	Constipation?	1 🔲	2 🗆	3 🔲	4 🗆
ff.	Abdominal pain?	1 🔲	2 🔲	3 🔲	4 🗆
gg.	Nausea or vomiting?	1 🗆	2 🔲	3 🔲	4 🗆
hh	Black or tarry stools?	1 🗆	2 🗆	3 🗆	4 🗆
ii.	Bright red blood in stools?	1 🗆	2 🗆	3 🔲	4 🔲
jj.	Incoordination or unsteadiness when standing?	1 🔲	2 🗆	3 🗆	4 🔲
kk. II.	Pain in any joint? SEBL_13 Coldness or blanching of fingers or toes?	1 🗆 1 🗖	2 🗆 2 🗖	3 <u> </u>	4 🗆
14.4.4.1.4.4.4.4.4.4.4.4.4.4.4.4.4.4.4.	Swelling of feet or ankles? SEBL_14	1 🔲	2 🔲	3 🗖	4 🗆
nn	Muscle pain or cramps? SEBL_15	1 🔲	2 🗆	3 🗆	4 🗆
/10000000	. Muscle tremors?	1 🗆	2 🗆	3 🔲	4 🗆
pp	Numbness or tingling? SEBL_16	1 🗆	2 🗆	3 🗆	4 🗆
qq		1 🗆	2 🔲	3 🔲	4 🗆
rr.		1 🔲	2 🗖	3 🔲	4 🗆
ss tt.	Nightmares? SEBL_18 Disturbances in memory?	1 🗆	2 🗆 2 🗖	3 🗆 3 🗖	4 🗆 4 🔲
uu		1 🔲	2 🔲	3 □	4 🔲
VV		1 🔲	2 🔲	3 □	4 🗆
wv	Feeling depressed (sad or blue) SEBL_20	1 🗆	2 🗆	з 🗖	4 🗆

PART I: DEMOGRAPHIC QUESTIONNAIRE

1.	Social Security Number:							
2.	What is your present job status?							
	 working at a job full-time for pay working at a job part-time for pay homemaker retired temporarily laid off unemployed other, specify: 							
3.	What is/was your occupation?							
4. What was your total family income last year before deductions and taxes? Include family income from all sources.								
	1 ☐ Less than \$9,999 5 ☐ \$40,000 to \$49,999 2 ☐ \$10,000 to \$19,999 6 ☐ \$50,000 to \$59,999 3 ☐ \$20,000 to \$29,999 7 ☐ \$60,000 to \$69,999 4 ☐ \$30,000 to \$39,999 8 ☐ \$70,000 or more							
5.	What is your present marital status? MARITAL							
	1 Never married 2 Separated 3 Divorced 4 Widowed 5 Married							
6.	How much formal education have you completed?							
1								

URINALYSIS (LABSTIX) Check the appropriate box for each determination:								
12. Blood 1 ☐ negative 2 ☐ small 3 ☐ moderate 4 ☐ large								
13. Ketones 1 ☐ negative 2 ☐ small 3 ☐ moderate 4 ☐ large								
trace + ++++++++++++++++++++++++++++++++++								
+ ++ +++ ++++ ++++ ++++ 15. Protein 1 ☐ negative 2 ☐ trace 3 ☐ 30 mg/dl 4 ☐ 100 5 ☐ 300 6 ☐ 1000								
16. pH 1 ☐ - 2 ☐ five (5) 3 ☐ six (6) 4 ☐ seven (7) 5 ☐ eight (8) 6 ☐ nine (9)								
1								
20. Do you smoke cigars, cigarillos or pipes? 1 yes 2 no Reminder: Complete items 7 through 9 on the exclusion checklist (page 11).								

The following questions are about your health and your daily activities. You may find that some of the questions seem alike. It is important for our study to ask the questions in this way. Please try to answer every question as accurately as you can. Check one box for each item.

	81.	In general, would you	say your health i	s:				
		1 Excellent 2 Very good 3 Good 4 Fair 5 Poor	QL12_1					
	82.	In the <u>past month</u> , to w (such as walking and c	hat extent did <u>he</u> limbing stairs)?	ealth problems	limit you in yo	our <u>everyday</u>	physical acti	vities
		1 Not at all 2 Slightly 3 Moderately 4 Quite a bit 5 Extremely	QL12_2					
	83.	During the past month, outside the house, bec	how much diffic ause of your phy	ulty did you ha ysical health or	ve doing you emotional pr	r daily work, oblems?	both inside a	nd
		1 None at all 2 A little bit 3 Some 4 Quite a bit 5 Could not do daily	QL12_3					
	84.	How satisfied are you w	rith your physical	ability to do wl	hat you want i	o do?		
		1 Completely satisfied 2 Very satisfied 3 Somewhat satisfied 4 Somewhat dissat 5 Very dissatisfied 6 Completely dissat	ied ed QL1 isfied	12_4				
	<mark>85.</mark>	How TRUE or FALS right or wrong answ	E are each of	the followin	g statemen	ts for you?	There are	e no
		g or wrong ansy		Definitely True	Mostly True	Don't Know	Mostly False	Definitely False
QL12	_5	a. My health is excelle	nt.	1 🗆	2 🗆	3 □	4 🔲	5 🗆
QL12	_6	b. I think my health will future than it is now	be worse in the	1 🗆	2 🗆	3 🗆	4 🗆	5 □
QL12	_7 [c. I have been feeling	bad lately.	1 🗆	2 🔲	3 □	4 🗆	5 🗆
		d. Good health is in my	future. QL12	_8 1 🗖	2 🔲	3 🔲	4 🗆	5 🗆
QL12_	_9	e. I feel about as good			2 🗆	3 □	4 🗆	5 🗆
1	FORM	135 (7-14) AUG 87						

86.	During the past month, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?
	1 Not at all 2 Slightly 3 Moderately 4 A great deal 5 Extremely
87.	During the past month, about how often have you had friends over to your home?
	1
88.	About how often have you visited with friends at their homes during the past month?
	1
89.	Compared to others your age, are your social activities more or less limited because of your physical health or emotional problems?
	1 Much more limited than others 2 Somewhat more limited than others 3 About the same as others 4 Somewhat less limited than others 5 Much less limited than others
the	se questions are about how you feel and how things have been with you during past month. For each question, check the box which comes closest to the way have been feeling.
90.	How much of the time during the past month has your daily life been full of things that were interesting to you?
	1 All of the time 2 Most of the time 3 A good bit of the time 4 Some of the time 5 A little of the time 6 None of the time

The next questions ask about your social activities.

91.	How often during the last month did you feel worn out?					
	1 All of the time 2 Most of the time 3 A good bit of the time 4 Some of the time 5 A little of the time 6 None of the time	QL12_15				
92.	During the past month, how n	nuch of the time have you felt tense or "high strung"?				
	1 All of the time 2 Most of the time 3 A good bit of the time 4 Some of the time 5 A little of the time 6 None of the time	QL12_16				
93.	How often during the last more	nth did you have enough energy to do the things you wanted to do?				
	1 All of the time 2 Most of the time 3 A good bit of the time 4 Some of the time 5 A little of the time 6 None of the time	QL12_17				
94.	How much of the time during	the past month have you felt downhearted and blue?				
	1 All of the time 2 Most of the time 3 A good bit of the time 4 Some of the time 5 A little of the time 6 None of the time	QL12_18				
95	During the past month, how m	nuch of the time were you a happy person?				
	1 All of the time 2 Most of the time 3 A good bit of the time 4 Some of the time 5 A little of the time 6 None of the time	QL12_19				
96.	During the past month, how m	nuch of the time have you been anxious or worried?				
	1 All of the time 2 Most of the time 3 A good bit of the time 4 Some of the time 5 A little of the time 6 None of the time	QL12_20				

97	During the past month, how m	uch of the time have you been in low or very low spirits?
	1 All of the time 2 Most of the time 3 A good bit of the time 4 Some of the time 5 A little of the time 6 None of the time	QL12_21
98.	How much of the time, during	the past month, have you felt calm and peaceful?
	1 All of the time 2 Most of the time 3 A good bit of the time 4 Some of the time 5 A little of the time 6 None of the time	QL12_22
99.	How often during the last mor	nth did you feel full of pep?
	1 All of the time 2 Most of the time 3 A good bit of the time 4 Some of the time 5 A little of the time 6 None of the time	QL12_23
100.	How much of the time during	the past month have you been a very nervous person?
	1 All of the time 2 Most of the time 3 A good bit of the time 4 Some of the time 5 A little of the time 6 None of the time	QL12_24
101.	During the past month, how r	nuch of the time have you felt depressed?
	1 All of the time 2 Most of the time 3 A good bit of the time 4 Some of the time 5 A little of the time 6 None of the time	QL12_25
102.	How much of the time during	the past month have you felt cheerful and light-hearted?
	1 All of the time 2 Most of the time 3 A good bit of the time 4 Some of the time 5 A little of the time 6 None of the time	QL12_26

	103.	During the past month, how	much of the	time have you fe	elt restless,	fidgety or imp	atient?	
		 All of the time Most of the time A good bit of the time Some of the time A little of the time None of the time 	QL12_27	7				-
	104.	How often during the past mup?	onth have y	ou felt so down	in the dum	ps that nothing	g could chee	er you
		1 Always 2 Very often 3 Fairly often 4 Sometimes 5 Almost never 6 Never	L12_28					
	105.	During the past month, how	much of the	e time have you	been mood	ly or brooded	about things	s?
		1 All of the time 2 Most of the time 3 A good bit of the time 4 Some of the time 5 A little of the time 6 None of the time	QL12_	29				
	106.	How often during the last m	onth did you	u feel tired?				
		1 All of the time 2 Most of the time 3 A good bit of the time 4 Some of the time 5 A little of the time 6 None of the time	QL12_	_30				
	107.	How TRUE or FALSE at		the following	statemer	nts for you?	There ar	e no
		right or wrong answers	·	Definitely True	Mostly True	Don't Know	Mostly False	Definitely False
QL	.12_31	a. I am somewhat ill.		1 🗆	2	3□	4 🗆	5 🗀
QL	.12_32	b. I expect to have a very i	healthy life.	1 🗆	2 🗆	3□	4 🔲	5 🗆
QL	.12_33	C. I am in poor health.		1 🗆	2 🔲	3 □	4 🗆	5 🗆
QL	.12_34	d. I am as healthy as anybo	ody I know.	1 🗆	2 🗆	3□	4 🗆	5 🗖
Οı	12 35	e. My future will be unheal	lthy.	1 🗆	2 🗆	3□	4 🗆	5□

TREATMENT OF MILD HYPERTENSION STUDY TWELVE MONTH VISIT (12MO)

Attach ID Label Here

	Date of Visit:		1 □ am 2 □ pm
INSTRUCTIONS: This visit should be conducted for all randomized participants 52 weeks ± 2 weeks after randomization. Please use a ball point pen and press firmly.			
Participant's name:			
Did the participant a	attend this visit?		
1	CONTINUE WITH QUESTION 3.		
2 🗆 no —	2. Why was this visit missed? (Check "yes" or "no" for each of	the reasons lis	ted below)
	a. Participant refuses to come to the clinic.	1 🔲 yes	2 🗆 no
	b. Clinical Center schedule or workload made it impossible to schedule the participant.	1 🔲 yes	2 🗆 no
	c. Participant's work schedule or other commitments made it impossible to schedule this visit.	1 🔲 yes	2 🔲 no
	d. Participant temporarily out of town.	1 🔲 yes	2 🔲 no
	e. Participant hospitalized or ill.	1 🔲 yes	2 🔲 no
	f. Participant moved out of the area of the Clinical Center.	1 🔲 yes	2 🔲 no
	g. Other (specify):	1 🔲 yes	2 🔲 no
3. Weight (nearest ha	f pound, without shoes):	12	
4. Room Temperature:	□□□ °F		
5. Pulse: Beats in 30	seconds x 2 =beats/min	ute	
PULSE12			