SH06: Baseline Visit 1 Form

Purpose

The *Baseline Visit 1 Form* (SH06) was completed at the first of two baseline evaluation visits attended by potential participants. Eligibility for the trial was based on study inclusion and exclusion criteria given in **Section 2.3** of the *SHEP MOO*. The SH02, SH03, and SH04 forms were reviewed at this visit to aid in determining eligibility. Form SH06 is described in detail in **Section 2.3.5** of the *MOO*.

| 30-32 (/) F | ORM NUMBER | | GIN SEQUENCE |
|--|--|---|--|
| \leq | E | BASELINE VISIT 1 | \smile_{40} |
| 33 (2) V Name: (| $3^{\underline{22-23}}$ | <u>4</u>)24-27 | |
| 1. SHEP I | | - 5 2. Acr | rostic: |
| 3. Today's | 5 Date: 3637 3839 Month Day | 3435 28-29 Year | (b) 41-46 |
| applica | ble, Drug Evaluation Vis | | nformation Sheet SH02 and, if |
| | ate of birth: Month | .7-49 | 51-54 |
| $55 (D)^{\vee}$ | as participant on anthy¶ es □ 1 No □ 2 | Don't know 🗆 3 | |
| | nitial Contact, or from l <u>Systolic</u> | ast Drug Evaluation Vi | ntact for those not on meds at sit for those taken off of meds: te of blood pressures in 4c. |
| R | 56-58 eading 1: | 12 59-61 76 Mor | 77 7879 7475 19 Day Year 80-88 |
| R | 62-64 eading 2: (13) | (14) ⁶⁵⁻⁶⁷ e. Soc | cial Security Number: 🗐 🎊 |
| R | 68-70 eading 3:(15) | | |
| f. M | edicare Number: | | |
| 5. Collect | review and complete th | he following items: | $(19)_{89-97}$ |
| | , review and complete th | 0 | |
| | onsent for Baseline Visi articipant Information Sh emographic Information aseline Medical History, | t 1 (and Baseline Visit neet, SH02 and Medication History, | 2, if allowed) |
| | onsent for Baseline Visi articipant Information Sh emographic Information aseline Medical History, | t 1 (and Baseline Visit neet, SH02 and Medication History, SH04 | 2, if allowed) |
| COMPLETE LEAVES. | onsent for Baseline Visi articipant Information Sh emographic Information aseline Medical History, | t 1 (and Baseline Visit neet, SH02 and Medication History, SH04 TERMINATION OF N | 2, if allowed) SH03 |
| | onsent for Baseline Visi articipant Information Sh emographic Information aseline Medical History, SECTION BELOW AT HEP ID and Acrostic cor II required items are cor | t 1 (and Baseline Visit neet, SH02 and Medication History, SH04 TERMINATION OF N | 2, if allowed) SH03 VISIT BEFORE PARTICIPANT |
| $\begin{bmatrix} C \\ C \\ D \\ P \\ D \\ D \\ D \\ B \\ C \\ C$ | onsent for Baseline Visi articipant Information Sh emographic Information aseline Medical History, SECTION BELOW AT HEP ID and Acrostic cor II required items are cor rocedures completed: 101 | t 1 (and Baseline Visit neet, SH02 and Medication History, SH04 TERMINATION OF TERMINATION OF Terect. mplete and legible. D 1 None, participant Yes No Real | 2, if allowed) SH03 VISIT BEFORE PARTICIPANT |
| $\begin{bmatrix} C \\ C \\ D \\ P \\ D \\ D \\ B \\ C \\ C$ | onsent for Baseline Visit articipant Information Sh emographic Information aseline Medical History, SECTION BELOW AT HEP ID and Acrostic cor II required items are con rocedures completed: 101 1) ECG | t 1 (and Baseline Visit neet, SH02 and Medication History, SH04 TERMINATION OF TERMINATION OF Terect. mplete and legible. □ 1 None, participant Yes No Rea □ 1 □ 2 → | 2, if allowed) SH03 VISIT BEFORE PARTICIPANT not BP eligible. |
| $\begin{bmatrix} C \\ C \\ D \\ P \\ D \\ D \\ D \\ B \\ C \\ C$ | onsent for Baseline Visit articipant Information Sh emographic Information aseline Medical History, SECTION BELOW AT HEP ID and Acrostic cor Il required items are con rocedures completed: 101 1) ECG 2) Physical exam 3) Dipstick urinalysis | t 1 (and Baseline Visit neet, SH02 and Medication History, SH04 TERMINATION OF TERMINATION OF Terect. mplete and legible. □ 1 None, participant Yes No Rea □ 1 □ 2 → | 2, if allowed) SH03 VISIT BEFORE PARTICIPANT not BP eligible. |
| $ \begin{array}{c} $ | onsent for Baseline Visit articipant Information Sh emographic Information aseline Medical History, SECTION BELOW AT HEP ID and Acrostic cor II required items are con rocedures completed: 101 1) ECG 2) Physical exam | t 1 (and Baseline Visit neet, SH02 and Medication History, SH04 TERMINATION OF M TERMINATION OF M Terect. mplete and legible. 1 None, participant \underline{Yes} No Real 1 0 2 \rightarrow 1 1 0 2 \rightarrow 1 1 0 2 \rightarrow 1 0 1 0 2 \rightarrow 1 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 | 2, if allowed) SH03 VISIT BEFORE PARTICIPANT not BP eligible. |
| $\begin{bmatrix} \Box & \Box \\ \Box & P \\ \Box & D \\ \Box & B \\ \end{bmatrix}$ $\begin{bmatrix} COMPLETE \\ LEAVES. \end{bmatrix}$ $\begin{bmatrix} COMPLETE \\ LEAVES. \end{bmatrix}$ $\begin{bmatrix} O & O \\ A \\ O \\ A \end{bmatrix}$ $\begin{bmatrix} O & O \\ A \\ O \\ A \end{bmatrix}$ $\begin{bmatrix} O & O \\ A \\ A \\ A \end{bmatrix}$ $\begin{bmatrix} O & O \\ A \\ A \\ A \\ A \end{bmatrix}$ $\begin{bmatrix} O & O \\ A \\ A \\ A \\ A \end{bmatrix}$ $\begin{bmatrix} O & O \\ A \\ A \\ A \\ A \end{bmatrix}$ $\begin{bmatrix} O & O \\ A \\ A \\ A \\ A \end{bmatrix}$ $\begin{bmatrix} O & O \\ A \\ A \\ A \\ A \end{bmatrix}$ $\begin{bmatrix} O & O \\ A \\ A \\ A \\ A \end{bmatrix}$ $\begin{bmatrix} O & O \\ A \\ A \\ A \\ A \end{bmatrix}$ $\begin{bmatrix} O & O \\ A \\ A \\ A \\ A \end{bmatrix}$ $\begin{bmatrix} O & O \\ A \\ A \\ A \\ A \end{bmatrix}$ $\begin{bmatrix} O & O \\ A \\ A \\ A \\ A \end{bmatrix}$ $\begin{bmatrix} O & O \\ A \\ A \\ A \\ A \end{bmatrix}$ $\begin{bmatrix} O & O \\ A \\ A \\ A \\ A \end{bmatrix}$ $\begin{bmatrix} O & O \\ A \\ A \\ A \\ A \end{bmatrix}$ $\begin{bmatrix} O & O \\ A \\ A \\ A \\ A \end{bmatrix}$ $\begin{bmatrix} O & O \\ A \\ A \\ A \\ A \end{bmatrix}$ $\begin{bmatrix} O & O \\ A \\ A \\ A \\ A \end{bmatrix}$ $\begin{bmatrix} O & O \\ A \\ A \\ A \\ A \end{bmatrix}$ $\begin{bmatrix} O & O \\ A \\ A \\ A \\ A \end{bmatrix}$ $\begin{bmatrix} O & O \\ A \\ A \\ A \end{bmatrix}$ $\begin{bmatrix} O & O \\ A \\ A \\ A \end{bmatrix}$ $\begin{bmatrix} O & O \\ A \\ A \\ A \end{bmatrix}$ $\begin{bmatrix} O & O \\ A \\ A \\ A \end{bmatrix}$ $\begin{bmatrix} O & O \\ A \\ A \end{bmatrix}$ $\begin{bmatrix} O & O \\ A \\ A \end{bmatrix}$ $\begin{bmatrix} O & O \\ A \\ A \end{bmatrix}$ $\begin{bmatrix} O & O \\ A \\ A \end{bmatrix}$ $\begin{bmatrix} O & O \\ A \\ A \end{bmatrix}$ $\begin{bmatrix} O & O \\ A \\ A \end{bmatrix}$ $\begin{bmatrix} O & O \\ A \\ A \end{bmatrix}$ $\begin{bmatrix} O & O \\ A \\ A \end{bmatrix}$ $\begin{bmatrix} O & O \\ A \\ A \end{bmatrix}$ $\begin{bmatrix} O & O \\ A \\ A \end{bmatrix}$ $\begin{bmatrix} O & O \\ A $ | onsent for Baseline Visit articipant Information Sh emographic Information aseline Medical History, SECTION BELOW AT HEP ID and Acrostic cor II required items are cor rocedures completed: 101 1) ECG 2) Physical exam 3) Dipstick urinalysis 4) Blood sample drawn for local determinatio | t 1 (and Baseline Visit neet, SH02 and Medication History, SH04 TERMINATION OF M TERMINATION OF M Terect. mplete and legible. 1 None, participant \underline{Yes} No Real 1 0 2 \rightarrow 1 1 0 2 \rightarrow 1 1 0 2 \rightarrow 1 0 1 0 2 \rightarrow 1 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 | 2, if allowed) SH03 VISIT BEFORE PARTICIPANT not BP eligible. |
| $ \begin{array}{c} $ | onsent for Baseline Visit articipant Information Sh emographic Information aseline Medical History, SECTION BELOW AT HEP ID and Acrostic cor Il required items are cor rocedures completed: 101 1) ECG 2) Physical exam 3) Dipstick urinalysis 4) Blood sample drawn for local determination of serum creatinine: esult of this visit: 1 Participant is not ell 2 Participant is eligibl 3 Participant is eligibl | t 1 (and Baseline Visit heet, SH02 and Medication History, SH04 TERMINATION OF TERMINATION OF TERMINATION OF TERMINATION OF TERMINATION OF None, participant Yes No Rea 1 02 \rightarrow 1 02 | 2, if allowed) SH03 VISIT BEFORE PARTICIPANT not BP eligible. ason |
| $\begin{bmatrix} 0 & 0 \\ 0 $ | onsent for Baseline Visit articipant Information Sh emographic Information aseline Medical History, SECTION BELOW AT HEP ID and Acrostic cor Il required items are cor rocedures completed: 101 1) ECG 2) Physical exam 3) Dipstick urinalysis 4) Blood sample drawn for local determination of serum creatinine: esult of this visit: 1 Participant is not ell 2 Participant is eligibl 3 Participant is eligibl | t 1 (and Baseline Visit heet, SH02 and Medication History, SH04 TERMINATION OF TERMINATION OF TERMINATION OF TERMINATION OF TERMINATION OF None, participant Yes No Rea 1 02 \rightarrow 1 02 | 2, if allowed) SH03 VISIT BEFORE PARTICIPANT not BP eligible. ason |



d. Eligibility check (use average of two corrected readings):

| \frown | SBP 150-2 | 219 a | nd DBP <95 mm Hg | → | Eligible | |
|----------|-----------|-------|------------------|---|----------|--|
| 206 (5) | Other | → | Not eligible | | | |
| e. Obs | erver: | | · | | | |

Ineligible persons should proceed to scheduling area for termination of their participation in the SHEP screening process. Only eligible participants should proceed with the remaining items in Baseline Visit 1.

PARTICIPANT SHOULD NOW BE SENT FOR ECG AND URINE SAMPLE.

7. <u>CLINICIAN REVIEW OF MEDICATION HISTORY</u> (To be completed by clinician using information from the Baseline Demographic Information and Medication History Form, SH03.)

Is the participant taking any of the drugs listed below? Drugs marked with an * may be involved in various exclusion criteria.

| | | Current (last 2 _weeks) | Not Current or Not Sure |
|------|---|-------------------------------|-------------------------------|
| * a. | Any medication for blood pressure, or drugs with antihypertensive action | | □ 2 |
| b. | Digitalis | 210(68) - 1 | □ 2 |
| c. | Nitrates including nitroglycerine | $211(\mathcal{A})^{-1}$ | □ 2 |
| * d. | Propranolol or other beta blockers for other than treatment of blood press | $\sum_{i=1}^{i} 212$ | □ 2 |
| e. | Anti-arrhythmic drugs | $213(\overline{\eta})^{-1}$ | □ 2 |
| f. | Lipid-lowering drugs, including | | □ 2 |
| g. | Agents for gout, including probenecid, allopurinol or colchicine | 215(73) $216(74)^{-1}$ | □ 2 |
| * h. | Insulin | | □ 2 |
| i. | Oral hypoglycemic agents | $217(15)_{-1}$ | □ 2 |
| * j. | Anticoagulants | 218 (14) - 1 | □ 2 |
| k. | Antibiotics or anti-infection agents | 219 (77) - 1 | □ 2 |
| 1. | Cortisone or other gluco corticoids $\ 22$ | $0 (\eta_8) = 1$ | □ 2 |
| m. | Amphetamines or other stimulant | 221 (19) - 1 | □ 2 |
| n. | Flurazepam or other sedative 222 | | □ 2 |
| о. | Anti-depressants | | □ 2 |
| р. | Librium, valium or other antianxiety ag | | □ 2 |
| | | 224 | S |

Code

7. CLINICIAN REVIEW OF MEDICATION HISTORY (continued):

| | | Current (last 2 weeks) | Not Current or Not Sure |
|----|--|------------------------------|-------------------------------|
| q. | Other psychotropic agents | 225 B = 1 | □ 2 |
| r. | Potassium supplementation other than dietary recommendations | 226 JU 1 | □ 2 |
| s. | Estrogen | $227(x)^{-1}$ | □ 2 |
| t. | Anturane [®] (Sulfinpyrazone) at least 4 | weeks D 1 | □ 2 |
| u. | Persantine [®] (Dipyridamole) at least 4 \sim | weeks 167229 | □ 2 |
| v. | Aspirin at least 4 weeks | 230 (1) - 1 | □ 2 |
| w. | Non-steroidal anti-inflammatory drugs | | □ 2 |

8. PHYSICAL EXAMINATION

The clinician should perform a general physical exam, paying particular attention to the specific items listed below, entering comments for each indicated abnormality.

| a. | Weight in pounds: 400 b. Height in in $232\text{-}234$ | The sector $235-236$ |
|------|---|----------------------|
| Area | Examined | Comments |
| c. | SKIN 237 Abnormal 🗆 1 Normal 🗆 2 | |
| d. | HEAD, EARS, 238 NOSE, THROAT 3 Abnormal 🗆 1 Normal 🗔 2 | |
| e. | EYES | |
| | Fundi: (1) Abnormal □ 1 239 4 Normal □ 2 Not Visualized □ 3 | |
| | Other 240 (Specify)? (2) Yes \Box 1 No \Box 2 | |

8. PHYSICAL EXAMINATION (continued)

| Area Examined | Comments |
|---|----------|
| f. NECK | |
| Raised jugular (1) Yes \Box 1 No \Box 2 | |
| Carotid bruits? (7) Yes \Box 1 No \Box 2 | |
| $242 (3) \\ 243 (3) \\ \text{Left only } \square 1 \\ \text{Bilateral } \square 3 \\ \end{array}$ | |
| Carotid pulses | |
| or markedly (4) Yes \Box 1 No \Box 2 | |
| $245 \bigoplus (5) \begin{cases} Right only \Box 1 \\ Left only \Box 2 \\ Bilateral \Box 3 \end{cases}$ | |
| Thyroid 246 (6) Yes 🗆 1 No 🗆 2 | |
| Other (Specify)? (7) Yes \Box 1 No \Box 2 | |
| g. LYMPH NODES 3 Abnormal \Box 1 Normal \Box 2 248 | |
| h. CHEST, LUNGS | |
| Bilateral rales that do not clear 249 with coughing? (1) Yes 🗆 1 No 🗆 2 | |
| Respiratory rate 20+? $250(05)$ (2) Yes \Box 1 No \Box 2 | |
| When $z = \sum_{i=1}^{N} (2)$ Vec $\Box = 1$ No $\Box = 2$ | |
| Other (Specify)? $251(106)$ (3) Fes \Box 1 No \Box 2 (4) Yes \Box 1 No \Box 2 (107) | |
| 252 | |

8. PHYSICAL EXAMINATION (continued)

| Area | Examined | Comments |
|------|--|----------|
| i. | HEART | |
| | line? (1) Yes \Box 1 No \Box 2 | 253 |
| | Any murmur? (2) Yes \Box 1 No \Box 2 | 254 |
| | Third heart sound? (3) Yes \Box 1 No \Box 2(10) | 255 |
| | Fourth heart sound?(4) Yes 🗆 1 No 🗆 2 | 256 |
| | Pulse irregular? (5) Yes 🗆 1 No 🗆 2 | 257 |
| | Other (Specify)? (6) Yes \Box 1 No \Box 2 | 258 |
| j. | BREASTS 259 Abnormal 🗆 1 Normal 🗆 2 | 2 |
| k. | ABDOMEN | |
| | Liver span 10 cm 260 or more? (1) Yes \Box 1 No \Box 2 | |
| | Abnormal abdominal pulse? 261 (2) Yes \Box 1 No \Box 2 | |
| | Any masses? (3) Yes \Box 1 No \Box 2 | |
| | Bruit? $262 \underbrace{10}_{(4)}$ Yes $\Box 1$ No $\Box 2 \underbrace{10}_{10}$ | 263 |
| | Other (Specify)? (19) (5) Yes \Box 1 No \Box 2 | |
| ۱. | EXTREMITIES | |
| | Pitting ankle edema?(1) Yes □ 1 No □ 2(/40) | 265 |
| | Femoral bruit? ((2) Yes □ 1 No □ 2 | |
| | Any peripheral pulses 266 absent or markedly diminished (specify | |
| | location)? $267(12)(3)$ Yes \Box 1 No \Box 2 | |
| | | 268 |

8. PHYSICAL EXAMINATION (continued)

| rea | Examined | | | | | | | | | | | Co | mments |
|-----|--|-----------------------|------------|-------------|-----|-------------------|----------|----|----------------------|--------------|-----------|----|--------|
| • | NEUROLOGICAL (U | A = u | nable | e to a | sse | 5S) | | | | | | | |
| | Gait | | | | | | | | | <u>م</u> و (| 39 | | |
| | Left hemiparetic? Right hemiparetic? | (1) (2) | | | | □ 2 □ 2 | UA UA | | | | 70 | | |
| | Walking on toes | | | | | | | | $\tilde{\mathbf{C}}$ | / \ | | | |
| | Left weakness? Right weakness? | (3) (4 <u>)</u> | | | | □ 2 □ 2 | UA UA | | | | 71 | | |
| | Walking on heels | <u>}</u> 273 | | | | | | | U |) 27 | 2 | | |
| | Left weakness? | $\mathcal{Y}_{(5)}$ | Yes Yes | | | □ 2 □ 2 | UA UA | | | | | | |
| | Stationary 30 secon | ds 274 | 4 | | | | | | | | | | |
| | Eyes closed? Eyes open (only if unable to do | 275 | | | | Cannot | | | | | | | |
| | with eyes closed | (⁸) | Can | do 🗆 | 1 | Cannot | do | | 2 U | | 3 | | |
| | Cranial nerves | 276 | | | | | | | | | | | |
| | Facial weakness left? 277 Facial weakness | | | 01 | No | 02 | UA | ۵ | 3 | | | | |
| | right? 278 Visual field deficit | 3)(10) | Yes | 01 | No | □ 2 | UA | | 3 | | | | |
| | Left side? 279 | (12) | Yes | _ 01 | | □ 2 □ 2 | UA UA | | \sim |)28 | 30 | | |
| | Motor wrist extense | ors 29 | 80 | | | | | | S. | " | | | |
| | Weakness left? Weakness right? | b (13) (14) | Yes | □ 1 □ 1 | | □ 2 □ 2 | UA UA | | | 28 | 3 | | |
| | Coordination | D 282 | 2 | | | | | | | 1 | | | |
| | Left hand patting? Right hand patting | | | | | Normal Normal | | | |] 3 3 | 99) | | |
| | Reflexes | _ | | | | | | | | 2 | 84 | | |
| | Assymetry of Patellar tendon | 40 (17) | L>R | 2 0 1 | | jual □ 3 \ □ 4 | | | \mathcal{C} | | | | |
| | Babinski sign left? Babinski sign righ | | Yes | . 🗆 1 | No | | UA UA | | | Ś | 86 87 | | |
| | Other | | | | | | | | Ċ | | 01 | | |
| | Any speech or language problems (specify) | ? (20) | Yes | ; 🗆 1 | No | 0 - 2 (43 |) 2 | 88 | | | | | |

n. OTHER PHYSICAL FINDINGS (SPECIFY):

1/0

o. Clinician's signature:

9. CLINICIAN'S JUDGMENT AND EXCLUSION CRITERIA REVIEW

To be completed by the clinician using information from the participant's history and from the physical examination. These are clinical data for study eligibility determination as well as analysis at the Coordinating Center and they should reflect the clinician's interpretation of the findings. The study eligibility questions are identified with \triangle . These questions must all be covered prior to scheduling the participant to return for Baseline Visit 2. Pertinent items on the Baseline Medical History (SH04) are listed with the section headings.

Hypertension - SH04 Items 2, 55

a. On the basis of your history and physical exam, do you believe that the participant 292 has ever had malignant hypertension? (146) Yes □ 1 No □ 2

Angina Pectoris - SH04 Items 4, 42

On the basis of your history and physical Ь. 293 exam, do you believe that the participant has angina pectoris? Yes 🗆 1 No 🗆 2 Note: The Rose Questionnaire for angina (from SH04) is positive if: Either 42a or 42b is "Yes," and either 42c or 42d is "Yes," and 42e is "Stop or slow down," and 42f is "Yes," and 42g is "10 minutes or less," and either 42h(1) is "Yes," (X placed in Sternum upper, middle or lower) or both 42h(2) and 42h(3) are "Yes" (X in both left anterior chest and in left arm).

290 - 291

Code

Myocardial Infarction (MI) - SH04 Items 3, 43, 44, 54

| | | ······································ |
|-------------|--|--|
| c. | On the basis of the ECG and your history and physical examination, do you believe the participant has ever had a myocardial | |
| | infarction? 294 Yes \Box 1 No \Box 2 | |
| | | |
| | SKIP to e. | |
| d. | Was it in the past 6 months? 295 49 Yes \Box 1 No \Box 2 | \bigotimes |
| e. | Is there a history of coronary bypass? (56) Yes 🗆 1 No 🗆 2 | |
| | | |
| | SKIP to g. | |
| f. | Was it in the past six months? 297 (5) Yes \Box 1 No \Box 2 | \circledast |
| Con | gestive Heart Failure - SH04 Item 47 | |
| g. | On the basis of your history and 298 \Box 1 Yes, controlled physical examination, do you believe that the participant has had congestive \Box 3 No heart failure during the past year? | ⊲ ↔ |
| ECC | 3 | |
| | | |
| h. | Are any of the following present? (153) 299 | |
| | (1) Atrial fibrillation or flutter? (2) Second or third degree A-V block? (154) Yes □ 1 No □ 2 | |
| | (3) VPBsmultifocal, pairs or runs, 300 |)1 (1) |
| | or more than 10% of beats? (4) Bradycardia (<50 beats/min.)? Yes □ 1 No □ 2 (5) Yes □ 1 No □ 2 | |
| • | | |
| i. | Does the participant currently have a pacemaker? 303 57 Yes \Box 1 No \Box 2 | \Re |
| Vas | scular System - SH04 Items 45, 48, 54 | <u> </u> |
| | | |
| j. | Is there a history of ∨ascular surgery? (159)Yes □ 1 No □ 2 | |
| | 304 | |
| | SKIP to k. | |
| | (1) Aortic, iliac, popliteal or femoral (133) 305 | |
| | bypass or graft? (2) Other (Specify) 306 Wes = 1 No = 2 306 Wes = 1 No = 2 | |
| | | |
| k. | On the basis of your history and physical examination, does the participant have | |
| | arterial disease with tissue necrosis 307 | $\langle h \rangle$ |
| | or related loss of an extremity? | SH06/9 |
| | | 000/0 |



SH06/1

Other Exclusion Criteria

| t. | <u>Alcohol</u> on the basis of your histor and physical examination, do you be the participant currently drinks 6 or more drinks/day, or that alcohol or alcoholic liver disease have been present in the past? | elieve | No 🗆 2 | |
|-----------|--|-------------------|--------|--------------|
| u. | Dementiaon the basis of your hist and physical examination, do you be the participant definitely has any fo of dementia? | elieve 292 | No 🗆 2 | \bigotimes |
| v. | <u>Allergy</u> on the basis of your histor and physical examination, do you b the participant is allergic to one of the SHEP medications? | - | No 🗆 2 | \oplus |
| w. | On the basis of your history and p examination is there any life-threated disease, or other reason which might seriously impair the individual's participation in the SHEP over the next five years? | ~ 325 | No 🗆 2 | |
| | | | | |
| Falls | s and Fractures | | | |
| ×. | Do you believe that the participant has ever had a fracture of: | _ | | |
| | (1) Hip? | 326 (177) Yes 🗆 1 | No □ 2 | |
| | (2) Spine? | 327 (78) Yes 🗆 1 | No 🗆 2 | |
| | (3) Forearm? | 328 (19) Yes 🗆 1 | No 🗆 2 | |
| у. | Do you believe that the participant has had a problem with frequent fa | / / • • • • | No 🗆 2 | |

Result Items marked with () are exclusions if answer is "Yes," or, in the case of CHF (Question 9g), answered "Yes, not controlled," or, in the case of TIA (Question 9n), answered "Yes, based on history and presence of carotid bruit" or "Yes, based on history of two or more TIAs in same location." Based on the information contained in this review: 7. □ 1 The participant remains eligible for the SHEP. [8] $\square 2$ The participant is not eligible for the SHEP. 330 331 - 332aa. Clinician's Signature: Code Ineligible persons should proceed to scheduling area for termination of their participation in the SHEP screening process. Only eligible persons should proceed with serum sample, if required. Baseline Visit 2 may then be scheduled. 10. Does the participant have a history of kidney disease, or protein (at least trace) or blood (at least non-hemolyzed trace) in urine? Yes 🗆 1 02 No T 333 A blood sample may be drawn at local option for local determination of serum creatinine. Document blood draw on front of this form. 3-8 BATCH DATE 184) RECORD TYPE DATE MODIFIED 11-16 DATE RECEIVED 335-340 185 (DUPDATE NUMBER 341-343 TIME MODIFIED 17-20 EDIT STATUS 21 DATE LAST PROCESSED 187 344-349 PAPER COPY 350

Keypuncher code 1-2 Verifyer code 9-10

351

CROSS FORM EDIT

334

| \bigcirc_{30} | FORM NUMBER -32 SEQUENCE 40 |
|---|---|
| | VERSION NUMBER (1) |
| | P ID: $22-23 - 24-27 - 28-295$. Acrostic: $41-46$ Wonth Day Year 7 |
| | TO INITIATING PROCEDURES FOR THIS VISIT, COLLECT, REVIEW AND FE THE FOLLOWING ITEMS. |
| | Consent for Baseline Visit 1 (and Baseline Visit 2, if allowed) SH02, Participant Information Sheet SH03, Demographic Information and Medication History Item 5 (page 2 of this form), Summary of Initial Contact and Drug Evaluation Visits |
| LEAVES. SURE T LEGIBLE PROCEDI | , |
| 4. a. | <u>Procedures completed</u> : \Box 1 None, participant not BP eligible (skip to 4b). |
| 352 (19) | $\begin{array}{c c} \underline{Yes} & \underline{No} & \underline{101} \\ \hline (1) & \Box & 1 \\ \hline (2) & \Box & 1 \\ \hline (2) & \Box & 1 \\ \hline (3) & \Box & 1 \\ \hline (3) & \Box & D \\ \hline (3) & \Box &$ |
| 103 (كمل | $\begin{array}{c} (2) \\ (3) \\$ |
| 104 (25 | $V(5) \square 1 \square \square 2 \forall \forall I \text{ local determination of serum creatining (SH11)}$ |
| b | Result of this visitplease check entire form carefully for eligibility: |
| 105 (ab) | 1 Participant is not eligible for Baseline Visit 2 (skip to 4d). 2 Participant is eligible but currently refuses Baseline Visit 2 (skip to 4d) 3 Participant is eligible and Baseline Visit 2 scheduled. 4 Participant was eligible and scheduled for BV2 but became ineligible or died or refused prior to BV2 (explain in Comments, Item 4d). |
| c. 106-111 | Baseline Visit 2 scheduled: Month Day Year at Hour Minute a.m. [] 1 p.m. [] 2 P.m. [] 2 116 |
| d. | Comments:112-115 |
| | |
| e. | Signature of person completing this section: |

SUMMARY OF INITIAL CONTACT AND DRUG EVALUATION VISITS--Copy from Initial Contact Form SH01, Participant Information Sheet SH02 and, if applicable, Drug Evaluation Visit Summary SH05:





PULSE AND BLOOD PRESSURE--If any pulse or blood pressure is not obtained, enter all 9s in the appropriate spaces.



d. Eligibility check (use average of two corrected seated readings):

-- 1 SBP 150-219 and DBP <95 mm Hg

Eligible

□ 2 SBP < 150 or SBP \ge 220 or DBP \ge 95 mm Hg \rightarrow

□ 2

Not blood pressure eligible

207-208 66 _____ Code

e. Observer:___

206

Ineligible persons should proceed to scheduling area for termination of their participation in the SHEP screening process.

Only blood pressure eligible participants should proceed with the remaining items in Baseline Visit 1. If the Baseline Medical History (SH04) has not been completed, it must be completed at this time.

PARTICIPANT SHOULD NOW BE SENT FOR ECG, TWO-MINUTE RHYTHM STRIP AND DIPSTICK URINALYSIS.

7. a. Does the participant have a history of kidney disease, or protein (at least trace) or blood (at least non-hemolyzed trace) in urine? **333** $\int \alpha \gamma$

Yes □ 1 No

A blood sample may be drawn at local option for local determination of serum creatinine. Document result on Local Laboratory Results, SH11, with dipstick urinalysis results. If a blood sample is drawn, hold this form and final determination of eligibility until local creatinine result is obtained.

| 440 | b. Was a blood sample drawn for Yes □ 1 No □ 2 → | local determination of serum creatinine? |
|-----|---|--|
| 441 | c. Local creatinine result: | → Ineligible |
| | $2 \square$ Creatinine $\leq 2.0 \text{ mg/dl}$ | → Eligible |

CLINICIAN REVIEW OF MEDICATION HISTORY--To be completed by clinician using information from the Baseline Demographic Information and Medication History Form, SH03. Do not count drugs that the participant discontinued in order to participate in the SHEP.

8. Is the participant taking any of the drugs listed below? Drugs marked with an * are exclusions if checked "Current." Current Not Current (last 2 or weeks) Not Sure * a. Any medication for blood pressure, 209or any drugs with antihypertensive action (including Neptazene and Diamox) 02 210 Digitalis b. J 2 п 1 211 Nitrates, including nitroglycerine, c. or other coronary vasodilator □ 2 (Continued on next page)

| CLINICIA | N REVIEW OF MEDICATION HISTORY (Conti | inued) | |
|---------------------------------------|--|--|----------------------|
| | | Current | Not Current |
| | | (last 2 | or |
| | | weeks) | Not Sure |
| * d. | Propranolol or other beta blockers | | |
| | for other than treatment of blood pressure | | |
| | (excluding Timoptic eye drops) 212 | $70)_{31}$ | □ 2 |
| e. | Timontic eve drons | \swarrow $\frac{1}{2}$ $(220)^{442}$ | □ 2 |
| f. | Anti-arrhythmic drugs 213 | $71) \circ 1$ | □ 2 |
| g. | Lipid-lowering drugs, including | | |
| 5 | clofibrate, cholestryramine, colestipol, 214 (| 22 | |
| | nicotinic acid, etc. | 1 L $1 L$ | □ 2 |
| h. | Agents for gout, including probenecid, | 215 | |
| | allopurinol or colchicine 216 | $\bigcap \square (13)^{210}$ | □ 2 |
| * i. | Insulin | [4])□ 1×017 | , 🗆 2 |
| j. | Oral hypoglycemic agents | $(1)^{\circ} (15)^{217}$ | □ 2 |
| * k. | Anticoagulants 218 | 76) - 1 - 1 | □ 2 |
| ١. | Antibiotics or anti-infection agents | × 1(77)21 | 9 02 |
| m. | Cortisone or other gluco corticoids 220 | $ 1 \cup 1 $ | □ 2 |
| n. | Amphetamines or other stimulant | 18 1 1 (19) 221 | |
| ο. | Flurazepam or other sedative 222 | | □ 2 |
| р. | Anti-depressants 222 | $80 \square 1 \bigcirc 1 \bigcirc 1 $ | |
| q. | Librium, valium or other antianxiety agents | $\overset{\circ}{\succ}$ $\overset{\circ}{}_{1}$ $(81)^{223}$ | |
| r. | Other psychotropic agents 224 (| 81 10 2 | □ 2 |
| s. | Potassium supplementation other than \ | $\binom{81}{2}$ (83)225 | |
| | dietary recommendations 226(| | □ 2 |
| t. | Estrogen 🔬 🔰 | 84) - 1(85) 227 | |
| u. | Anturane [®] (Sulfinpyrazone) at least 4 week Persantine [®] (Dipyridamole) at least 4 week | | ⊇ 2(۶ ۲)228 □ |
| v. | | 87) - 1 | |
| w. | Aspirin at least 4 weeks 229 | | $^{[2]}_{[2]} 2231$ |
| х. | Non-steroidal anti-inflammatory drugs | (%) [□] ¹ · · · · | |
| * у. | Any experimental drug 230 | □ 1 (2) 144: | 3 □ 2 • |
| · · · · · · · · · · · · · · · · · · · | | | |

If any of 8a, 8d, 8i, 8k, or 8y are marked "Current," the participant is not eligible for participation in the SHEP. Ineligible persons should proceed to the scheduling area for termination of their participation in the SHEP screening process. Only eligible participants should proceed with the physical examination.

<u>PHYSICAL EXAMINATION</u>--The clinician should perform a general physical examination, paying particular attention to the specific items listed below, entering comments for each indicated abnormality.

| 9. | a. Weight in pounds: 232 | 2-234 90 b. Height | in inches: 91 | 36 |
|-----|--|---------------------------------------|-----------------|-----------|
| | Area Examined | | Comments | |
| 10. | SKIN 237 (92) Abr | normal 🗆 1 🛛 Normal 🗆 2 | · | |
| 11. | HEAD, EARS, 238 NOSE, THROAT 93 Abr | normal 🗆 1 Normal 🗆 2 | | |
| 12. | EYES Fundi: a. | Abnormal 1 Normal 2 | 239 | |
| | Other (Specify)? 95 b. | Not Visualized 🗆 3) Yes 🗆 1 No 🗆 2 | | |

(Physical examination continued on the next page)

PHYSICAL EXAMINATION (Continued)

| | Area Examined | | Comments |
|-----|---|-----------------------|----------|
| 13. | NECK | | |
| | Raised jugular 241 | | |
| | Carotid bruits? b. Yes 🗆 1 No 🗆 | 2(97)2 | 242 |
| | 243 98 (Right only □ 1 Left only □ 2 Bilateral □ 3 | | |
| | Carotid pulses absent or markedly diminished? d. Yes □ 1 No □ ↓ | 2 99 2 | 244 |
| | 245 e. (Right only □ 1 Left only □ 2 Bilateral □ 3 | 2 | 246 |
| | Thyroid abnormality? f. Yes 🗆 1 No 🗆 | | |
| | Other (Specify)? g. Yes □ 1 No □ | 2 (102) 2 | 247 |
| 14. | LYMPH NODES Abnormal D 1 Norr | $al \Box 2$ | 3)248 |
| 15. | CHEST, LUNGS | | 2 |
| | Bilateral rales that do not clear with coughing? a. Yes □ 1 No □ | 2 2 104 2 | 249 |
| | Respiratory rate $20+(105)$ b. Yes \Box 1 No \Box | | 771 |
| | Wheezing? 250 c. Yes \Box 1 No \Box | 2(106) 2 | 251 |
| | Other (Specify)? Other (Specify)? Other (Specify)? | 12 | |
| 16. | HEART | | |
| | PMI more than 2 centimeters lateral 253 | | |
| | to midclavicular line (0) a. Yes \Box 1 No \Box | | |
| | Any murmur? 255 $($ b. Yes \Box 1 No \Box | 2 (109) ² | 254 |
| | Third heart sound? (10)c. Yes 🗆 1 No 🗆 | 1^{2} | 256 |
| | Fourth heart sound? d. Yes 1 No 1 | 1 2(U) ² | 290 |
| | Pulse irregular? $^{257}(2)$ e. Yes \Box 1 No \Box | 1^{2} | 258 |
| | Other (Specify)? f. Yes 🗆 1 No 🗆 | | |
| 17. | BREASTS $259(14)$ Abnormal \Box 1 Norr | nal 🗆 2 | |
| 18. | ABDOMEN 260 | | |
| | Liver span 10 cm (15) a. Yes \Box 1 No \Box | 2 | |
| | Abnormal abdominal pulse? 261 (16) b. Yes 🗆 1 No 🗆 | (117) | 262 |
| | Any masses? c. Yes \Box 1 No \Box Bruit? 263(10) d. Yes \Box 1 No \Box | | |
| | | (11a)9 | 264 |
| | Other (Specify)? | 」2 UV | - |

PHYSICAL EXAMINATION (Continued)

| Area Examined | | | | | | | | | | Comments |
|--|----------------------|----------------|------|--------------|------------------|---|----------|--------|-------------------------------|----------|
| EXTREMITIES 26 | 5(1) | | | | | | | | | |
| Pitting ankle edema? | a a | • | Yes | 01 | No | | 2 | \sim | \266 | |
| Femoral bruit? 26 | | • | Yes | □ 1 | No | | 2() | | 200 | |
| Any peripheral pulses absent or markedly dimished? (specify locat | (AL)c | • | Yes | □ 1 | No | | 2 | - | | |
| Other (Specify)? 26 | 8 (123) _d | • | Yes | 01 | No | | 2 | | | |
| NEUROLOGICAL (UA = | unable t | to as | sess |) | | | | | | |
| Gait 269 (1) | 2 | | | | | | | | | |
| Left hemiparetic? Right hemiparetic? | / | 'es 🗆 'es 🗆 | | No [No [| | | UA UA | | | 270 |
| Walking on toes 271 | \ | | | | | | | | Ŭ | |
| Left weakness? | / | 'es 🗆 'es 🗆 | | No [No [| | | UA UA | | F i a | 272 |
| Walking on heels | 、 、 | | | | | | | | \mathbf{O} | |
| Left weakness? 273 (12) Right weakness? | / | ′es □ ′es □ | | No [No [| | | UA UA | | | 274 |
| Stationary 30 seconds | | | | | | | | | $\mathbf{\tilde{\mathbf{v}}}$ | |
| Eyes closed? 30 g. Eyes open (only h. if unable to do 275 with eyes closed) | Can do Can do | | | | | | | | | 3])276 |
| Cranial nerves | | | | | | | | | | |
| Facial weakness 277 |) i. Y | ′es ⊏ | 1 I | No 🛙 | נ <mark>2</mark> | | UA | | 3 | |
| Facial weakness 278 | | ′es 🗆 | 1 1 | No [| 12 | | UA | п | 3 | |
| Visual field deficit | ッ [,] ' | | | | | | 57 | | - | |
| Left side? $279(13)$ | €) ^k ∨ | ′es ⊏ | 1 1 | No 🗆 | 12 | | UA | П | 3 | |
| Right side? | / | es c | | No C | | | UA | | | 280 |
| Motor wrist extensors | 、 | | | | | | | | 9 | |
| Weakness left? 281 (3 Weakness right? | · / | ′es ⊏ ′es ⊏ | | No [No [| | | UA UA | | | 282 |
| Coordination | | | | | | | | | | 009 |
| Left hand patting? o. | Slowed | 01 | No | ormal | | 2 | UA | | | 283 |
| Right hand patting? p. | Slowed | | | ormal | | | UA | | | 284 |

PHYSICAL EXAMINATION (Continued)

| Area Examined | | | Comments |
|--|-----------------------------|----------------|----------|
| Neurological (Continued) (UA = | unable to as | ssess) | |
| $\frac{\text{Reflexes}}{285}$ | | | |
| Assymetry $286 \underbrace{170}_{0} q$ of Patellar tendon | . L>R □ 1 R>L □ 2 | Equal D 3 | |
| Babinski sign left? | $\frac{K}{L} = \frac{1}{2}$ | | |
| Babinski sign right? | | | |
| <u>Other</u> 287 (12) | | | |
| Any speech or language problems (specify)? t. | Yes □ 1 | No □ 2(143)288 | |

21. OTHER PHYSICAL FINDINGS (SPECIFY):

22. Clinician's signature:

CLINICIAN'S JUDGMENT AND EXCLUSION CRITERIA REVIEW--To be completed by the clinician using information from the participant's history and from the physical examination. These are clinical data for study eligibility determination as well as analysis at the Coordinating Center and they should reflect the clinician's interpretation of the findings. The study eligibility questions are identified with \bigotimes . These questions must all be covered prior to scheduling the participant to return for Baseline Visit 2. Pertinent items on the Baseline Medical History (SH04) are listed with the section headings.

Hypertension - SH04 Items 2, 55

23. On the basis of your history and physical **292** exam, do you believe that the participant has ever had malignant hypertension? **292** (146) Yes □ 1

Angina Pectoris - SH04 Items 4, 42

24. On the basis of your history and physical **293** exam, do you believe that the participant has angina pectoris?

3 (147) Yes□1 No□2

No \Box 2

Note: The Rose Questionnaire for angina (from SH04) is positive if:

Either 42a or 42b is "Yes," and either 42c or 42d is "Yes," and 42e is "Stop or slow down," and 42f is "Yes," and 42g is "10 minutes or less," and either 42h(1) is "Yes," (X placed in sternum upper, middle or lower) or both 42h(2) and 42h(3) are "Yes" (X in both left anterior chest and in left arm).





Contraindications and Allergies to Study Drugs



Result

Items 23 through 44 that are marked with are <u>exclusions</u> if answer is "Yes," or, in the case of CHF (Question 27), answered "Yes, not controlled," or, in the case of TIA (Question 34), answered "Yes, based on history <u>and</u> presence of carotid bruit" or "Yes, based on history of two or more TIAs in same location." Please review these criteria very carefully before answering Item 45.

45. Based on the information contained in this review:

 $\left(\right) \square 1$ The participant remains eligible for the SHEP.

 \sim (\Box 2 The participant is not eligible for the SHEP.

330

46. Clinician's signature:

331-332 Code

Ineligible persons should proceed to scheduling area for termination of their participation in the SHEP screening process. Baseline Visit 2 may then be scheduled for eligible persons.

