SECTION 4. SCREENING VISITS

The purpose of the screening period is to identify participants who are eligible for and interested in the AASK Study. U.S. citizens or non-citizens with a permanent residency visa, who are African American with a history of hypertension, treated or untreated, aged 18-70 years who express an interest in the trial are eligible for screening. Patients may be screened through October 31, 1997. The majority of potential study participants are likely to be identified by chart screening. In addition, potential study participants may be identified through other means (e.g., mass mailing, advertisements). Eligible and interested participants will be scheduled for clinic screening visits.

The screening visit 1 (SV1) is intended to (1) introduce potential participants to the research staff and protocol, (2) assess their interest in the trial and (3) determine basic eligibility (medical history, certain laboratory studies). The screening visit 2 (SV2) continues the determination of participant eligibility for entering subsequent phases of the study. SV2 should be scheduled no more than 3 weeks after SV1 whenever possible.

For certain participants, SV1 and SV2 may be combined into one visit, at the discretion of clinical center staff and investigators. The data collection and eligibility of all participants entered into screening will be tracked using Eligibility Report #54, which is included in the forms manual.

4.1 Screening Visit 1 (SV1)

Those participants who are still eligible for the trial after completing chart pre-screening or personal pre-screening (in person or by telephone) can be scheduled for this screening visit.

1. Prior to the visit, the study coordinator or designee should:

Decide if this visit will be an SV1 or combined SV1/SV2 visit (see item 4.3 for a description of the combined screening visit). A combined SV1/SV2 visit can be considered for persons who are likely to be blood pressure eligible and who are known to have impaired renal function (past documentation of elevated serum creatinine, impaired creatinine clearance, or reduced GFR).

If it is an SV1, make sure the AASK Participant Handbook, Consent Forms, and SV1 Form (Form 02), are available.

2. At the SV1 visit the participant will:

a.Receive information about the study including the AASK Participant Handbook.

b.Be introduced to members of the study team.

c.Read (or have read to him or her) the AASK informed consent form. At most centers, the participant will be asked to sign the form prior to data collection at SV1. If the participant declines to sign the consent form, he or she should be asked to identify the major reason(s). Then, the person should be thanked for having undergone screening up to this point.

d.Fill out Form 1 (if not already completed) and Form 2.

3.The participant should be scheduled for the second screening visit (SV2). The second screening

visit will usually be about one week later. It is suggested that it should be no more than 3 weeks later than the SV1. The scheduling can be planned so that the results of serum creatinine or other local SV1 laboratory studies are available. This may be especially relevant for persons with hypertension but unknown renal function.

4.After the visit, the study coordinator or designee should complete Form 2, and make sure it is entered and rekey verified.

4.2 Screening Visit 2 (SV2)

Those participants still eligible and interested in AASK after the first screening visit (SV1) will be scheduled for the second screening visit (SV2).

1. Prior to the visit, the study coordinator or designee should:

a.Check any local values of plasma creatinine, creatinine clearance (if available), serum potassium or WBC.

2.At this visit, the participant will:
a.Sign the first informed consent statement (if not previously signed).
b.Have blood pressure recorded (Form 10).
c.Provide medication and additional information (Form 4).
d.Have an annual physical examination (Form 12).
e.Have baseline form filled out (Form 4).
f.Have an EKG performed (Form 14).
g.24-hour Urinalysis (Form 19 (can be completed at SV2 or G1) or anywhere in between, and is labelled B-1.
h.Local whole blood tests (Form 13)
i.Central serum tests (Form 22)
j. Complete a short-form health survey (Form 80)

3.After these data are collected, the study coordinator or designee should:
a.Review Form 04
b.Ship serum to the Central Lab.
c.Send whole blood and urine specimen to the local lab.
d.If the person remains interested and appears eligible, schedule the participant for the next follow-up visit. Consult the Eligibility Checklist (Report 54) to determine which visit is appropriate.
(1)If participant is on blood pressure medications and has had a qualifying BP at SV2, the next visit is G1. The screenee should be given instruction for a GFR and be informed that this visit will take the whole morning. (Note: The GFR test should not be performed until Report 54 shows the patient is eligible for a GFR.)

(2)For participants who are not on BP medications and have had 2 qualifying blood pressures, the next visit will be G1 (usually 1 week later, with a suggested range from 1-3 weeks) in which case the screenee should be given instruction for a GFR and be informed that this visit will take the whole morning. (Note: The GFR test should not be performed until Report 54 shows the patient is eligible for a GFR.)

(3)For participants who are on blood pressure medications and who have not had a qualifying blood pressure, the next visit is BT1. Instruction for reducing the dosage of medication may be given now.

e.Give instructions for the G1 collection of 24-hour urine, and a 4-liter container with 250 ml of 5% acetic acid added for collection of a 24-hour urine. The participant should be instructed to bring the urine to a subsequent scheduled visit (usually G1) or to an unscheduled visit for special drop-off. At the G1, the urine volume should be recorded. A 5 ml aliquot should be refrigerated and then sent to the Central Biochemistry Laboratory within one week of collection. The urine will be shipped to the Central Laboratory (Form 23) and labelled as the B1-0 urine.

To correct a measured calculated creatinine clearance (ml/min) for body surface area (BSA), use the following formula:

$$\text{Creatinine clearance (ml/min/1.73 m}^2\text{)} = \frac{\text{Creatinine clearance (ml/min) x 1.73}}{\text{BSA}}$$

To calculate BSA, use the following formula:

$$\text{BSA (m}^2\text{)} = [W^{0.425} \times H^{0.725} \times 71.84]/10{,}000 \quad ,$$

where W = weight in kilograms, and H= height in centimeters.

4. After the visit, the following must be done:

a.Enter and rekey verify the forms.

4.3 Combined Screening Visit (SV1/SV2)

1.A combined screening visit can be considered for persons, generally known to the investigator, who likely have hypertension-related renal disease and who likely will be eligible. At the combined SV1/SV2 visit, the screenees must:

a. Sign informed consent statement
b. Receive the AASK Participant Handbook
c. Complete the Personal Contact Pre-screening form (Form 02)
d. Have BP (Form 10), weight and height recorded
e. Complete the Medications List (Form 04)
f. Complete Baseline (Form 04)
g. Have an annual physical examination (Form 12)
h. Have laboratory studies drawn (Forms 13 and 22)
i. 24-hour Urinalysis (Form 19) (can be completed at SV2 or G1)
j. Receive instructions for collection of a 24-hour urine.
k. Have an EKG (Form 14)
l. Complete a short-form health survey (Form 80)

2. After these data are collected, the study coordinator or designee should:

a. Review forms 01, 02, and 04 for eligibility.

b.If the person remains interested and appears eligible, schedule the participant for the next follow-up visit.

(1)For participants who are now BP eligible, the next visit will be G1 (usually 1 week later but can be 1-3 weeks), in which case the screenee should be given instructions for a GFR and be informed that this visit will take the whole morning. The screenee should be given instruction for a GFR and be informed that this visit will take the whole morning. (Note: The GFR test should not be performed until Report 54 shows the patient is eligible for a GFR.)

(2)For participants who are on blood pressure medications and who have not had a qualifying blood pressure, the next visit is BT1. Instruction for reducing the dosage of medication may be given now.

3. After the visit, the following must be done:

a. Review/Edit relevant forms. Key enter and rekey verify.

4.4 Doing the "B1" 24-Hour Urine During Screening

If desired, the G1 urine (labelled B1) may be done at either SV2 or G1. This allows you to check the urine protein/serum creatinine ratio of the patient. The Form 23 urine mailing form should be labelled visit number B1. The date sample collection began may be at, before, or after the SV2 visit. (Note: If the urine is done at SV2, you should not do a second 24-hour urine on the day of the G1 GFR.