SECTION 20. STUDY COORDINATOR

20.1 Introduction

The AASK Study Coordinator plays an integral role at each Clinical Center of the AASK Study. Working with the Principal Investigator and Co-Investigator, insuring that the entire study runs smoothly and the protocol is being implemented correctly to collect quality data. The Study Coordinator must promote a team approach and work closely with all staff which may include the following:

Recruitment Coordinator or staff who have been identified to implement successful strategies to recruit study eligible participants. It is of the utmost importance for staff to establish effective communication with community resources and interdepartmental resources at one's institution. The coordinator will play a key role in establishing an ongoing interaction with recruitment sources.

Secretary and or Receptionist or staff whose responsibility it is to schedule participants to maintain adherence to follow up visits within the designated window.

Blood Pressure Technician or staff responsible for collecting blood pressure measurements using the AASK Blood Pressure Protocol. This individual must be certified by a certified trainer and observed at least bimonthly and recertified annually. The coordinator must ensure that all staff taking blood pressures are accurately following the protocol and that the appropriate forms are being completed. It is also the coordinator's responsibility to make sure that all staff are up to date on certification.

GFR Technician or staff performing AASK GFR's. This individual must be trained and certified centrally before they can perform AASK GFR's. The coordinator will be responsible for careful monitoring of GFR's to ensure the accuracy and quality of GFR's being done by all staff at this clinic.

Data Entry personnel who are responsible for entering all data. The coordinator must see that the data entry is done in a timely and accurate fashion.

The AASK Study Coordinator is responsible for maintaining up-to-date certification for all personnel and maintenance calibration of random zero sphygmomanometers.

All AASK Study Coordinators must attend central training and recertification in order to be certified to participate in the AASK Study. This training assures that all Coordinators are properly trained and that data is collected in a uniform and standard fashion at all centers. At the training, Study Coordinators are trained and certified in several areas: form completion entering data in the oracle database and responding to data discrepancy inquiries. Those who will be Blood Pressure Supervisors are also trained in measuring blood pressure using random-zero sphygmomanometer and will be responsible for following and maintaining the AASK BP protocol. The Coordinator will work on counseling for adherence and for eliciting information from study participants in a uniform

manner and maintaining good adherence performing GFR's.

The Coordinator must be trained and ready to handle all aspects of the study in the absence of other personnel. If the Study Coordinator should leave the position before the completion of the study, he/she should train their replacement (if at all possible). Any new Study Coordinator must be certified at central training session at the Data Coordinating Center.

Each Study Coordinator must be thoroughly familiar with the Protocol and Manual of Operations and must keep copies current by inserting any revised pages, and is also responsible for maintaining copies of all study correspondence. The Coordinator is also responsible for making sure that all IRB communication and approval are achieved and that all correspondence is maintained. He or she will serve on the Study Coordinator's Subcommittee and will act as a liaison between the clinical center and the DCC, making sure that needed information reached the appropriate persons. He/she will work with other Study Coordinators in the development of good study practices.

20.2 Participant Instructions During Baseline

Study Coordinators assume the primary role of assuring that participants are instructed in the goals and responsibilities of the AASK Study. This includes making sure that all participants have signed the informed consent at the appropriate time. In cases where the coordinator serves as the Blood Pressure Technician, he or she will do all of the instruction; however in cases where the Coordinator is not the Blood Pressure Technician, he/she will work closely with this person to ascertain that all Baseline procedures are carried out.

The study Coordinator is responsible for making sure that an AASK Study file is established for every participant who enters the Baseline period. This file includes all study forms for each participant and all other pertinent medical history information.

20.3 Randomization and Initiation of Follow-up

Following the signing of informed consent, completion of all baseline procedures, submission of all baseline forms to the DCC, and fulfillment of eligibility requirements, the Study Coordinator will interactive randomization programs for a randomized treatment assignment. Although the Study Coordinator has the primary responsibility for processing the randomization request, other persons who have been trained and certified by the DCC may randomize participants when the Study Coordinator is not available.

Before accessing the interactive randomization program, the Study Coordinator should make certain he or she has the Eligibility Report for Randomization (Report 57 and Form 52). These items are needed to randomize each participant. If the participant is eligible, the assignment is populated by the database upon verification of Form 52.

Randomization of the participant to their medication assignment and blood MAP goal marks the participant's official and irrevocable entry into the follow-up period. Once a participant has been randomized, it is the Study Coordinator's responsibility to conduct all evaluations irrespective of the participant's compliance to the assigned drug regimen or blood pressure MAP goal. The Coordinator must continue efforts until termination of the follow-up period. The DCC will provide a follow-up appointment schedule which will include the visit windows for each participant visit.

20.4 Monitoring and Promoting Adherence

Adherence promotion strategies utilized in the AASK Study must be implemented by the Study Coordinator. The Study Coordinator must try to maintain that all staff interactions with the study participants are consistent with maintaining a general environment intended to promote adherence. Each participant should be given an individualized plan for lifestyle modification at the appropriate protocol visits. Participants should also be given educational material if any lifestyle modification is required. Review of this material should be done by the Study Coordinator or if necessary by a dietitian or other staff.

20.5 Hospitalization and Death Procedures

Adverse events are defined as significant clinical events which are potentially related to the intervention of death.

The Study Coordinator is responsible for completing the Hospitalization Form 44 for an adverse event requiring hospitalization. When a participant is hospitalized or experiences an adverse event, the Study Coordinator must notify the DCC in a timely fashion by the submission of the Hospitalization Form 45. If a participant refuses to be hospitalized, this should be noted in the clinic chart. The Coordinator may be asked to provide primary documents such as the hospital discharge summary to the DCC at the request of the Clinical Management Subcommittee.

All deaths will require the Study Coordinator and Study Physician to notify the DCC immediately via the Death Notification Form 48.

The Study Coordinator will also be responsible for sending the DCC any primary paper documents surrounding the death. These include death certificates, autopsy reports, and hospitalization discharge summary if death occurred in the hospital.

20.6 Stop Points

It is the Study Coordinator's responsibility to complete a Stop Point Form 30 in the event of a stop point. A stop point denotes the occurrence of an event which necessitates unblinding or altering one of the two interventions in the study (i.e., cessation of the coded medication or

cessation of one of the two levels of blood pressure control). The Coordinator must continue to schedule follow-up visits according to protocol. Outcome measures are documented in the same fashion as if there had been no stop point. If for example, the participant can no longer take a study drug but can still safely be in their assignment blood pressure group, every effort should be made to keep this participant at his/her assigned blood pressure goal. For off AASK medication, the Coordinator will be notified every three months by the DCC with an "Is it possible to restart" report to remind the clinic to consider restarting the study drug.

20.7 Ordering and Filing Data Forms

The Study Coordinator is responsible for maintaining updated data collection forms to be used by the clinic.

20.8 Electronic Mail (E-Mail) Files

The Study Coordinator is primarily responsible for ensuring e-mail is printed and distributed as needed.

20.9 Logs or Minutes of Staff Meetings

The funded AASK Staff members at each clinic should meet regularly during the Study. Weekly meetings are recommended. The Study Coordinator should keep a log of when these meetings were held, who attended, and any major issues raised or resolved.

20.10 Study Site Visit

Site visits are to be made to each clinical centers in years 1 and 2. The Study Coordinator will play a key role in preparing staff for the site visits. The primary goals of the site visits are: to raise/improve communication between the study administrator, the clinic personnel and the DCC; to demonstrate the study's concern for quality of data collection, to discuss pressing current issues such as recruiting or adherence.

Site visit teams consist of a DCC staff member familiar with the AASK protocol and blood pressure requirements and a NIH representative. A member of the GFR lab staff may be included as well as a Study Coordinator from another clinical center.

Throughout the course of the study, each Clinical Center's performance will be monitored by a series of reports. These include reports of enrollment, number of missing forms, rates of invalid data, rates of patients list to follow-up, and number of missed visits. These reports will routinely be sent to the Clinical Centers, the Steering Committee, and the NIH Program Office.

20.11 Emergency Unblinding Procedure

The emergency unblinding procedure is outlined in Section 18 of this manual.