SECTION 16. SITE VISITS

Special committees will be formed to site visit the clinical centers on a regular basis, at least once during the full-scale trial. The exact membership of these committees will be determined by NIDDK. They are expected to include a representative from the Data Coordinating Center, a representative from NIDDK, a compliance and retention expert, a blood pressure certification expert and a representative from the AASK External Monitoring Committee. A principal investigator from another clinical center (not the one being site-visited) and the Chairman of the Steering and Planning Committee may be included.

Site visits will be scheduled well in advance, with mutual agreement on the timing and the agenda of the meeting between a Clinical Center's Principal Investigator and the site visit team. It is the responsibility of the Clinical Center's P.I. and study coordinator to ensure that appropriate staff are available to meet with the site visit team as scheduled. These may include institutional support personnel and local laboratory personnel as well as Clinical Center staff. If it is necessary for the team to go to more than one physical location, the clinic study coordinator should arrange for them to be escorted there.

The Clinical Center staff should prepare for the site visit by making sure that their files and records are well organized and patient records can be easily found. Some random checking of patient records against the submitted AASK forms will occur. All log books recording data or information transmission to and from the central labs and to and from the DCC should be available for viewing. If there are special sources of concern for either the DCC or other members of the site visit team, the clinical centers will be apprised of them in advance of the actual visit in order to allow the clinical centers time to prepare responses on those issues.

The sorts of issues that will typically be of concern to the DCC representative are recruitment problems, compliance problems, high frequencies of missed visits, difficulty with getting participants to the GFR visits, delays in query responses, missing data forms, unusually prolonged time intervals between visits (beyond the allowable windows), missing consent forms, missing data/incomplete forms, out of expected range laboratory values, missing or slow responses to queries, inaccuracies in values recorded on forms, major inconsistencies between values recorded from local laboratory tests when compared with those from the central laboratory and large fluctuations in laboratory results or clinical findings across several successive visits. The lists of forms transmitted to and received by the DCC should match. Adequate time should be allocated for these types of questions to be addressed.

The Clinical Center should provide some summary information on each of its participants. This should include their stage in the recruitment/screening/baseline/randomization processes, demographic information (age, sex, education level), concomitant illnesses, randomized assignments, success at attaining

blood pressure goal and number of medications required, compliance and such information as is available to them regarding renal function status at study entry.

Time will be allowed at the site visit for the Clinical Center staff to bring forward any issues with which they would like to discuss with the site visit team These might include difficulties in communications or shipments with any of the central laboratories, the drug distribution center or the Data Coordinating Center. They may also ask for suggestions for resolving local problems.

The site visit team will meet in executive session at the end of the site visit in order to provide feedback to the Principal Investigator. The results will be formalized in a written report about one month following the visit.