# SECTION 2. CLINIC MANAGEMENT

## 2.1 Recommendations for Space

Office, storage, and patient care space will be different at each clinical center. Adequate space to see participants, to complete and store forms, to file or store participant records, and for private workspace for team members must be available. Thus the goal is to have organized and efficient use of available space to facilitate successful implementation of the study.

Each clinical center will need space for the following:

### 2.1.1 Patient Care Space

Many clinical centers will have the use of an outpatient clinic, hospital facility, or Clinical Research Center (CRC). If possible, the patient care area should be convenient for participants and near a parking facility and/or public transportation. A room that is quiet and free of distractions must be available for blood pressure measurements. GFRs should be done in a comfortable room which has a sink and a restroom nearby. A private and quiet room is necessary for examinations and counseling. A centrifuge for spinning blood, a refrigerator to store blood and urine samples, a work table/counter with sink for handling and processing blood and urine samples, and an area for storing laboratory supplies and data forms should be in or near the patient care area. It would be helpful to have the pharmacy nearby if medications are stored with the pharmacist. Team members will need work space for forms completion and/or technical duties while seeing participants in the patient care area.

### 2.1.2 Office Space

Adequate space should be available for team members to conduct their work when they are not with study participants. Privacy for phone calls with study participants and for participant conferences is essential. A room to conduct study team meetings should be available. A copy machine, FAX, and computer should be nearby.

### 2.1.3 Storage Space

Space must be available for participant records, data collection forms, medications, and office and laboratory supplies. A file cabinet which can be locked should be convenient to store medications and participant records.

## 2.2 Recommendations for Supplies/Equipment

The Study Coordinator or designated person will be responsible for ordering and maintaining an inventory of supplies sent from the central facilities and those purchased or obtained locally. Supplies will include office and laboratory supplies as well as data forms.

### 2.2.1 Office Supplies/Equipment

Office supplies such as xerox paper, pens, pencils, water proof markers, staples labels, notebooks, dividers, file folders, computer maintenance supplies, etc. should be readily available.

### 2.2.2 Laboratory Supplies/Equipment

Supplies for laboratory functions, processing, and handling should include items from the following list that is comprehensive but not inclusive: urine collection equipment for participants (jug or other collection container, speci-pans, and triangular containers); cylinders for measuring urine (250 mL and 1000 mL or 2000 mL); vacutainer needles and holders, butterflies, and leur locks (orheparin lock) tourniquets and rubber gloves; 3 and 12 mL syringes; gauze, cotton balls, bandaids, alcohol wipes; 9.5 ml serum separator tubes; 7 ml EDTA tubes; 30 ml polypropylene urine mailing tubes; 15 ml polypropylene serum mailing tubes; routine urinalysis conical tubes; tape; armboards (optional); biohazard garbage liners and Sage-Sharps disposables; Fed Ex pouches, ziplock plastic bags, mailing box and styrofoam insert, ice packs, (reusable polar or freezer packs), SSKI, glacial acetic acid, saline, and heparin; thermometers; Pasteur pipettes; pH test paper; distilled water or deionizer cartridge; pregnancy test kits (see below); a champ wrap (optional); and a pill count tray.

For the pregnancy tests that must be done before each GFR for women who have child-bearing potential, the hCG-Combs Kit (Abbot Laboratories) is recommended. Results using the hCG-Combs (Abbott Laboratories) are available within 7 minutes for serum. The hCG-Combs method is a one-step immunoassay using both anti-alpha hCG mouse monoclonal and anti-beta HCG (goat) polyclonal antibodies to identify the HCG hormone at levels as low as 25 mIU/mL. Controls are used to verify sensitivity of the low level detection.

### 2.2.3 Blood Pressure Equipment

Each clinical center will need two MKII random-zero sphygmomanometers plus 2 pounds of mercury, two blood pressure bulbs and control, blood pressure tubing, a dual teaching stethoscope, and a variety of cuff sizes (pediatric, adult regular, adult large, and thigh), height board, weight scale, and a chair with a back on it.

## 2.3 Scheduling of Activities

A system and an organization that will facilitate the orderly and efficient management of multiple activities including administrative, recruitment, patient care, data management, and quality control must be developed. The Study Coordinator will be in charge of these activities but has the authority to delegate when appropriate to team members.

### 2.3.1 Administrative Activities

These activities include: 1) securing adequate space, equipment, and supplies for study needs; 2) developing a working relationship with liaisons such as pharmacist, clinic and/or CRC non-study staff, and personnel from pathology, local laboratory, ECG lab, nuclear medicine and radiation safety, medical records, participant registration, and billing/accounting; 3) ordering and maintaining a supply and the storage of study medications; 4) communicating with referring physicians about participant test results and updates; 5) coordinating study activities with consortium institutions, if appropriate; 6) scheduling clinic appointments that are compatible with the participants, staff schedules, and clinic/CRC schedules and available space; and 7) arranging for reimbursement for participation fee and/or fee for parking and transportation.

The liaison personnel must be informed about the study goals and provide information about the procedures pertinent to their role in the study. The Study Coordinator will notify team members of AASK activities and facilitate study-related communication and problem-solving. Team meetings should be scheduled at least on a monthly basis and more when needed. The Study Coordinator will be responsible for ensuring that Protocols, Manuals of Operations, and data forms are current. Every effort should be made to create a clinic setting in which workspace, workloads, and communication will facilitate conducting the trial as efficiently and effectively as possible.

### 2.3.2 Recruitment Activities

The Study Coordinator or designated person will coordinate and implement strategies to ensure that recruitment goals are met and enrollment proceeds in an organized manner. Maintaining a log of all participant contacts is encouraged. Enrolling participants in a staged and uniform manner will avoid work overloads for staff.

### 2.3.3 Scheduling Participant Visits

During all phases of the study, special emphasis should be placed on adhering to the participant's target visit window. Participants should be scheduled, if possible, at their convenience but also at a time that is compatible with team and other clinic/CRC activities. Phone calls and/or reminder cards are encouraged to promote adherence to appointments. When visits are missed, attempt to reschedule immediately for an appointment within the window. Special attention should be given to interim visits, making sure participant and staff are aware of these "non-routine type" visits.

#### 2.3.4 Quality Data Collection

The Study Coordinator will review all data forms for completeness and accuracy and to ensure timely submission to the Data Coordinating Center. The procedure for mailing blood and urine samples will be coordinated with the Study Coordinator and technical personnel to ensure prompt shipment to the Central Labs. The Study Coordinator or designated person will monitor and ensure the calibration of blood pressure equipment. Data forms will be filed in an area convenient for study personnel's access. Prior to each visit, appropriate forms will be assembled, headed, and distributed to designated personnel. To ensure that the study has quality data, team members must know the purpose of the study, the protocol design, and the sections of the Manual of Operations that are pertinent to their roles in the study. If protocol expectations and study goals are clear and common to all team members, then protocol adherence by staff will help ensure quality data collection and a pleasant working environment.

## 2.4 AASK Reference Materials

#### 2.4.1 Reference Materials

Each center should maintain four hole-punched copies of the Protocol, Manual of Operations, Forms Manual/Forms Usage Instructions, and Address Directory.

#### 2.4.2 The Paper Copy of the Medication Logbook

The DCC also distributed one paper copy of the Medication Logbook to each center. The paper copy is bound and will not be updated. Updates appear in the computer. Remember how some drugs have more than one NDC number in the paper copy of the medication log book? In some cases, this is because the numbers are for different size packages with different prices.

The first drug code for the drugs that have more than 1 NDC code number for the same dosage of a particular drug may not be the one that you want. The paper copy of the codes doesn't include a column specifying if the medication is in the form of a tablet or suppository.

The example we have found is NDC #00536134012 which shows up in the paper copy of the medication logbook as Aspirin 325 mg. However, if you look on the medication screen for this code or print out a Medication Flowsheet for a patient with this code entered, you'll see that it refers to 325 mg aspirin suppositories. If it is a liquid, you'll see units in ml and if it is a tablet, you'll see units in mg. We didn't include the "form" of the med in the paper books.

Try to either watch the screen during data entry or print and review your patients' Medication Flowsheets to make sure that the correct medication, dosage, and especially form is displayed, and send us an email if you see something that is likely to impact other centers, too.

Depending on whether the form was entered before or after the 7 day window will determine if the CC can change the data or need to initiate a Data Change Request to the DCC.