

## SECTION 13. RANDOMIZATION

In order to be eligible for randomization to a treatment regimen and blood pressure goal, all of the inclusion criteria for the study must be met and none of the exclusion criteria should be met. Many of the items in the checklist will have been evaluated prior to the participant's entering into the baseline period. **Those which may have changed during the baseline period should be reconfirmed prior to randomization.** This includes, but is not limited to, such items as the absence of any disease which might shorten survival or affect renal function, the absence of any condition which might necessitate the use of a randomized drug for reasons other than hypertension, and pregnancy or an increased likelihood of becoming pregnant. (Details on randomization are in the Protocol.)

The concept of a patient dropping out or being lost to follow-up is not encouraged. While every effort should be made to hold all protocol defined visits, it is recognized that this may not always be possible. It is important to continue ongoing discussions with the patients who are having a difficult time meeting the study requirements. If it is not possible to have them come in, one approach may be to give the patient a temporary reprieve. Ask them at a minimum to schedule GFR visits until they can return to the full schedule.