SECTION 17. PARTICIPANT CLOSE-OUT PROCEDURES

When a participant has completed all protocol visits, the Termination/Close-Out Form (to be developed) must be completed.

17.1Normal Study Close-Out, All Protocol Visits Completed

If all protocol visits have been completed and the close-out represents a normal study termination, items 1-7 of the Termination/Close-Out Form # 53 should be completed. Items 8-17 of the form should be left blank. You may, however, add comments on page 4 of that form, if you wish.

17.2Death

17.2.1Participant Death

In the event of a participant death, the Data Coordinating Center is to be notified via Form 48 (Death Notification Form). If the probable cause of death is known at that time, this information must also be reported. It is the responsibility of the Data Coordinating Center to convey this information immediately to NIDDK and to the Chairman of the External Advisory Committee.

As soon as the information is available to complete AASK Participant Death Form #48, this form is to be executed and sent to the Data Coordinating Center. It is especially important to determine, if possible, whether or not the death is study-related, that is, whether it is related to any of the study protocol elements: medications, blood pressure goals, special procedures or clinical management guidelines.

Supporting documentation including copies of the death certificate, hospital records if applicable, follow-up reports and autopsy report if an autopsy has been done should all be filed with the DCC as soon as these become available. The Clinical Center should actively pursue the obtaining of these records in as short a time interval following the death report as is feasible.

The DCC will send copies of all of the participant's executed study forms and death records to NIDDK and to the Chairman of the External Advisory Committee.

In the event that the death appears to be study-related, the Chairman of the Clinical Management Subcommittee will be notified and sent copies of the participant's forms and records.

17.2.2 Participant has reached a Medical Stop Point other than Death

Stop Point Form # 30 must be completed. Every effort must be made to determine whether the occurrence of the Stop Point is related to study clinical management guidelines, treatments protocols, blood pressure goal assignment or special study procedures. When a Stop Point is reached, a GFR should be obtained along with the clinical and laboratory data which would have been obtained at a normal close-out visit. These data should be collected and sent to the DCC as soon as possible following the occurrence of the Stop Point, preferably within two weeks. Outcome measures should continue to be documented after the occurrence of the Stop Point according to protocol as if no Stop Point had occurred.

Medical stop points are listed in Section 11 of the Protocol.

The DCC will notify the Chairman of the Clinical Management Subcommittee of all occurrences of Medical Stop Points.

17.3 Participant Does Not Wish to Continue in Study

Participant drop-out or loss to follow-up does not constitute a reason for close-out procedures. All reasonable efforts should be made to prevent the problem and to entice participants to remain in the study when drop-out seems imminent (see Section 13. Randomization).