AFRICAN AMERICAN STUDY OF KIDNEY DISEASE AND HYPERTENSION
AASK STUDY
CLINICAL CENTER STOP POINT FORM # 30

STOP POINTS CAN ONLY BE DECLARED IN FOLLOW-UP

This form is completed at the Clinical Center. It will be printed out into a "Potential Stop Point Report" including a symptom summary, an adherence report, the medication flow sheet, an action item report and a hospitalization summary. The "Potential Stop Point Report" will be transmitted to the two primary reviewers from the Clinical Management Subcommittee and the DCC.

1. Identification Number.....	2. Name Code.....	3. Date Stop Point Declared: mm/dd/yyyy.....

4. Which stop point does the clinic staff feel the patient has reached? . . . . . __ STOP-PT

0=CC unblinded to randomized meds, but not a stop point
1=GFR Decline
2=Pregnancy
3=Need for a new blood pressure goal
4=Need additional medication for blood pressure control
5=Need additional medication due to a serious medical condition
6=Need to stop blinded medication due to serious medical condition
7=Need to stop blinded medication due to hypotensive side effect
8=Need to stop blinded medication due to other side effects
9=Need to begin dialysis or have a transplant

CC-STOP-POINT

5. If the Clinical Management Subcommittee and the DCC confirm this stop point, will you want to be unblinded? (0=no, 1=yes) . . . . . __ UNBLIND

6. a. Which blinded medication does the P.I. believe the patient was on? (1=ACE, 2=Beta Blockers, 3=Calcium Channel Blockers, 9=couldn't tell) . __ BLND-MED

b. Does the P.I. think this stop point was related to the patient's randomized study blood pressure goal intervention? (0=no, 1=yes, 9=couldn't tell) . . . . __ BP_RELA

c. Does the P.I. think this stop point was related to the patient's randomized blinded drug intervention? (0=no, 1=yes, 9=couldn't tell) . . . . . __ MED-RELA

7. **Required:** Physician's text describing the potential stop point. Please provide complete detail on signs and symptoms, as well as any previous history of these signs and symptoms in this patient. Please provide complete characterization of any episodes of angioedema (including degree and location of swelling, occurrence of hives, rash or itching, and your treatment of any angioedema episode). Write on back of form or use an attached sheet if necessary. (Key enter, but do not rekey verify.)

PHY_TEXT

8. Certification ID of the AASK physician who wrote the text (first letter of first name and first 7 letters of last name; must be in AASK directory) _ _ _ _ _ _ _ _ PHY_CERT

9. Has any original paperwork been faxed to the DCC (i.e., discharge summary, lab reports, etc.)? (0=no, 1=yes) . . . . . __ FAX_DOC

CERTIFICATION

201. Certification ID of person completing this form . . . . . _ _ _ _ _ _ _ _ COMPL-BY
202. Certification ID of person entering this form . . . . . _ _ _ _ _ _ _ _ ENTER_BY

For Clinical Center Use Only

Date Entered __/__/__ **Verified?** _____