PRE-RANDOMIZATION INFORMATION

The variables related to this form are located in the LADS.PRERAND data file.

This form should be completed for all eligible patients who have signed the PEACE Informed Consent and who consent to participate in the run-in.

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A. IDENTIFYING INFORMATION

1. PEACE Center: deleted __ __ __
2. PEACE I.D.: __ __ __ __ __ __ __
   New variable generated - new random ID [NEW_ID]
3. Patient Initials: deleted __ __ __   __ __
   Last        First
4. Today's Date: deleted __ __/__ __/__ __
   Mo    Day     Yr

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B. BLOOD PRESSURE MONITORING

Have the patient sit quietly for five minutes before measuring the blood pressure.

1. Sitting systolic blood pressure [SYSBP] __ __ __ mmHg
2. Sitting diastolic blood pressure [DIABP] __ __ __ mmHg
3. Prior history of dizziness within past 12 months [PHDIZZ] (   1) (   2)
4. Prior history of syncope within past 12 months [PHSYNC] (   1) (   2)

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C. MOST RECENT SERUM CREATININE

New variable generated - estimated glomerular filtration rate - using the 4-variable MDRD equation [EGFR]

Date of most recent serum creatinine deleted __ __/__ __/__ __
   Mo    Day     Yr

If > 1 year old, obtain new measurement. If serum creatinine ≥ 1.5mg/dL (133 µmol/L), recheck after at least one week on study medication.

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D. MOST RECENT SERUM POTASSIUM [SER_POT]

Date of most recent serum potassium deleted __ __/__ __/__ __
   Mo    Day     Yr

If > 1 year old obtain new measurement. If new measurement > 5.5mEq/L (5.5mmol/L), patient is ineligible.

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E. MOST RECENT SERUM CHOLESTEROL [SER_CHOL]

Date of most recent serum cholesterol deleted __ __/__ __/__ __
   Mo    Day     Yr

If > 1 year old, obtain new measurement. Do not wait for new measurement of cholesterol to initiate run-in.
F. BASELINE BLOOD AND URINE SAMPLES COLLECTED

1. Baseline blood sample collected deleted
2. Baseline urine sample collected deleted

G. NUMBER OF CAPSULES DISPENSED deleted

Record the 5-digit run-in period box I.D. number dispensed deleted

Instruct the patient to take the first capsule tomorrow and then daily until the next appointment.

Give patient the instruction sheet and run-in medication. Schedule next visit at least 14 days but no more than 20 days from today.

H. SIGN-OFF

Signature of individual who completed this form

Certification # __ __ __ __ deleted