

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.

A. IDENTIFYING INFORMATION

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

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] | YES NO
(1) (2) |
| 4. Prior history of syncope within past 12 months [PHSYNC] | (1) (2) |

C. MOST RECENT SERUM CREATININE

___ . ___ mg/dL OR ___ ___ μmol/L
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 ≥ 1.5 mg/dL (133μmol/L), recheck after at least one week on study medication.

D. MOST RECENT SERUM POTASSIUM [SER_POT]

___ . ___ mEq/dL OR ___ . ___ mmol/L

Date of most recent serum potassium **deleted** ___ / ___ / ___
Mo Day Yr

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

E. MOST RECENT SERUM CHOLESTEROL [SER_CHOL]

___ ___ mg/dL OR ___ . ___ mmol/L

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

YES NO

(1) (2)

1. Baseline blood sample collected ~~deleted~~

2. Baseline urine sample collected ~~deleted~~

(1) (2)

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

___/___/___ ~~deleted~~
Mo Day Yr

Certification # ___ ___ ___ ___ ~~deleted~~