RANDOMIZATION

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

This form should be completed at the randomization visit.

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)

B. RUN-IN EXPERIENCE (If patient did not return for randomization visit and there are no measurements to record, indicate here and go to B.5.)..... [ ]

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

1. Blood pressure monitoring

   a. Sitting systolic blood pressure **[SSYSBP]** __ __ __ mmHg

   b. Sitting diastolic blood pressure **[SDIABP]** __ __ __ mmHg

2. Since the date of the run-in visit, has the patient experienced: YES NO

   a. Dizziness **[DIZZIN]** (1) (2)

   b. Syncope **[SYNCOP]** (1) (2)

For those patients whose pre-randomization serum creatinine was ≥ 1.5 mg/dL (133 μmol/L) enter most recent . If serum creatinine > 2.0 mg/dL (177μmol/L), patient is excluded. Go to Section E. If pre-randomization serum creatinine was < 1.5, check NA and go to #4.

3. Recheck of serum creatinine deleted NA (1) __.__ mg/dL OR __ __ __ μmol/L

4. Adherence criteria

   a. Number of days since pre-randomization visit deleted __ __

   b. Number of capsules dispensed at that time deleted __ __

   c. Number of capsules returned deleted __ __

Days since date of Pre-randomization visit. deleted	10	11	12	13	14	15	16	17	18	19	20
Maximum number of capsules remaining to attain 80% or more adherence. deleted	12	11	10	9	8	8	7	6	5	4	4

   d. Was the patient's adherence ≥ 80% deleted YES (1) NO (2)

If adherence is < 80% patient is excluded. Go to Section E.

B.5. Medication tolerance (indicate all side effects the patient experienced) since the date of the Pre-randomization visit.

		YES	NO
a.	Skin rash **[SKINRA]**	(1)	(2)
b.	Headache **[HEADAC]**	(1)	(2)
c.	Cough **[COUGH]**	(1)	(2)
d.	Other significant (please print) deleted - rare events _____	(1)	(2)
	_____		
	_____		
	_____		
	_____		
		YES	NO
e.	Is patient willing to continue on medication deleted	(1)	(2)

If patient is not willing to continue medication, patient is excluded. Go to Section E.

C. RANDOMIZATION INFORMATION

1. Weight **[WT_KG]** __ __ __ kg OR __ __ __ lb
2. Height **[HT_CM]** __ __ __ cm OR __ __ __ in
3. Cigarette use (indicate one) **[CIGARE]**
   - current smoker (≥1 cigarette/day) (1)
   - ever smoked (2)
   - never smoked (3)

4. Current Canadian Cardiovascular Society functional classification (indicate one): **[NSYANG]**

No symptoms of angina		(1)
Class I	Ordinary physical activity does not cause angina, such as walking or climbing stairs. Angina with strenuous or rapid or prolonged exertion at work or recreation.	(2)
Class II	Slight limitation of ordinary activity. Walking or climbing stairs rapidly, walking uphill, walking or stair climbing after meals, or in cold, or in wind, or under emotional stress, or during the few hours after awakening. Walking more than 2 blocks on the level and climbing more than one flight of ordinary stairs at a normal pace and in normal conditions.	(3)
Class III	Marked limitation of ordinary physical activity. Walking one to two blocks on the level and climbing one flight of stairs in normal conditions and at normal pace.	(4)
Class IV	Inability to carry on any physical activity without discomfort or anginal syndrome may be present at rest.	(5)

5. Current medication

		YES	NO
a.	Use of calcium channel blocker **[CALCBL]**	(1)	(2)
b.	Use of beta blocker **[BEBLOC]**	(1)	(2)
c.	Use of potassium-sparing diuretics **[POSPDI]**	(1)	(2)
d.	Use of other diuretics **[OTDIUR]**	(1)	(2)
e.	Use of digitalis **[DIGITS]**	(1)	(2)
f.	Use of anti-arrhythmic **[ANARRC]**	(1)	(2)
g.	Use of anticoagulants **[ANTICO]**	(1)	(2)
h.	Use of aspirin or other antiplatelet therapy **[ASANT]**	(1)	(2)
i.	Use of hormone replacement therapy **[HPREP]**	(1)	(2)
j.	Use of lipid-lowering therapy **[LIPLOW]**	(1)	(2)
k.	Is patient known to be diabetic? **[DIABTC]**	(1)	(2)

If yes, (mark all that apply)

Use of insulin **[INSLIN]** (1)
Use of oral agents **[ORAGEN]**(1)
Use of diet control **[DICONL]** (1)

l.	Use of other non-cardiac medication **[MOTHER]**	(1)	(2)
m.	Use of other cardiac medication **[CMOTH]**	(1)	(2)

6. Medical history

a.	History of hypertension **[HIHYPERT]**	(1)	(2)
b.	History of diabetes **[HIDIABET]**	(1)	(2)
c.	History of angina **[HIANGINA]**	(1)	(2)
d.	History of intermittent claudication **[HICLAUDI]**	(1)	(2)
e.	History of TIA **[HITIA]**	(1)	(2)
f.	History of stroke **[HISTROKE]**	(1)	(2)
g.	History of documented MI **[HIMI]**	(1)	(2)

If YES, date of most recent MI **[DATEMI_X]** __ __/__ __ (Mo Yr)

Obtain required documentation as specified in manual; file at clinic.

		YES	NO
h.	History of angiographic coronary disease meeting PEACE eligibility criteria **[HIANGIOG]**	(1)	(2)

If YES, date of angiogram **[DATEANGI_X]** __ __/__ __ (Mo Yr)

i.	History of PTCA **[HIPTCA]**	(1)	(2)

If YES, date of most recent PTCA **[DATEPTCA_X]** __ __/__ __ (Mo Yr)

j.	History of CABG **[HICCABG]**	(1)	(2)

If YES, date of most recent CABG **[DATECABG_X]** __ __/__ __ (Mo Yr)

k. Date of left ventricular evaluation: **[DATEODLV_X]** __ __/__ __
Mo Yr

Documented by: (indicate one) **[LVEDOC]**
contrast ventriculography ..... (1)
radionuclide ventriculography..... (2)
echocardiogram..... (3)

	YES	NO
Is a quantitative ejection fraction available? **[QUANEF]**	(1)	(2)
IF YES, ___ ___% **[LVEEJF]**		
Was the left ventricular function qualitatively abnormal? **[QUALAB]**	(1)	(2)

D. RANDOMIZATION

If patient is eligible, adherent, and willing to be randomized, call 055/5001703 and obtain the four-digit randomization code.

1. PEACE Center: deleted ___ ___ ___
2. Randomization code deleted ___ ___ ___ ___
3. Record drug therapy Kit ID numbers dispensed deleted

   (Under usual circumstances two kits are to be dispensed.)

   Drug Therapy Kit 1 __ __ - __ __ - __ __

   Drug Therapy Kit 2 __ __ - __ __ - __ __

   Drug Therapy Kit 3 __ __ - __ __ - __ __

Send the white copy of this form to ANMCO in the biweekly mailing. Give the patient the instruction sheet and a 6-month supply of medication. Schedule next visit. If the date of next appointment is more than 6 months after today then dispense 3 kits.

Another variable in the LADS.RAND data file is randomized treatment group **[TX]**

0 = placebo

1 = active drug, trandolapril

E. SIGN-OFF

_____ __ __/__ __/__ __ deleted
Signature of individual who completed this form Mo Day Yr

*Certification #*__ __ __ __ __ deleted