FOLLOW-UP VISIT

The variables related to this form are located in the LADS.FOLLOWUP data file or in the LADS.OUTCOMES data file (when noted).

This form should be completed for all Semi-Annual and Annual follow-up visits. Print clearly when entering a response to an open-ended question. Send the white copy of this form to the CSCC in the biweekly mailing.

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. Date of Visit: __ __ / __ __ / __ __ __ __
Mo Day Yr
Recoded - days since randomization **[FORMDATE_FOLLOWUP]**

5. Circle only the visit number representing this visit: **[VISIT]**

Visit Number: (1) (2) (3) (4) (5) (6) (7) (8) (9) (10) (11) (12) (13) (14) (15)

(Study Month) (6) (12) (18) (24) (30) (36) (42) (48) (54) (60) (66) (72) (78) (84) (90)

6. Type of Contact:
Clinic visit *(go to C.1)* (1) deleted
Telephone contact or other source *(go to C.3)* (2)
Missed visit (go to B) (3)

B. VISIT ADHERENCE deleted

1. If the visit was missed and the window has closed, indicate the main reason this visit was missed:
a. Patient did not attend but is still on study medication (Reschedule Visit) (1)
b. Patient did not attend and is off study medication (Continue Telephone Contact) (2)
c. Not able to contact patient (Contact Private Physician or Relative) (3)
d. Patient died (4)

Outcome variables for deaths were based on medical record confirmation and events committee adjudication, and are included in the LADS.OUTCOMES data file:
All deaths **[DEATH]**
Cardiovascular deaths **[CVDEATH]**
Non-cardiovascular or unknown cause deaths **[OTHERDEATH]**

Also included in the LADS.OUTCOMES data file:
Days since randomization to death **[DEATHDT]**
Days since randomization to cardiovascular death **[CVDEATHDT]**
Days since randomization to non-cardiovascular or unknown cause death **[OTHERDEATHDT]**

e. Patient refused further contact (5)

1. STOP HERE AND PLEASE MAKE EVERY EFFORT TO CONTACT HIM/HER AND COMPLETE ANOTHER COPY OF THIS FORM.

C. BLOOD PRESSURE AND SIDE EFFECTS MONITORING

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

1. Sitting systolic blood pressure: **[SSYSBP]** __ __ __ mmHg

2.	Sitting diastolic blood pressure: **[SDIABP]**	__ __ __ mmHg	
3.	Medication tolerance (indicate 'yes' or 'no' for all side effects the patient has experienced since the last PEACE visit attended):	**YES**	**NO**
	a. Dizziness **[DIZZI]**	(1)	(2)
	b. Syncope **[SYSCPE]**	(1)	(2)
	c. Skin rash **[SKRASH]**	(1)	(2)
	d. Headache **[HEADCH]**	(1)	(2)
	e. Cough **[COUGH]**	(1)	(2)
	f. Fatigue **[FATGUE]**	(1)	(2)
	Earlier versions of the follow-up form did not have this variable		
	g. Other significant (please print): deleted - rare events	(1)	(2)

D. INTERIM MEDICAL HISTORY SINCE PATIENT'S LAST VISIT

		YES	NO
1.	Was the patient diagnosed with cancer since the patient's last protocol visit? deleted - rare events	(1)	(2)
2.	Has the patient been hospitalized overnight for a cardiovascular reason or had PTCA as an outpatient? (If YES, indicate 'yes' or 'no' for each question D3 –D12.) deleted **If NO, DO NOT ANSWER QUESTIONS D3-D12; go to Section E.**	(1)	(2)
3.	Was the patient hospitalized for an MI? deleted	(1)	(2)
4.	Was the patient hospitalized for unstable angina? deleted	(1)	(2)
5.	Was the patient hospitalized for CABG? deleted	(1)	(2)
6.	Was the patient hospitalized for PTCA/stent, or other coronary revascularization (e.g., laser)? deleted	(1)	(2)
7.	Was PTCA performed on an outpatient basis? deleted	(1)	(2)
8.	Was the patient hospitalized for congestive heart failure? deleted	(1)	(2)
9.	Was the patient hospitalized for stroke? deleted	(1)	(2)
10.	Did the patient require angioplasty, bypass grafting, or aneurysm repair for peripheral vascular disease? deleted	(1)	(2)
11.	Was the patient hospitalized for cardiac arrhythmia? deleted	(1)	(2)
12.	Was the patient hospitalized for other cardiovascular reason? deleted	(1)	(2)

Outcome variables for the questions above were based on medical record confirmation and/or events committee adjudication, are non-fatal events, and are included in the LADS.OUTCOMES data file:
Hospitalization for cardiac arrhythmia **[ARR]**
Coronary-artery bypass grafting **[CABG]**
Hospitalization for congestive heart failure **[CHF]**
Myocardial infarction **[MI]**
Percutaneous coronary intervention **[PTCA]**
Peripheral vascular disease requiring angioplasty, bypass grafting, or aneurysm repair **[PVASC]**
Stroke **[STROKE]**
Hospitalization for unstable angina **[UA]**

Also included in the LADS.OUTCOMES data file are the days since randomization for these events: Days since randomization to arrhythmia **[ARRDT]**
Days since randomization to CABG **[CABGDT]**
Days since randomization to CHF **[CHFDT]**
Days since randomization to MI **[MIDT]**

Days since randomization to PTCA **[PTCADT]**
Days since randomization to PVASC **[PVASCDT]**
Days since randomization to STROKE **[STROKEDT]**
Days since randomization to UA **[UADT]**

Derived variables in the LADS.OUTCOMES data file include two composite outcomes:
The original PEACE outcome (a composite outcome of death from cardiovascular causes or non-fatal MI) **[ORIGINAL]**
The PEACE primary outcome (a composite outcome of death from cardiovascular causes, non-fatal MI, CABG or PTCA) **[PRIMARY]**

Also included in the LADS.OUTCOMES data file are the days since randomization for these composite outcomes: Days since randomization to original PEACE outcome **[ORIGINALDT]**
Days since randomization to PEACE primary outcome **[PRIMRYDT]**

Another variable in the LADS.OUTCOMES data file is days since randomization to the final visit **[DAYSSINCERAND]**

IF ANY OF QUESTIONS D1 or D3 – D12 WERE MARKED YES, COMPLETE AN OUTCOMES DOCUMENTATION FORM (FORM 007).

E. DRUG ADHERENCE

		YES	NO
E. 1	**Was the dose of study drug changed by PEACE clinic staff or any medical personnel since the last PEACE study visit?** deleted	(1)	(2)

If NO, go to Section F.

If YES, indicate dose given at each change and reason for change. Start with the first dosage change since the last PEACE visit. If dose was changed more than once, please call the CSCC for directions.

1. Dosage Change 1

A. Dose changed to: deleted

1mg	**2mg**	**4mg**	**Off**
(1)	(2)	(3)	(4)

B. Reason(s) for change deleted

a.	Intercurrent event	(1)	(2)
b.	Medication intolerance/side effects	(1)	(2)
c.	Patient insistence	(1)	(2)
d.	Other (please print): _____	(1)	(2)

C. If Drug Therapy Kits dispensed, please record Kit ID numbers: deleted
Drug Therapy Kit 1 __ __ - __ __ - __ __Drug Therapy Kit 2 __ __ - __ __ - __ __

F. CURRENT INFORMATION (THIS SECTION SHOULD BE COMPLETED AT ALL VISITS.)

During the first few years of the study, Section F was optional at semi-annual (odd numbered) follow-up visits.

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

3. Current Canadian Cardiovascular Society functional classification (indicate one): **[NSYANG]** (1)
No symptoms of angina

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)

4. Current medication (please answer all items):	YES	NO
a. Use of an open label ACE inhibitor **[ACE]**	(1)	(2)
benazapril (Lotensin, Lotrel), captopril (generic), enalapril (Vasotec, Vaseretic, Lexxel), fosinopril (Monopril), lisinopril (Prinivil, Zestril, Zestoretic, Prinizide), moexipril (Univasc, Uniretic), perindopril (Aceon), quinapril (Accupril, Accuretic), ramipril (Altace)		
Earlier versions of the follow-up form did not have this variable.		
b. Use of an Angiotensin II Receptor Blocker (ARB) **[ARB]**	(1)	(2)
candesartan (Atacand), eprosartan (Teveten), irbesartan (Avapro, Avalide), losartan (Cozaar, Hyzaar), telmesartan (Micardis), valsartan (Diovan, Diovan HCT), olmesartan (Benicar)		
Earlier versions of the follow-up form did not have this variable.		
c. Use of calcium channel blocker **[CALCBL]**	(1)	(2)
d. Use of beta-blocker **[BEBLOC]**	(1)	(2)
e. Use of any type of nitroglycerin (e.g. tabs, patch, spray) **[NITRO]**	(1)	(2)
Earlier versions of the follow-up form did not have this variable.		
f. Use of potassium-sparing diuretic **[POSPDI]**	(1)	(2)
g. Use of other diuretic **[OTDIUR]**	(1)	(2)
h. Use of digitalis **[DIGITS]**	(1)	(2)
i. Use of other anti-arrhythmics (besides digitalis, beta-blocker or calcium channel blocker) **[ANARHY]**	(1)	(2)
j. Use of aspirin **[ASPIR]**	(1)	(2)
Earlier versions of the follow-up form did not have this variable.		
k. Use of other antiplatelet agents e.g. clopigrel (Plavix), ticlodipine (Ticlid) **[PLATE]**	(1)	(2)
Earlier versions of the follow-up form did not have this variable.		
l. Use of warfarin or coumadin **[WARF]**	(1)	(2)
Earlier versions of the follow-up form did not have this variable.		
m. Use of lipid-lowering therapy **[LIPLOW]**	(1)	(2)
n. Use of estrogen replacement therapy **[HORREP]**	(1)	(2)

4. Current medication (please answer all items):

	YES	NO
o. Is patient known to be diabetic? **[DIABTC]**	(1)	(2)

This variable was used to create the outcome variable of new-onset diabetes in the LADS.OUTCOMES data file **[NEWDM]**
Also included in the LADS.OUTCOMES data file: Days since randomization for new-onset diabetes **[NEWDMDT]**

If yes, mark all that apply:

Use of insulin **[INSULN]**	(1)	
Use of oral agents **[AGENTS]**	(1)	
Use of diet control **[DIETCT]**	(1)	

p. Use of any antioxidants (e.g. vitamins C, E, $_{B12,}$ selenium) beyond multivitamin **[OXID]**	(1)	(2)

Earlier versions of the follow-up form did not have this variable.

q. Use of other vitamins/mineral supplements beyond multivitamin **[VITMIN]**	(1)	(2)

Earlier versions of the follow-up form did not have this variable.

r. Use of any other cardiac medications not specifically mentioned above **[OTHCAR]**	(1)	(2)
s. Use of other <u>non</u>-cardiac medication **[NONCAR]**	(1)	(2)

Earlier versions of this form had the following variables:
Use of anticoagulants **[ANTICO]**
Use of aspirin or antiplatelet therapy **[ASPANT]**

G. STUDY MEDICATION [Phone 1-800-9-PEACE-1 to obtain new drug assignment.]

	YES	NO
1. Will the PEACE medication dosage be changed at this visit? deleted	(1)	(2)

If NO, go to Question 3.

2. If yes, indicate reason(s) for change: deleted

a. Protocol	(1)	(2)
b. Intercurrent event	(1)	(2)
c. Medication intolerance/side effects	(1)	(2)
d. Patient insistence	(1)	(2)
e. Other (Please Print): _____	(1)	(2)

3. Indicate dosage given at this visit: **[STRENGTH]**

1mg	**2mg**	**4mg**	**Off**
(1)	(2)	(3)	(4)

If "Off", go to Section H.

4. Record Drug Therapy Kit ID numbers dispensed: deleted

(**NOTE:** Under usual circumstances, two kits are dispensed.)

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

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

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

_____

Signature of individual who completed this form

__ __ / __ __ / __ __ __ __ deleted
Mo Day Yr
(Date of sign-off)

Certification # ___ ___ ___ ___ ___ deleted