ACIP

DATA TAPE CODING MANUAL

SECTION 2

FORMS

MAY 9 6

ASYMPTOMATIC CARDIAC ISCHEMIA PILOT

ACIP FORM 3D

CONFIRMATION OF ELIGIBILITY

GENERAL INSTRUCTIONS

This form should be completed for all potential ACIP candidates (PAC) for whom a 48-hour AECG is being submitted to the AECG Core Laboratory. These patients should have an abnormal exercise treadmill stress test by any screening protocol.

If a check mark (J) is made in any space on this form designated as "STOP," the patient is ineligible for further consideration for entry into the study. Do not complete the rest of the form and do not send form to the Clinical Coordinating Center.

If a check mark (J) is made in any space on this form designated as "INEL," the patient is ineligible for randomization in this study. Complete the entire form through Part III: Exclusion Checklist even if an "INEL" item is encountered and send in Form 3E -- Change of Status Form.

ITEM INSTRUCTIONS: Items with instructions outlined below have the symbol [*] preceding the item number on the form.

Refer to Item 12.

Symptomatic Ischemia

Chest pain characteristic of myocardial ischemia. Asymptomatic patients who develop symptoms during medication tapering or off medication for the required screening tests are subsequently considered symptomatic.

Asymptomatic Ischemia

a. No angina within the 6 weeks prior to qualifying AECG in patients with previous history of chronic stable angina, new onset angina, or myocardial infarction.

b. No history of angina.

ASYMPTOMATIC CARDIAC ISCHEMIA PILOT

CONFIRMATION OF ELIGIBILITY

CURCLIN

Clinic No.			-				
NEWID ID No.			-				
VISIT Visit Type	Q	V	0	0			

PART I: VISIT IDENTIFICATION

1. Patient's NAME CODE: ---------- NAMECODE _ _ _ _ _

2. Screening date: ---------- VISDT __ __ Day __ __ __ Month __ __ Year

3. A. Patient consent: ---------- PT_CONS (1) Yes (INEL) No

   B. Physician consent: _____ ---------- PHYSCONS (1) Yes (INEL) No

4. Gender: ---------- SEX (1) Male (2) Female

5. Ethnic origin: RACE

   North American Indian ---------- (1)
   Asian ---------- (2)
   Black ---------- (3)
   Hispanic ---------- (4)
   White ---------- (5)

6. Date of birth: ---------- BIRTHDT __ __ Day __ __ __ Month __ __ Year

   A. Age: ---------- AGE __ __

PART II: INCLUSION

7. Abnormal screening exercise tolerance test (ETT) or arm exercise test or stress image perfusion study? ---------- ABSCETT (1) Yes (STOP) No

8. A. Angiographic evidence of obstructive coronary artery disease? ---------- OBCAD (1) Yes (STOP) No (3) Not Yet Availablt

   B. At least one coronary artery narrowing ≥ 50% (measured with calipers) in a major vessel suitable for coronary revascularization? ---------- GT1CAN50 (1) Yes (STOP) No (3) Not Yet Available

ID No.			-				

PART III: EXCLUSION CHECKLIST

9. Are any exclusion conditions present? (Answer each item.)

		Yes	No
A.	**Age**	Not Applicable	
B.	Pregnancy — PREGEXC	(INEL)	(2)
C.	Myocardial infarction within four weeks of qualifying AECG — MI4EX	(INEL)	(2)
D.	PTCA within six months of qualifying AECG — PTCAEXC	(INEL)	(2)
E.	Coronary artery bypass grafting (CABG) within three months of qualifying AECG — CABG3EXC	(INEL)	(2)
F.	Unstable angina at the time of qualifying AECG — UANGEXC	(INEL)	(2)
G.	Noncardiac illness which would significantly contribute to mortality (i.e., renal disease, lung disease) — ILLEXC	(INEL)	(2)
H.	**The** presence of a significant noncoronary cardiac disorder which in itself would require surgery or increase mortality — CARDEXC	(INEL)	(2)
I.	**Left** ventricular failure of **NYHA** Class 111 or IV, and on medical therapy — VENTEXC	(INEL)	(2)
J.	Inadequate angina control on maximal medical therapy — ANGEXC	(INEL)	(2)
K.	Left main coronary artery disease ≥50% — CADEXC	(INEL)	(2)
L.	**Inability** to perform exercise **tolerance** test	Not Applicable	
M.	ECG findings which interfere with AECG analysis — ECGEXC	(INEL)	(2)
N.	Presence of abnormal baseline ST-segment morphology — STSEGEXC	(INEL)	(2)
0.	Inability to discontinue digitalis — DIGITEXC	(INEL)	(2)
P.	Investigational new drug within 30 days of qualifying AECG — INVEXC	(INEL)	(2)
Q.	Participation in competing protocol — PROTEXC	(INEL)	(2)
R.	Unreliable — UNRELEXC	(INEL)	(2)
S.	Geographically inaccessible for follow-up — GEOEXC	(INEL)	(2)
T.	Requires beta blocker in dose **>** atenolol 50 **mg** qd which cannot be safely discontinued for two to three **days** for eligibility assessment — BETAEXC	(INEL)	(2)
U.	Requires calcium channel blocker in dose **> diltiazem sr** 60 mg bid which cannot be safely discontinued for two to three days for eligibility assessment — CALCEXC	(INEL)	(2)
V.	Contraindication to both Regimen D/I (**diltiazem sr** followed by isosorbide dinitrate) and Regimen A/N (atenolol followed by nifedipine **sr**) — COUNTEXC	(INEL)	(2)

10. Are any **"INEL"** conditions checked in Part III? — INELEXC (INEL) (2)

Yes ↓ No

Send in Form 3E -- Change of Status Form.

Skip to Part VI.

ID No.						

PART IV: **MEDICATION**

11. Treatment information to assign randomization:

TRT_ASMT

Random assignment with no restrictions ---------- (1)

Atenolol/nifedipine sr without background therapy (i.e., contraindication to **diltiazem sr/isosorbide** dinitrate) ---------- (2)

Atenolol/nifedipine sr **with** background therapy (i.e., requires beta-blocker **therapy**) ---------- (3)

Diltiazem **sr/isosorbide** dinitrate **without** background therapy (i.e., contraindication to **atenolol/nifedipine sr**) ---------- (4)

Diltiazem **sr/isosorbide** dinitrate **with** background therapy ---------- (5)

PART V: STRATUM

[*]12. Angina1 status during the 6 weeks prior to qualifying **AECG**:

STRATO3

Symptomatic ---------- (1)
Asymptomatic ---------- (2)

13. Previous CABG more than 3 months prior to qualifying **AECG?** PREVCABG ---------- (1) **Yes** (2) No

↓

CABGMON CABGYR

A. Date of CABG: • _ _ m m - - Month Year

PART VI: **ADMINISTRATIVE MATTERS**

14. Research Coordinator:

Signature: COMPSIG ACIP Staff No. COMPCRT

ID No.							

ASYMPTOMATIC CARDIAC ISCHEMIA PILOT

ACIP FORM 3E

CHANGE OF STATUS FORM

GENERAL INSTRUCTIONS

This form should be completed and submitted to the Clinical Coordinating Center if the patient is identified as being ineligible for ACIP and any one or more screening or qualifying forms have been submitted to the Clinical Coordinating Center and before the Randomization Visit has been completed.

CURCLIN
NEWID
VISIT

Clinic No.								
ID No.								
Visit Type	Q	V	0	0				

PART I. IDENTIFYING INFORMATION

1. Patient's NAME CODE: ---------- NAMECODE _ _ _ _ _

2. Date this form started: _____ __ __ - VISDT - - -
Day Month Year

PART II. REASON FOR INELIGIBILITY

3. Primary reason for ineligibility: *(Check only one.)*

INELREA

Qualifying angiogram shows that patient does not have CAD which meets study eligibility ---------- (01)

Qualifying angiogram shows that patient is not suitable for revascularization ---------- (02)

Qualifying exercise tolerance test shows that patient does not meet study eligibility ---------- (03)

Qualifying AECG shows that patient does not meet study eligibility ---------- (04)

Exclusion criteria ---------- (05)

Death ---------- (06)

↓

*If **DEATH**, submit the Notification of Death Form (Form **15**), Cause of Death Form (Form 16).*

Myocardial infarction ---------- (07)

PTCA or CABG ---------- (08)

Patient not willing to participate ---------- (09)

Patient missed Qualifying Visit(s) ---------- (10)

Personal physician not willing for patient to participate ---- (11)

Other ---------- (12)

↓

If **Other**, **specify:** _____

PART III. ADMINISTRATIVE MATTERS

4. Has the Treatment Allocation Mailer been received for this patient? ---------- TRTMAIL (1) Yes (2) No

If **YES**, the Treatment Allocation Mailer should be returned **unopened** to the Clinical Coordinating Center with this form. If the Treatment Allocation Mailer is not returned, the Clinical Unit will be responsible for follow-up of the patient. If the Treatment Allocation Mailer is returned opened, the Principal Investigator must submit a letter of explanation to the Clinical Coordinating Center and the Clinical Unit will be responsible for follow-up of the patient.

5. ACIP Staff member completing form:

Name: _____ COMPSIG

ACIP Staff No.: ---------- _ _ _ _ _ COMPCRT

FOR CLINICAL COORDINATING CENTER USE ONLY

6. Treatment Allocation Mailer

Not sent to Clinical Unit _____ (1)
Not included with this form ---------- (2)
Unopened and included ---------- (3)
Opened and included ---------- (4)

A. Has a letter of explanation been provided by the Principal Investigator? ---------- (1) Yes (2) No

ID No.							

ASYMPTOMATIC CARDIAC ISCHEMIA PILOT

ACIP FORM 04

BASELINE FORM

GENERAL INSTRUCTIONS

Complete this form at the Randomization Visit for all patients entered into ACIP.

ITEM INSTRUCTIONS: Items with instructions outlined belov have the symbol **[*]** preceding the item number on the form.

Refer to Item 7.

DESCRIBE THE PATIENT'S CURRENT OR MOST RECENT MAJOR OCCUPATION:

Professional, technical, and related occupations (ex: teachers, professors, nurses, lawyers, physicians, and engineers).

Managers, administrators, or proprietors (ex: sales managers, real estate agents, or postmasters).

Clerical and related occupations (ex: secretaries, clerks, or mail carriers).

Sales occupations (ex: sales persons, demonstrators, agents and brokers).

Service occupations (ex: police, cooks, or hairdressers).

Skilled crafts, repairers, and related occupations (ex: carpenters, repairers, or telephone line workers).

Equipment or vehicle operators and related occupations (ex: drivers, railroad brakemen, or sewers).

Laborers (ex: helpers, longshoreman, or warehouse workers).

Farmers (ex: owners, managers, operators, or tenants).

ASYMPTOMATIC CARDIAC **ISCHEMIA** PIMT

ACIP FORM 4

BASELINE **FORM**
(Continued)

Refer to Item 10.

FUNCTIONAL CLASSIFICATION: A method of assessing the patient's general cardiovascular disability taking into consideration the symptoms of CHF. Record the class that best characterize the patient's overall level of disability due to congestive heart failure.

1. Patients with cardiac disease but without resulting limitations of physical activity. Ordinary physical activity does not cause undue fatigue, palpitations, or dyspnea.

2. Patients with cardiac disease resulting in slight limitation of physical activity. They are comfortable at rest. Ordinary physical activity results in fatigue, palpitations or dyspnea. Ordinary physical activity includes walking more than 2 blocks on level ground, climbing more than 1 flight of stairs at normal pace, walking uphill, walking or climbing stairs rapidly, walking or stair climbing under adverse conditions (cold, wind, emotional stress).

3. Patients with cardiac disease resulting in marked limitation of physical activity. They are comfortable at rest. Less than ordinary activity causes fatigue, palpitations or dyspnea. Less than normal activity includes walking 1 to 2 blocks on level ground or climbing 1 flight of stairs at a normal pace.

4. Patients with cardiac disease resulting in inability to carry out any physical activity without symptoms of fatigue, palpitations or dyspnea. Symptoms may be present even at rest. If any physical activity is undertaken, these symptoms are increased.

CURCLIN
NEWID
VISIT

Clinic No.								
ID No.								
Visit Type	R	V	0	1				

PART I: IDENTIFICATION

1. Patient's NAME CODE: ---------- NAMECODE _ _ _ _ _

2. Randomization date: ---------- VISDT _ _ - _ _ - _ _
Day Month Year

PART II: BACKGROUND DATA

3. Education (check **highest grade completed**):

EDUC

Grade 11 or **less** ---------- (1)
High School **Graduate** ---------- (2)
High School **Graduate plus additional training** ---------- (3)
College Graduate ---------- (4)
College Graduate plus additional training ---------- (5)
Unknown ---------- (6)

4. Native Language:

LANG

English ---------- (1)
French ---------- (2)
Spanish ---------- (3)
Other ---------- (4)

5. Current marital status (check one):

MARITAL

Married ---------- (1)
Separated or divorced ---------- (2)
Widowed ---------- (3)
Not married, living in spouse-like relationship ---------- (4)
Single ---------- (5)

6. Homemates (check all that apply):

A. Lives alone ---------- LIVALONE ---------- (1)
B. Spouse or significant other ---------- SPOUSE ---------- (1)
C. Other independent adults ---------- OTHINDEP ---------- (1)
D. Children ---------- CHILDREN ---------- (1)
E. Other dependent adults ---------- OTHDEPEN ---------- (1)

[*]7. Which category best describes the patient's current or most recent major occupation?

OCC

Professional, technical, and related occupations ---------- (01)
Managers, administrators, or proprietors ---------- (02)
Clerical and related occupations ---------- (03)
Sales occupations ---------- (04)
Service occupations ---------- (05)
Skilled crafts, repairers, and related occupations ---------- (06)
Equipment or vehicle operators and related occupations ---------- (07)
Laborers ---------- (08)
Farmers ---------- (09)
Members of the military ---------- (10)
Other ---------- (11)

Describe: _____

Never worked ---------- (12)

7A. Homemaker ---------- HOME ---------- (1) Yes (2) No

Employment at time of screening:

EMPL

Full-time (≥ 35 hours per week) ---------- (1)
Part-time (< 35 hours per week) ---------- (2)
Retired ---------- (3)
Disabled ---------- (4)
Unemployed ---------- (5)

PART III: MEDICAL HISTORY

MIHIST

9. History of myocardial infarction (MI) ---------- (1) Yes (2) No (3) Unknown

A. Date of most recent MI: ---------- MIMON - - Month - MIYR - - Year - MIUNK (1) **Unknown**

ID No.			-				

[*]10. Does patient have a history of congestive heart failure requiring treatment? ---------- CHF
(1) Yes (2) No (3) Unknown

↓

A. Current Functional Classification: CHFCLASS
One ---------- (1)
Two ---------- (2)
Three ---------- (3)
Four ---------- (4)

11. History of cigarette smoking? ---------- SMOKER
(1) Yes (2) No

↓ CURSMOKE

A. Current smoker (within 4 weeks)? ---------- (1) Yes (2) No

	Yes	No	Unknown
12. Family history (parent, sibling, child) of coronary artery disease before age 55? CADB55	(1)	(2)	(3)
13. History of hypertension requiring medical treatment? HPT	(1)	(2)	(3)
14. History of diabetes? DIABETES	(1)	(2)	(3)

↓

A. Record current therapy: DIABRX
Oral medical ---------- (1)
Insulin ---------- (2)
Neither ---------- (3)
Both ---------- (4)

	Yes	No	Unknown
15. Does patient have a history of hypercholesterolemia (>240 mg/dl or 6.0 mMol/L) HICHOL	(1)	(2)	(3)

↓

A. Does patient know a recent cholesterol level? ---------- (1) Yes (2) No

↓ HICHLVL

Cholesterol level: ----------1) _ _ _ mg/dl HICHMG
or 2) __ __.__ mMol/L HICHMMOL

ID No.							

16. History of other **significant** illness:

		Yes	No	Unknown
A.	Cerebrovascular accident, transient ischemic **attack or** carotid surgery ---------- STROKE	(1)	(2)	(3)
B.	Peripheral vascular disease (claudication, peripheral vascular surgery, or abdominal aneurysm) ---------- PVD	10	(2)	(3)
C.	Asthma ---------- ASTHMA	(1)	(2)	(3)
D.	Chronic bronchitis ---------- BRONCH	(1)	(2)	(3)

17. Any prior cardiovascular procedures? ---------- HXPROC (1) Yes (2) NO

		Yes	No	Unknown
A.	**PTCA** ---------- PTCA	(1)	(2)	(3)

PTCAUNK

PTCAMON ___ - PTCAYR ___ (1)
Month Year Unknown

B.	Other cardiac revascularization interventional technique ---------- OTHRTECH	(1)	(2)	(3)

Specify: _____

C.	Heart surgery other than CABG -------- HTSURG	(1)	(2)	(3)

Specify: _____

ID No.			-				

18. Record all treatment taken within 2 weeks of date of study entry:

		Yes	No	Unknown
A.	Long acting nitrates ---------- LAN ---------- If **YES**, specify name and dose: _____	(1)	(2)	(3)
B.	Short acting nitrates ---------- SAN ---------- If **YES**, specify name and dose: _____	(1)	(2)	(3)
C.	Beta Blocker therapy ---------- BB ---------- **YES**, specify name and dose: _____	(1)	(2)	(3)
D.	Calcium channel blockers ---------- CCB ---------- If **YES**, specify name and dose: _____	(1)	(2)	(3)
E.	**Aspirin (ASA)** ---------- ASA ----------	(1)	(2)	(3)
F.	**Dipyridamole/sulfinpyrazone** ---------- DIPSULF ----------	(1)	(2)	(3)
G.	**ASA** or dipyridamole or **sulfinpyrazone** _____ ANTIPLAT ----------	(1)	(2)	(3)
H.	Anticoagulant ---------- ANTICOAG ----------	(1)	(2)	(3)
I.	Lipid lowering agent ---------- LIPID ----------	(1)	(2)	(3)
J.	Diuretics ---------- DIUR ----------	(1)	(2)	(3)
K.	ACE inhibitors ---------- ACE ----------	(1)	(2)	(3)
L.	Other vasodilators or antihypertenaives _____ OTHRVAS	(1)	(2)	(3)
M.	Antiarrhythmic agent _____ ANTIARR	(1)	(2)	(3)
N.	Digitalis ---------- DIGITAL ----------	(1)	(2)	(3)
O.	---------- IVNITRO ---------- **YES**, _____	(1)	(2)	(3)

PART IV: PHYSICAL EXAM

19. Height (without shoes): _____ HEIGHT ---------- _ _ _ **cm**

20. Weight: ---------- WEIGHT ---------- __ __ __ **kg**

ID No.							

21. Blood pressure (sitting):

A. Systolic: ---------- SBP ___ mm Hg

B. Diastolic: ---------- DBP ___ mm Hg

22. Heart Rate: ---------- HTRATE ___ bpm

23. Findings:

	Yes	No
A. S3 ---------- S3	(1)	(2)
B. Rales that do not clear with cough ---------- RALES	(1)	(2)
C. JVP > 8 cm of water ---------- JVP	(1)	(2)
D. Carotid bruit ---------- BRUIT	(1)	(2)

BRUITR
BRUITL

1. Right ---- (1) (2)
2. Left ----- (1) (2)

E. Peripheral edema ---------- PEREDEMA	(1)	(2)
F. Hepatomegaly ---------- HEPATOME	(1)	(2)

PART Q: **ADMINISTRATIVE MATTERS**

24. Research Coordinator:

Signature: _____ COMPSIG _____ ACIP Staff No.: --- COMPCRT

ID No.							1

ASYMPTOMATIC CARDIAC ISCHEMIA PILOT

ACIP FORM 6A

PTCA AND OTHER INTERVENTION PROCEDURES

GENERAL INSTRUCTIONS

Complete this form each time the patient undergoes an attempted PTCA procedure or other interventional procedures. Include all parts of a staged procedure on one form. The original form is sent to the Clinical Coordinating Center. A copy of this form is sent to the Angiography Core Laboratory for protocol procedures performed in patients assigned to revascularization.

A narrative is required if complications occur or if non-standard procedures are performed.

ITEM INSTRUCTIONS. Items with instructions outlined below have the symbol [*] preceding the item number on the form.

Refer to Item 11:

% Stenosis: Measure % diameter stenosis by calipers.

Refer to Item 12:

Intervention Outcome:

If the residual stenoses in the major coronary arteries are all < 50% diameter as measured by electronic calipers, the patient is free of angina, has not had a procedurally related myocardial infarction and has not had to undergo emergency CABG, the immediate intervention outcome will be classified as successful.

ASYMPTOMATIC CARDIAC ISCHEMIA PILOT

ACIP FORM 6A

PTCA AND OTHER INTERVENTION PROCEDURES
(Continued)

Refer to Item 20:

The cineangiogram which documents performance of PTCA for patients assigned to revascularization (i.e., Item 3 = 1) should be submitted to the Angiography Core Laboratory along with a copy of Form 6A.

Refer to Item 21:

A narrative is required if certain complications occur or if non-standard procedures are performed. If any of the following items has the indicated answer, a narrative is required.

Item(s)	Answer
10	Yes
11	Unstable or Deceased
11A	Yes
12	No
13C 2-6	Yes
14C 2-6	Yes
15C 2-6	Yes
16C 2-6	Yes
17	Yes

The narrative should describe 1) the clinical circumstances under which the complication occurred, 2) treatment administered and 3) outcome or clinical impact of the complication.

CURCLIN
NEWID
VISIT

Clinic No.			-					
ID No.			-					
Visit Type								

PART I: IDENTIFICATION

1. Patient's NAME CODE: ---------- NAMECODE

2. Date of procedures: ---------- VISDT
Day Month Year

PART · ROCEDURE NOTES

3. Why was this procedure performed? PROCPERF

Protocol Randomization (Revascularization Strategy) --------- (1) → *Skip to Item 7.*

All others ---------- (2) ↓

4. Check all the reasons for revascularization which were fulfilled at the time of performance of this procedure:

A. **MI** ---------- MIPROC (1)*
B. **Unstable angina** ---------- ANGPROC (1)*
C. **Canadian Cardiovascular Society Classification of Angina Class III or IV** ---------- CCSCPROC (1)
D. **Severe ischemic response on exercise ECG** ---------- (1)*
E. Coronary anatomy ---------- ANATPROC (1)**
F. Decision of personal physician ---------- PHYSPROC (1)**
G. Clinical decision not **specified by protocol** ---------- CLINPROC (1)**
H. Other ---------- OTHPROC (1)** ↓

Specify: _____

5. **Indicate priority of procedure:**

Urgent ---------- PRIORITY (1)
Elective ---------- (2)

6. **Patient's anginal status at time of procedure:**

None ---------- ANGSTAT (1)
Stable ---------- (2)
Unstable ---------- (3)
Acute MI ---------- (4)

**Submit appropriate event forms.*
***PROTOCOL VIOLATION if procedure performed within twelve weeks of study entry and none of Items A-D is checked.*

ID No.								

7. Category of procedure:

Initial revascularization ---------- PROCCAT ---------- (1)

Kepeat revascularization ---------- _____ (2)

8. Is there a significant change in anatomy from the qualifying angiogram? ---------- CHGANAT (1) (2)
Yes No

↓

Complete Cardiac Catheterization and Angiography Form 7A.

9. Was thrombolytic therapy administered during procedure? THRM-ADM _____ (1) (2) (3)
Yes **No** Unknown

10. Was cardiopulmonary support used during procedure? ---- CPRSPRT ---- (1)† (2) (3)
Yes No Unknown

11. Condition of patient upon leaving Cath Lab: PTCOND

Stable ---------- (1)

Unstable ---------- (2)†

Deceased ---------- (3)†

↓

*If deceased, Submit Death Notification Form 15 and Cause of Death **Form** 16.*

11A. Was patient admitted to a special care unit (Coronary Care Unit or Intensive Care Unit) for more than 24 hours following the procedure? ----- CCU24HR (1)† (2)
Yes No

[*]**12.** Was intervention outcome successful? ---------- OUTCOME (1) (2)†
Yes No

†**Submit** Narrative

ID No.			-				
Visit Type							

PART III: LESION DETAILS

Refer to the diagram after instruction page to answer Items in Part III. Complete this section for each lesion attempted by operator.

13. Coronary Artery segment code (record native coronary artery or insertion site of bypass graft): ---------- CASCODE1

A. Native Coronary Artery or bypass graft? ---------- NCAI (1) Native (2) Graft

B. Stenosis pre-intervention ---------- STENPRE1 - - -%

C. Type of intervention (check all that apply):

1. Standard Balloon Angioplasty ---------- BLLOON1 (1)
†2. **Stent** ---------- STENT1 (1)
†3. **Atherectomy** ---------- ATHER1 (1)
†4. **Laser** ---------- LASER1 (1)
†5. **Laser Balloon** ---------- LASBLLN1 (1)
†6. Other device ---------- OTHDEV1 (1)
Specify: _____

D. Stenosis post-intervention ---------- STENPST1 - - -%

14. Coronary Artery segment code (record native coronary artery or insertion site of bypass graft): ---------- CASCODE2 - -

A. Native Coronary Artery or bypass graft? ---------- NCA2 (1) Native (2) Graft

B. Stenosis pre-intervention ---------- STENPRE2 - - -%

C. Type of intervention (check all that apply):

1. Standard Balloon Angioplasty ---------- BLLOON2 (1)
†2. **Stent** ---------- STENT2 (1)
†3. **Atherectomy** ---------- ATHER2 (1)
†4. **Laser** ---------- LASER2 (1)
†5. **Laser Balloon** ---------- LASBLLN2 (1)
†6. Other device ---------- OTHDEV2 (1)
Specify: _____

D. Stenosis post-intervention ---------- STENPST2 ___ %

E. Part of staged procedure ---------- STAGED2 (1) Yes (2) No

1. Date if different than first stage ___ ___ **Day** ___ ___ Month ___ ___ Year or (1) same date — STAGE2DT ↓ AME2

†**Submit** narrative for non-standard procedures.

ID No.			-				
Visit Type							

15. Coronary Artery segment code (record native coronary artery or insertion site of bypass graft): CASCODE3 ----------

A. Native Coronary Artery or bypass graft? NCA3 ----------(1) (2)
Native Graft

B. Stenosis pre-intervention STENPRE3 ---------- - - -%

C. Type of intervention (check all that apply):
1. Standard Balloon Angioplasty BLLOON3 ---------- (1)
†2. Stent STENT3 ---------- (1)
†3. **Atherectomy** ATHER3 ---------- (1)
†4. **Laser** LASER3 ---------- (1)
†5. **Laser Balloon** LASBLLN3 ---------- (1)
†6. Other device OTHDEV3 ---------- (1)
Specify: _____

D. Stenosis post-intervention STENPST3 ---------- __ __ __%

E. Part of staged procedure STAGED3 ---------- (1) (2)
Yes No

STAGE3DT ↓SAME3

1. Date if different than first stage __ __ - __ __ __ __ __ or (1)
Day Month Year **same** date

16. Coronary Artery segment code (record native coronary artery or insertion site of bypass graft): CASCODE4 ----------

NCA4
Native Coronary Artery or bypass graft? ----------(1) (2)
Native Graft

B. Stenosis pre-intervention STENPRE4 ---------- - - -%

C. Type of intervention (check all that apply):
1. Standard Balloon Angioplasty BLLOON4 ---------- (1)
†2. Stent STENT4 ---------- (1)
†3. Atherectomy ATHER4 ---------- (1)
†4. Laser LASER4 ---------- (1)
†5. **Laser Balloon** LASBLLN4 ---------- (1)
†6. Other device OTHDEV4 ---------- (1)
Specify: _____

D. Stenosis post-intervention STENPST4 ---------- __ __ __%

E. Part of staged procedure STAGED4 ---------- (1) (2)
Yes No

STAGE4DT ↓SAME4

1. Date if different than first stage m m - - m m - - or (1)
Day Month Year same date

†**Submit** narrative for non-standard procedures.

ID No.			-				
Visit Type							

PART IV: MAJOR EVENTS

17. Did patient experience any major events during or within 24 hours after PTCA? ---------- MAJOREVT (1) Yes ↓ (2) No (3) Unknown

Answer each item:		Did Not Occur	Occurred in Lab	Occurred Within 24 Hours
A.	Death _____ DTHPTCA	(1)	(2)*	(3)*
	CARDIOVASCULAR EVENTS			
B.	Non-fatal cardiac arrest ---- CAPTCA	(1)	(2)	(3)
C.	Suspected non-fatal MI ---- MIPTCA	(1)	(2)**	(3)**
D.	Abrupt reclosure ---------- RECLPTCA	(1)	(2)**	(3)**
E.	**Congestive heart failure (isolated) or Pulmonary edema (cardiac)** -- CHFPTCA	(1)	(2)	(3)
F.	**Cardiogenic shock** ---------- SHKPTCA	(1)	(2)	(3)
G.	**Cardiac tamponade** --------- TAMPPTCA	(1)	(2)	(3)
H.	**Hemorrhage requiring transfusion** HMRRPTCA	(1)	(2)	(3)
I.	Arterial embolus of extremity **or** loss of pulse requiring **treatment** EMBPTCA	(1)	(2)	(3)
J.	Hypotension requiring treatment HYPOTCA	(1)	(2)	(3)
	NEUROLOGIC EVENTS			
K.	**TIA** ---------- TIAPTCA	(1)	(2)	(3)
L.	**Stroke** ---------- STRKPTCA	(1)	(2)	(3)
M.	Coma ---------- COMAPTCA	(1)	(2)	(3)
	ALLERGIC EVENT			
N.	Hypersensitivity reaction -- ALLGPTCA	(1)	(2)	(3)
	PULMONARY EVENTS			
0.	Respiratory failure (include **ARDS &** non-cardiac edema) ---------- ARDSPTCA	(1)	(2)	(3)
P.	Pulmonary embolus ---------- PEPTCA	(1)	(2)	(3)
	RENALEVENT			
Q.	Renal failure requiring dialysis RENLPTCA	(1)	(2)	(3)
	PROCEDURAL EVENTS			
R.	Emergency CABG ---------- CABGPTCA	(1)	(2)***	(3)***
	OTHER EVENTS			
S.	Other events _____ OTHPTCA	(1)	(2)	(3)
	Specify: _____			

*Submit Death Notification Form 15 and Cause of Death Form 16.
**Submit Suspect Ischemic Event Form 23.
***Submit CABG Surgery Form 25.

'Submit narrative

ID No.							
Visit Type							

PART V: ADMINISTRATIVE MATTERS

18. PTCA Operator:

Name: PTCA3IG ACIP Staff No.: PTCACRT ___ ___ - ___ ___ ___

19. Research Coordinator:

Signature: COMPSIG ACIP Staff No.: COMPCRT ___ ___ - ___ ___ ___

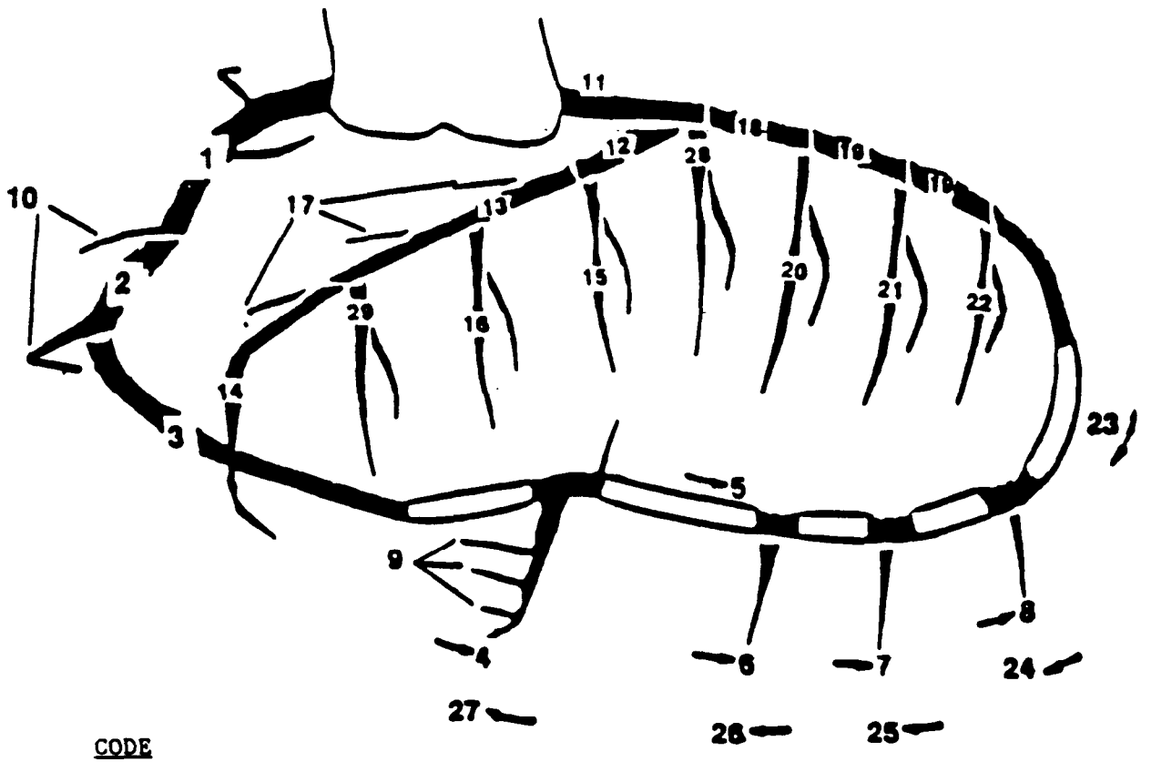
[*]20. Was the PTCA cineangiogram submitted to the **Angiography Core Laboratory?** ---------- ACLSUB (1) (2)
Yes **No**

[*]21. Is narrative attached? ---------- NARRATT (1) (2) (3)
Yes No Not required

22. CCC Use		
	Yes	No
Narrative -----	(1)	(2)

ID No.							
Visit Type							

ACIP Coronary Artery Diagram



CODE

01 Proximal right coronary artery (Prox RCA)
02 Hid-right coronary artery (Hid RCA)
03 Distal right coronary artery (Dist RCA)
04 Right posterior descending artery (RDPA)
05 Right posterior atrioventricular (RPLS)
06 First right posterolateral (1st RPL)
07 Second right posterolateral (2nd RPL)
08 **Third** right posterolateral (3rd RPL)
09 Posterior descending septal perforators (Inf septal)
10 Acute marginal (Ac marg)
11 Left main coronary artery **(LMCA)**
12 Proximal LAD artery (Prox **LAD)**
13 Mid **LAD** artery **(Mid LAD)**
14 Distal LAD artery (Dist LAD)
15 First diagonal branch (1st **Diag)**
16 Second diagonal branch (2nd Diag)
17 First septal perforator (1st Septal)
18 Proximal circumflex artery (Prox CX)
19 Mid circumflex artery (Mid, dist CX)
20 First obtuse marginal branch (1st Ob marg)
21 Second obtuse marginal branch (2nd Ob ❑ arg)
22 Third obtuse marginal branch (3rd Ob marg)
23 Circumflex artery AV groove continuation (LAV)
24 First left posterolateral branch (1st LPL)
25 Second left posterolateral branch (2nd LPL)
26 Third left posterolateral branch (3rd LPL)
27 Left posterior descending artery (LPDA)
28 **Ramus** intermedius **(Ramus)**
29 Third diagonal branch (3rd Diag)

- *Complete this form for any patient*
- *randomized to revascularization who*
- *does not receive the procedure.*

CURCLIN Clinic No. | | | | | |

NEWID ID No. | | | | | | | | |

VISIT Visit Type | I | T | 0 | 1 |

PART I: **IDENTIFICATION**

1. Patient's NAME CODE: ---------- NAMECODE - - - - -

2. Date form completed: ---------- VISDT - - - - - - -
Day Month Year

3. Reason Protocol revascularization was not performed: *(Check all that apply):*

A. Physician refused ---------- PHYREF (1)
B. Patient refused ---------- PTREF (1)
C. Patient deceased ---------- PTDEAD (1)
D. Complications of **cathe**terization ---------- CATHNA (1)
E. Unsuitable anatomy ---------- ANATOMY (1)
Specify: _____

F. Inability to cross the lesion ---------- NOLESION (1) ↓

1. Inability to enter the artery ---------- NOARTERY (1)
2. Inability to pass wire ---------- NOWIRE (1)
3. Inability to pass balloon ---------- NOBALLN (1)
4. Other cause ---------- OTHCROSS (1)
Specify: _____

G. Inability to dilate the lesion ---------- NODILATE (1) ↓

1. Complication ---------- DILATCMP (1)
2. Rigidity of the lesion ---------- RIGIDITY (1)
3. Elasticity of the lesion ---------- ELASTIC (1)
4. Technical failure ---------- TECHFAIL (1)
5. Other cause ---------- OTHDILAT (1)
Specify: _____

H. **Intercurrent event** ---------- INTEREVT (1)

I. **Other** ---------- NOVASOTH (1)
Specify: _____

4. Research Coordinator:

Signature: COMPSIG ACIP Staff No.: --- COMPCRT - - - - -

ID No. | | | - | | | | |

ASYMPTOMATIC CARDIAC ISCHEMIA PILOT

ACIP FORM 7A

QUALIFYING CARDIAC CATHETERIZATION AND ANGIOGRAPHY FORM

GENERAL INSTRUCTIONS

This form should be completed to document the qualifying catheterization and angiography procedures:

The original form is sent to the Clinical Coordinating Center. A copy of this form is sent to the Angiography Core Laboratory.

ITEM INSTRUCTIONS: Items with instructions outlined below have the symbol [*] preceding the item number on the form.

Refer to Item 4.

Col 1. Artery Code - refer to diagram at end of instruction pages to answer Artery Code.

Refer to Item 4.

co1 2. Enter % diameter stenosis measured by calipers.

ASYMPTOMATIC CARDIAC **ISCHEMIA** PILOT FORM REV ACIP Form 7A
Rev 3 05/26/92
QUALIFYING CARDIAC CATHETERIZATION AND **ANGIOGRAPHY** FORM

CURCLIN	Clinic No.			-					
NEWID	ID No.			-					.
VISIT	Visit	Q	V	0	0				

PART I: IDENTIFICATION

1. Patient's NAME CODE: ---------- NAMECODE - - - - -

2. Date of catheterization: ---------- VISDT __ __ (Day) __ __ __ (Month) . __ __ (Year)

PART II. CORONARY **ARTERIOGRAPHY**

3. Coronary Anatomy:

	Vessel or Major **Branch Diseased** ≥ **50%** diameter stenosis by caliper	
	Yes	**No**
A. **RCA** ---------- RCA	(1)	(2)
B. **LAD** ---------- LAD	(1)	(2)
C. **LCX** ---------- LCX	(1)	(2)
D. **Bypass graft** ---------- BYPASS	(1)	(2)

4. Complete for each lesion ≥ 50% diameter stenosis.
For multiple lesions in the same artery **code**, record only the most **severe.**

	1) [*] **Artery Code**	2) **Vein Graft** Yes (1) No (2)	3) [*] **% Stenosis**		1) [*] **Artery Code**	2) **Vein Graft** Yes (1) No (2)	3) [*] **% Stenosis**
A.	ACA	VGRAFTA	STENA	F.	ACF	VGRAFTF	STENF
B.	ACB	VGRAFTB	STENB	G.	ACG	VGRAFTG	STENG
C.	ACC	VGRAFTC	STENC	H.	ACH	VGRAFTH	STENH
D.	ACD	VGRAFTD	STEND	I.	ACI	VGRAFTI	STENI
E.	ACE	VGRAFTE	STENE	J.	ACJ	VGRAFTJ	STENJ

5. Coronary anatomy suitable for revascularization ---------- ANATELIG **Yes** (1) **No** **(INEL)**

ID No.			-					1

6. Ventricular function:

A. Is the ventricular function adequate for revascularization? VENTELIG --------- (1) (INEL)
Yes No

B. Date: VENTDT ---------- __ __ __ __ __ - __ __
Day Month Year

C. Method used:

Radionuclide ventriculography VENTMETH ---------- (1)
LV contrast angiography ---------- (2)
Echo ---------- (3)

D. Global ejection fraction (recent estimate): EF ---------- 0. __ __ EFN (1)
Not Available

PART III: ADMINISTRATIVE MATTERS

7. Procedure to be performed if this patient is assigned to revascularization: ITPROC

PTCA ---------- (1)
Staged PTCA ---------- (2)
CABG ---------- (3)

8. Angiographer reviewing cineangiogram and ventricular function data:

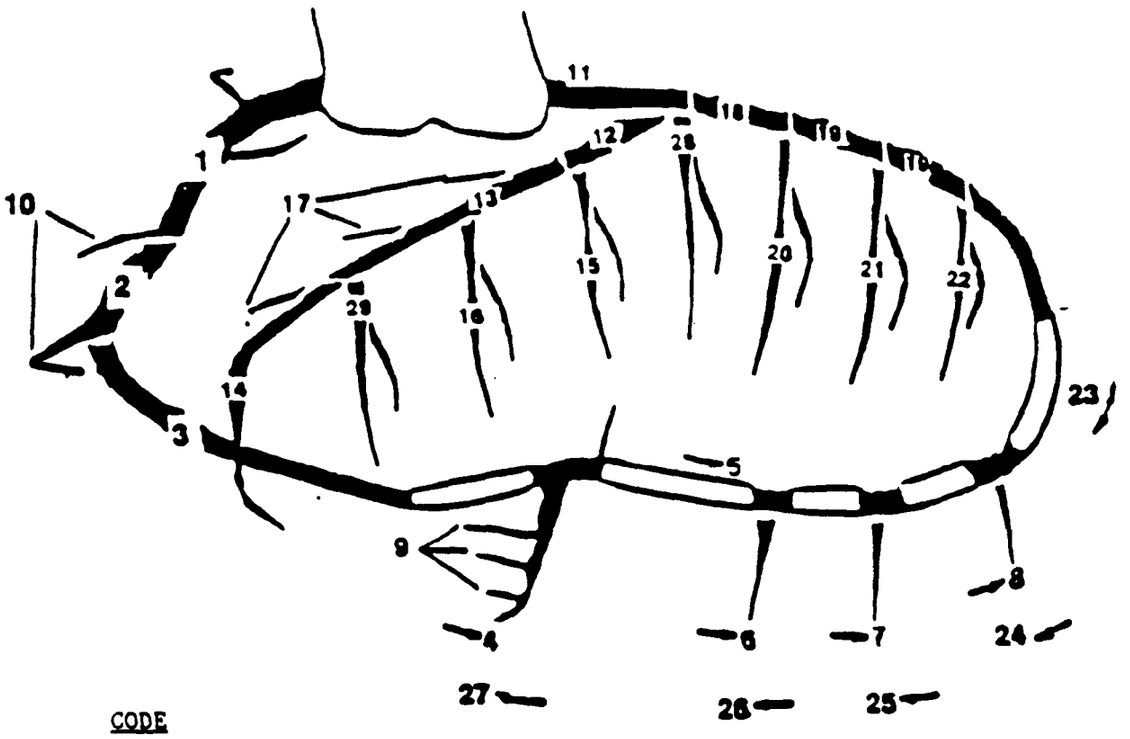
Name: ANGSIG ACIP Staff No.: --- ANGCRT __ __ - __ __ __

9. Research Coordinator:

Signature: COMPSIG ACIP Staff No.: --- COMPCRT - - - - -

ID No.			-				

ACIP Coronary Artery Diagram



CODE

01 Proximal right coronary artery (Prox RCA)
02 Mid-right coronary artery (Mid RCA)
03 Distal right coronary artery (Dist RCA)
04 Right posterior descending artery (RDPA)
05 Right posterior atrlovantrfcular (RPLS)
06 First right posterolateral (1st RPL)
07 Second right posterolateral (2nd RPL)
08 Third right posterolateral (3rd RPL)
09 Posterior descending septal perforators (Inf septal)
LO Acute marginal (Ac marg)
11 Left main coronary artery (LMCA)
12 Proximal LAD artery (Prox LAD)
13 Hid LAD artery (Mid LAD)
14 Distal LAD artery (Dist LAD)
15 First diagonal branch (1st Diag)
16 Second diagonal branch (2nd Diag)
17 First septal perforator (1st Septal)
18 Proximal circumflex artery (Prox CX)
19 Hid circumflex artery (Mid, dist CX)
20 First obtuse marginal branch (Lst Ob marg)
21 Second obtuse marginal branch (2nd Ob marg)
22 Third obtuse marginal branch (3rd Ob marg)
23 Circumflex artery AV groove continuation (LAV)
24 First Left posterolateral branch (Lst LPL)
25 Second left posterolateral branch (2nd LPL)
26 Third Left posterolateral branch (3rd LPL)
27 Left posterior descending artery (LPDA)
28 Ramus intermedius (Ramus)
29 Third diagonal branch (3rd Diag)

CORONARY ANGIOGRAM VISUAL ASSESSMENT
(FOR **ANGIOGRAPHIC** CORE LAB USE)

CURCLIN
NENID
VISIT

Clinic No.	
ID No.	
Visit Type	

PART I: IDENTIFICATION

1. **Patient's NAME CODE:** ---------- NAMECODE _ _ _ _ _

2. Date of **angiogram:** _____ VISDT
- - - - - -
Day Month Year

3. Angiogram type (Answer all that apply.):

A. Qualifying ---------- QVANG ---------- (1)
B. Confirmation of anatomy prior to protocol revascularization ---- CONFANG ---- (1)
C. Protocol PTCA ---------- PTCAANG ---------- (1)

PART II: ASSESSMENT OF **ANGIOGRAM** QUALITY

4. Quality: _____ ANGQUAL

(1) Superior (2) Satisfactory (3) Unsatisfactory (4) Uninterpretable

A. This coronary **angiogram** was *(check one):* -- (1) Suboptimal (2) Rejected (3) Incomplete — ANGWAS

Answer B - G.

Indicate reason(s): *(Check all that apply.)*

B. Image film qualify too poor to permit analysis ---------- BADFILM ---------- (1)
C. Lesion(s) obscured by overlying branch arteries ---------- LESOBS ---------- (1)
D. The entire artery **was** not visualized because of
1) Too **high magnification** ---------- HIGHMAG ---------- (1)
2) **Excess collimation** _____ COLLIM ---- (1)
3) **Inappropriate panning** _____ PANNING ---- (1)
E. Injection rate too slow/contrast does not fill the artery lumen throughout the cardiac cycle ---------- SLOWRATE ---------- (1)
F. Incorrect projection ---------- INCPROJ ---------- (1)
G. Other ---------- OTHR ---------- (1)

Specify: _____

Skip *to Part VII.*

PART III: **ANGIOGRAPHIC** ASSESSMENT

5. Native segment assessment (list only site codes with stenosis > 50%).

	1) Site Code	2) Perfusion Grade 0-3	3) % Stenosis	4) Collateral 0-2	5) Stenosis Contour 0-2	6) Ulcer Grade 0-2	7) Thrombus Grade	8) Eccentric (E) or Concentric (C)
A.	ANGSITEA	ANGPERFA	ANGSTENA	ANGCOLLA	ANGCONTA	ANGULCA	ANGTHRMA	ANGECCA
B.	ANGSITEB	ANGPERFB	ANGSTENB	ANGCOLLB	ANGCONTB	ANGULCB	ANGTHRMB	ANGECCB
C.	ANGSITEC	ANGPERFC	ANGSTENC	ANGCOLLC	ANGCONTC	ANGULCC	ANGTHRMC	ANGECCC
D.	ANGSITED	ANGPERFD	ANGSTEND	ANGCOLLD	ANGCONTD	ANGULCD	ANGTHRMD	ANGECCD
E.	ANGSITEE	ANGPERFE	ANGSTENE	ANGCOLLE	ANGCONTE	ANGULCE	ANGTHRME	ANGECCE
F.	ANGSITEF	ANGPERFF	AN	ANGCOLLF	ANGCONTF	ANGULCF	ANGTHRMF	ANGECCF
G.	ANGSITEG	ANGPERFG	ANGSTENG	ANGCOLLG	ANGCONTG	ANGULCG	ANGTHRMG	ANGECCG
H.	ANGSITEH	ANGPERFH	ANGSTENH	ANGCOLLH	ANGCONTH	ANGULCH	ANGTHRMH	ANGECCH

6. **Bypass** grafts assessment

	1) Site Code	2) SVG/IMA	3) Stenosis > 50%* Yes	No	Not Assessed	4) Location P-M-D-A**	5) Perfusion Grade 0-3	6) % Stenosis	7) Stenosis Contour 0-2	8) Ulcer Grade 0-2	9) Thrombus Grade 0-4	10) Eccentric (E) or Concentric (C)
A.	GRFSITEA	GRFSVGA (1) (2)	GRFGTSOA (1)	(2)	(3)	GRFLOCA	GRFPERFA	GRFSTENA	GRFCONTA	GRFULCA	GRFTHRMA	GRFECCA
B.	GRFSITEB	GRFSVGB (1) (2)	GRFGTSOB (1)	(2)	(3)	GRFLOCB	GRFPERFB	GRFSTENB	GRFCONTB	GRFULCB	GRFTHRMB	GRFECCB
C.	GRFSITEC	GRFSVGC (1) (2)	GRFGTSOC (1)	(2)	(3)	GRFLOCC	GRFPERC	GRFSTENC	GRFCONTC	GRFULCC	GRFTHRMC	GRFECCC
D.	GRFSITED	GRFSVGD (1) (2)	GRFGTSOD (1)	(2)	(3)	GRFLOCD	GRFPERD	GRFSTEND	GRFCONTD	GRFULCD	GRFTHRMD	GRFECCD
E.	GRFSITEE	GRFSVGE (1) (2)	GRFGTSOE (1)	(2)	(3)	GRFLOCE	GRFPERE	GRFSTENE	GRFCONTE	GRFULCE	GRFTHRME	GRFECCE
F.	GRFSITEF	GRFSVGF (1) (2)	GRFGTSOF (1)	(2)	(3)	GRFLOCF	GRFPERF	GRFSTENF	GRFCONTF	GRFULCF	GRFTHRMF	GRFECCF
G.	GRFSITEG	GRFSVGG (1) (2)	GRFGTSOG (1)	(2)	(3)	GRFLOCG	GRFPERG	GRFSTENG	GRFCONTG	GRFULCG	GRFTHRMG	GRFECCG
H.	GRFSITEH	GRFSVGH (1) (2)	GRFGTSOH (1)	(2)	(3)	GRFLOCH	GRFPERH	GRFSTENH	GRFCONTH	GRFULCH	GRFTHRMH	GRFECCH

**If NO ot NOTASSESSED do not answer columns 4-10 for that site code.*

***Jump Grafts - Assign Proximal and/or Mid location for lesions ove 1st anastomosis.*
Distal location for lesions between 1st and 2nd anastomosis.

ID No.			-				
Visit Type							

EXTCAD

6X. Extent of CAD (0-3, 8) ----------

PART IV: ANGIOGRAPHIC ELIGIBILITY

Answer Part IV only for qualifying angiograms.

		Yes	No
7.	Angiographic Inclusion Criteria		
	≥ 50% stenosis in a major native vessel or bypass graft ---------- GT50STEN	(1)	(2)
8.	Angiographic Exclusion Criteria		
	A. ≥ 50% left main coronary artery stenosis in non-bypass patients GT50LM	(1)	(2)
	B. **Significant mitral regurgitation** ---------- MITRAL	(1)	(2)
	C. Other ---------- OTHEXC	(1)	(2)

Specify: _____

9. Does this cineangiogram meet ACIP eligibility criteria? ---------- ANGELIG (1) (2)

10. Is there any unusual feature to be discussed with the Clinical Unit investigator? ---------- UNUSUAL (1) (2)

PART V: INTERVENTIONAL PROCEDURES

Answer Part V only for protocol PTCA.

11. Interventional procedures lesions

1) Site Code	2) Vein Graft Yes	2) Vein Graft No	3) Procedures Code	4) Procedure Approach (G-N)	5) Location (P-M-D-A)**	6) % Stenosis pre	7) Stenosis pre	8) % Stenosis post	9) Grade post
A. LESSITEA **Lesion 1**	LESVEINA (1)	(2)	LESPROCA	LESAPPRA	LESLOCA	LESSPREA	LESGPREA	LESSPSTA	LESGPST
B. LESSITEB **Lesion 2**	LESVEINB (1)	(2)	LESPROCB	LESAPPRB	LESLOCB	LESSPREB	LESGPREB	LESSPSTB	LESGPST
C. LESSITEC **Lesion 3**	LESVEINC (1)	(2)	LESPROCC	LESAPPRC	LESLOCC	LESSPREC	LESGPREC	LESPSTC	LESGPST
D. LESSITED **Lesion 4**	LESVEIND (1)	(2)	LESPROCD	LESAPPRD	LESLOCD	LESSPRED	LESGPRED	LESPSTD	LESGPST
E. LESSITEE **Lesion 5**	LESVEINE (1)	(2)	LESPROCE	LESAPPRE	LESLOCE	LESSPREE	LESGPREE	LESPSTE	LESGPST
F. LESSITEF Lesion 6	LESVEINF (1)	(2)	LESPROCF	LESAPPRF	LESLOCF	LESSPREF	LESGPREF	LESPSTF	LESGPST

Procedures Code
1 = Standard Balloon Angioplasty
2 = Stent
3 = Atherectomy
4 = Laser
5 = Laser Balloon
6 = Other

Procedure Approach Code
G = Graft N = Native

Location Code
P = Proximal D = Distal
M = Mid A = Distal Anastomasis

**Jump Grafts - Assign Proximal and/or Mid location for lesions above 1st anastomosis.
Distal location for lesions between 1st and 2nd anastomosis.

ID No.			-				
Visit Type							

12. Post procedural angiographic observations Lesion 1 ---------- Site Code PP1SITE - - -

A. Dilated segment luminal abnormalities:

(1) PP1NA ——— Not assessable →→→ *Skip to B.*

		Yes	No
1.	Dissection PP1DISS	(1)	(2)
2.	Transient occlusion PP1TRAN	(1)	(2)
3.	**Sustained occlusion** PP1SUST	(1)	(2)

B. Intraluminal opacities:

1.	Undefined lucencies PP1UND	(1)	)
2.	Intimal **flap** PP1FLAP	(1)	It)
3.	Definite thrombus PP1THRM	(1)	(2)

C. Non-dilated segments:

1.	**Ostial dissection** PP1OST	(1)	(2)
2.	**Non-ostial dissection** PP1NOST	(1)	(2)
3.	Side-branch **occlusion** PP1SIDE	(1)	(2)
4.	**New side-branch stenosis** PP1NEW	(1)	(2)
5.	Distal embolization PP1DIST	(1)	(2)

13. Post procedural angiographic observations Lesion 2 ---------- Site Code PP2SITE - - -

A. Dilated segment luminal abnormalities:

(1) PP2NA --------- Not assessable →→→ *Skip to B.*

		Yes	No
1.	Dissection PP2DISS	(1)	(2)
2.	Transient occlusion PP2TRAN	(1)	(2)
3.	Sustained occlusion PP2SUST	(1)	(2)

B. Intraluminal opacities:

1.	Undefined lucencies PP2UND	(1)	(2)
2.	Intimal flap PP2FLAP	(1)	(2)
3.	Definite thrombus PP2THRM	(1)	(2)

C. Non-dilated segments:

1.	Ostial dissection PP2OST	(1)	)
2.	Non-ostial dissection PP2NOST	(1)	I:)
3.	Side-branch occlusion PP2SIDE	(1)	)
4.	New side-branch stenosis PP2NEW	(1)	I:)
5.	Distal embolization PP2DIST	(1)	(2)

ID No.			-				
Visit Type							

PP3SITE

14. Post procedural angiographic observations Lesion 3 ---------- Site Code _ _ _

A. Dilated segment luminal abnormalities:

PP3NA

(1) --------- Not assessable → → → *Skip to B.*

		Yes	No
1.	**Dissection**	PP3DISS	(1) (2)
2.	Transient occlusion	PP3TRAN	(1) (2)
3.	Sustained occlusion	PP3SUST	(1) (2)

B. Intraluminal opacities:

1.	Undefined **lucencies**	PP3UND	(1) (2)
2.	Intimal **flap**	PP3FLAP	(1) (2)
3.	Definite thrombus	PP3THRM	(1) (2)

C. Non-dilated segments:

1.	Ostial dissection	PP3OST	(1) (2)
2.	Non_ostial dissection	PP3NOST	(1) (2)
3.	Side-branch occlusion	PP3SIDE	(1) (2)
4.	New side-branch stenosis	PP3NEW	(1) (2)
5.	Distal embolization	PP3DIST	(1) (2)

PP4SITE

15. Post procedural angiographic observations Lesion 4 ---------- Site Code _ _ _

A. Dilated segment luminal abnormalities:

PP4NA

(1) _____ Not assessable → → → *Skip to B.*

		Yes	No
1.	Dissection	PP4DISS	(1) (2)
2.	Transient occlusion	PP4TRAN	(1) (2)
3.	Sustained occlusion	PP4SUST	(1) (2)

B. Intraluminal opacities:

1.	Undefined lucencies	PP4UND	(1) (2)
2.	Intimal flap	PP4FLAP	(1) (2)
3.	Definite thrombus	PP4THRM	(1) (2)

C. Non-dilated segments:

1.	Ostial dissection	PP4OST	(1) (2)
2.	Non-ostial dissection	PP4NOST	(1) (2)
3.	Side-branch occlusion	PP4SIDE	(1) (2)
4.	New side-branch stenosis	PP4NEW	(1) (2)
5.	Distal embolization	PP4DIST	(1) (2)

ID No.								
Visit Type								

16. Post procedural angiographic observations Lesion 5 ------ ------ Site Code PP5SITE _ _ _

A. Dilated segment luminal abnormalities:

(1) PP5NA --------- Not assessable →→→ *Skip to B.*

		Yes	No
1. Dissection	PP5DISS	(1)	(2)
2. Transient occlusion	PP5TRAN	(1)	(2)
3. Sustained occlusion	PP5SUST	(1)	(2)

B. Intraluminal opacities:

1. Undefined lucencies	PP5UND	(1)	(2)
2. Intimal flap	PP5FLAP	(1)	(2)
3. Definite thrombus	PP5THRM	(1)	(2)

C. Non-dilated segments:

1. Cstial dissection	PP5OST	(1)	(2)
2. Non_ostial dissection	PP5NOST	(1)	(2)
3. Side-branch occlusion	PP5SIDE	(1)	(2)
4. New side-branch stenosis	PP5NEW	(1)	(2)
5. Distal embolization	PP5DIST	(1)	(2)

17. Post procedural angiographic observations Lesion 6 ---------- Site Code PP6SITE _ _ _

A. Dilated segment luminal abnormalities:

(1) PP6NA --------- Not assessable →→→ *Skip to B.*

		Yes	No
1. Dissection	PP6DISS	(1)	(2)
2. Transient occlusion	PP6TRAN	(1)	(2)
3. Sustained occlusion	PP6SUST	(1)	(2)

B. Intraluminal opacities:

1. Undefined lucencies	PP6UND	(1)	(2)
2. Intimal flap	PP6FLAP	(1)	(2)
3. Definite thrombus	PP6THRM	(1)	(2)

C. Non-dilated segments:

1. Ostial dissection	PP6OST	(1)	(2)
2. Non-ostial dissection	PP6NOST	(1)	(2)
3. Side-branch occlusion	PP6SIDE	(1)	(2)
4. New side-branch stenosis	PP6NEW	(1)	(2)
5. Distal embolization	PP6DIST	(1)	(2)

18. Complete revascularization ---------- COMPLETE (1) (2)

ID No.			-					
Visit Type								

PART VI: ASSESSMENT OF **VENTRICULOGRAM**

19. Ventricular function

A. LV gram not available ---------- VGRAMNA (1) → → → *Skip to Part VII.*

B. Global ejection fraction ---------- EJFR 0 . - - (1) Not Available

C. RAO projection not available ---------- RAOPNA (1) → → → *Skip to Item D.*

Answer each item:	Normal	Hvookinetic	Dvskinetic	**Akinetic**	Not Assessed
1) **Anterobasal** ---- ANTBASAL	(1)	(2)	(3)	(4)	(5)
2) **Anterolateral** -- ANTLATER	(1)	(2)	(3)	(4)	(5)
3) **Apical** ---------- APICAL	(1)	(2)	(3)	(4)	(5)
4) **Diaphragmatic** -- DIAPHRAG	(1)	(2)	(3)	(4)	(5)
5) **Posterobasal** --- POSBASAL	(1)	(2)	(3)	(4)	(5)

D. LAO projection not available ---------- LAOPNA (1) → → → *Skip to Item 20.*

Answer each item:	Normal	Hvookinetic	Dvskinetic	**Akinetic**	Not Assessed
6) **Basal septal** ----- BASSEPT	(1)	(2)	(3)	(4)	(5)
7) **Apical septal** ---- APISEPT	(1)	(2)	(3)	(4)	(5)
8) **Posterolateral** --- POSLATER	(1)	(2)	(3)	(4)	(5)
9) Inferior lateral - INFLATER	(1)	(2)	(3)	(4)	(5)
10) Superior lateral - SUPLATER	(1)	(2)	(3)	(4)	(5)

20. Comments: _____

_____

PART VII: ADMINISTRATIVE **MATTERS**

21. ACL Investigator:

Signature: _____ ACIP Staff No.: ---- COMPCRT - - - - - -

22. Date form completed: ---------- COMPDT - - - - - - -
Day Month Year

ID No.			-				
Visit Type							

If the AECG was performed, send the original of this form with the AECG tracings to the AECG Core Lab. Send a copy of the form to the CCC. If the AECG was not performed, send this form only to the CCC.

NEWID

Clinic No.	CURCLIN
ID No.	

VISIT

Visit Type	

PART I: IDENTIFICATION

1. Patient's NAME CODE: ---------- NAMECODE - - - - -

2. Date of study or last date of window if study not done: ---------- VISDT - - - - - -
Day Month Year

3. Check here if AECG was not performed: ---------- ND (1)

4. Reason procedure was not performed *(check all that apply):*

A. Physician refused ---------- PHYREF (1)
B. Patient refused ---------- PTREF (1)
C. Procedure contraindicated (cardiac **reason**) ---------- CONTCARD (1)
D. Procedure contraindicated (**physical** disability *or* other **reason**) ---------- CONTPHYS (1)
E. Equipment unavailable ---------- NOEQUIP (1)
F. Equipment malfunctioned ---------- BADEQUIP (1)
G. Other ---------- NOPEROTH (1)

Specify: _____

5. Research Coordinator:

Signature: NOPERSIG ACIP Staff No: NOPERCRT - - - - -

*DO NOT COMPLETE **REST** OF FORM. SEND ONLY PAGE 1 TO CCC.*

6. Item skipped.

PART II: DATA DESCRIPTION

7. First tape recordings started:

A. Date and military time: _____ T1STDT - - - - - T1STHR T1STMI
Day Month Year Hours Minutes

ID No.	

Recordings ended:

B. Date and military time: ---------- T1SPDT (Day Month Year) T1SPHR T1SPM (Hours Minutes)

8. Second tape recordings started:

A. Date and military time: ---------- T2STDT (Day Month Year) T2STHR T2STM (Hours Minutes)

Recordings ended:

B. Date and military time: ---------- T2SPDT (Day Month Year) T2SPHR T2SPM (Hours Minutes)

9. Which ECG position strips were obtained (answer all items):

	Yes	No
A. Standing	(1)	(2)
B. Sitting	(1)	(2)
C. R-lateral decubitus	(1)	(2)
D. Supine	(1)	(2)
E. L-lateral decubitus	(1)	(2)
F. Hyperventilation	(1)	(2)
G. Calibration	(1)	(2)

10. Did the patient have an episode of ischemic chest pain during the recording? ISCHREC ---------- (1) Yes (2) No

10A. Was patient compliant in using the event marker? EVTMARK ---------- (1) Yes (2) No

PART III: ADMINISTRATIVE MATTERS

11. AECG Monitoring Technician:

Name: AECGSIG ACIP Staff No: AECGCRT

12. Research Coordinator:

Signature: CompSIG ACIP Staff No: CompCRT

13. Date mailed to AECG Monitoring Core Lab: ---------- MAILDT (Day Month Year)

14. Comments: _____

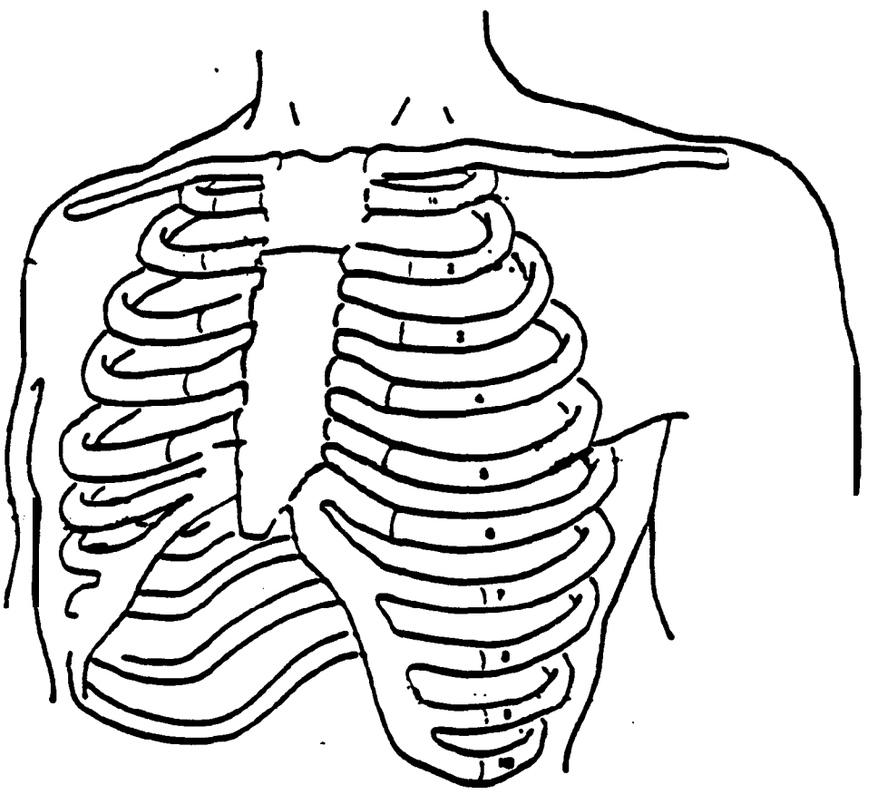
ID No. | | | | - | | | | |

Visit Type | | | | |

AECG Lead Selection

Please note where the electrode leads have been placed for this patient.

Please confirm that the morphology of the QRS-T record by the AECG matches the morphology of the desired leads from the **12-lead** ECG.



Leads: Channel 1 = White - Red

Channel 2 = Brown - Black

Green = Ground

Note: For each bipolar lead, the **upper** lead on the chest wall should be the white lead for channel and the brown lead for channel 2.
The lower lead on the chest wall should be the **red** lead for channel 1 and the black lead for channel 2.

Modified ACIP Protocol Worksheet

Instructions:

- Indicate HR and BP at each stage of exercise and for each minute of Recovery until symptoms or ST segment changes normalize.
- Indicate the RPE at each stage of exercise.
- For prolonged recovery > 5:00 minutes, indicate the time of recovery (_:__) as well as HR and BP values.
- If angina occurs, indicate (1) at the stage-et occurence, and an (x) at offset:
- If angina worsens as exercise continues. indicate (2).
- If ST segment change > 1.0 mm, indicate an (1) at the stage of onset. and an (x) at offset.

Stage	Speed	Grade	Est. Mets	Total Time	Time/ Stage	HR	BP	Angina	Onset ST Δ ≥ 1.0 mm	RPE Scale
Standing Rest						[ ]	[/]			
EXERCISE										
1	2.0	0.0	2.5	1:00	1:00	[ ]	[/]	[ ]	[ ]	[ ]
2	2.0	3.5	3.5	2:00	1:00	[ ]	[/]	[ ]	[ ]	[ ]
3	2.0	7.0	4.5	4:oo	2:oo	[ ]	[/]	[ ]	[ ]	[ ]
4	2.0	13.5	6.2	6:00	2:oo	[ ]	[/]	[ ]	[ ]	[ ]
5	2.0	18.5	7.8	8:00	2:00	[ ]	[/]	[ ]	[ ]	[ ]
6	2.0	24.0	9.1	lo:oo	2:00	[ ]	[/]	[ ]	[ ]	[ ]
7	2.3	24.0	10.5	12:00	2:00	[ ]	[/]	[ ]	[ ]	[ ]
8	2.7	24.0	12.0	14:oo	2:oo	[ ]	[/]	[ ]	[ ]	[ ]
9	3.1	24.0	13.4	16:00	2:00	[ ]	[/]	[ ]	[ ]	[ ]
10	3.4	24.0	15.1	18:00	2:00	[ ]	[/]	[ ]	[ ]	[ ]
RECOVERY: IMMEDIATE POST-EX				0:00		[ ]	[/]	[ ]	[ ]	
1				1 :oo		[ ]	[/]	[ ]	[ ]	
2				2:oo		[ ]	[/]	[ ]	[ ]	
3				3:oo		[ ]	[/]	[ ]	[ ]	
4				4:oo		[ ]	[/]	[ ]	[ ]	
5				5:00		[ ]	[/]	[ ]	[ ]	
PROLONGED RECOVERY TIME: _:__						[ ]	[/]	[ ]	[ ]	

Comments:_____

Revised: August 18, **1991**

ASYMPTOMATIC CARDIAC ISCHEMIA PILOT

ACIP FORM 8E

ACIP EXERCISE TOLERANCE TEST FORM

GENERAL INSTRUCTIONS

Complete for ACIP Exercise Tolerance Test performed as required by protocol. Send original of this form with required ECGs to Rest and Exercise ECG Core Laboratory and a copy of the form to the Clinical Coordinating Center.

ITEM INSTRUCTIONS: Items with instructions outlined below have the symbol [*] preceding the item number on the form.

Refer to Items 10 and 11.

- Indicate HR and BP at each stage of exercise and for each minute of Recovery until symptoms or ST segment changes normalize.
- Indicate the RPE at each stage of exercise. For prolonged recovery > 5:00 minutes, indicate the time of recovery (_ _ : _ _) as well as HR and BP values.

NOTE : Even if the final stage entered is not for the complete time, enter the final HR, BP and RPE.

Refer to Item 10 Column 5.

Ratings of Perceived Exertion (RPE) Scale

6	
7	Very, Very Light
8	
9	Very Light
10	
11	Fairly Light
12	
13	Somewhat Hard
14	
15	Hard
16	
17	Very Hard
18	
19	Very, Very Hard
20	

ASYMPTOMATIC CARDIAC ISCHEMIA PILOT

ACIP FORM 8E

ACIP EXERCISE TOLERANCE TEST FORM

Instructions for Item 12.

Recording Staee

Enter stage of onset or offset. If during exercise enter‘ 01 to 10 corresponding to Stage labels for Item 10. If during recovery enter RO to R+ corresponding to Stage labels for Item 11.

Recording Time

Enter time of onset or offset. If during exercise enter total exercise time, possible values are 00:01 to 18:00. If during recovery enter total recovery time, possible values are 00:01 to time recorded as prolonged recovery time.

Item 12D and E

Enter stage angina first worsened.

CURCLIN
NEWID
VISIT

Clinic No.	-
ID No.	
Visit Type	

PART I: IDENTIFICATION

1. Patient's NAME CODE: ---------- NAMECODE _ _ _ _ _

2. Date of study or last date of window if study not done ---------- VISDT m m - - v - - -
Day Month Year

3. Check here if test not performed? ---------- (1)

4. Reason procedure was not performed (Check all *that apply*.)

A. Physician refused ---------- PHYREF (1)
B. Patient refused ---------- PTREF (1)
C. Procedure contraindicated (cardiac reason) ---------- CONTCARD (1)
D. Procedure contraindicated (physical disability or other reason) CONTPHYS (1)
E. Equipment unavailable _____ NOEQUIP (1)
F. Equipment problem ---------- BADEQUIP (1)
G. Other ---------- NOPEROTH (1)

Specify: _____

5. Research Coordinator: Signature: NOPERSIG ACIP Staff NO: NOPERCRT _ _ - _ _ _

DO NOT COMPLETE REST OF FORM. SEND IN ONLY PAGE 1 TO CCC AND RECL.

ID No.

PART II: TESTING

6. Did the patient take any of the following cardiovascular medications prior to the start of the exercise treadmill test? DO NOT LIST ACIP BLINDED MEDICATION.

	Yes	No	Unknown
A. Nitrates (within two hours): NIT2HR	(1)	(2)	(3)
B. Beta-blockers (within 48 hours): BB48	(1)	(2)	(3)
C. Calcium channel blockers (within 24 hours): C&W	(1)	(2)	(3)
D. Digitalis (within 2 weeks): DIGIT2WK	(1)	(2)	(3)

7. Protocol description:

A. Protocol type:

Standard ACIP Protocol (3 miles/hour) ETTPROT (1)
Modified ACIP Protocol (2 miles/hour for patients with physical limitations) (2)

B. Total exercise time in seconds: ETTSCND ____

C. Final stage of exercise entered (01 to 10) FINSTGE ____

8. Reasons for stopping: *(Check one Primary and, if appropriate, one Secondary.)*

	A Primary ETTPRIM	B Secondary ETT2ND
Angina (grade 3 or 4 out of 4)	(01)	(01)
ST-segment depression ≥ 3.0 mm	(02)	(02)
ST-segment elevation ≥ 1.0 mm in non-infarct lead(s)	(03)	(03)
Ectopic supraventricular tachycardia	(04)	(04)
Ventricular tachycardia	(05)	(05)
Hypertension	(06)	(06)
Hypotension	(07)	(07)
Fatigue/exhaustion	(08)	(08)
Dyspnea	(09)	(09)
Ataxia	(10)	(10)
Bradycardia	(11)	(11)
Poor motivation	(12)	(12)
Physician's request	(13)	(13)
Technical problems (with ECG or Blood Pressure Measurement)	(14)	(14)
Adequate heart rate achieved	(15)	(15)
Claudication	(16)	(16)
Other	(17)	(17)

Specify: _____

9. Was test part of imaging study? IMAGING (1) Yes (2) No

ID No.			-				
Visit Type							

[*]10.

		1)	2)	3) 4)	5)
	Stage	Total Exercise Time	HR bpm	BP SBP/DBP	RPE Scale
A.	Standing at Rest		HRA ___	SBPA ___ / DBPA ___	
B.	01	1:00	HRB ___	SBPB ___ / DBPB ___	BORGB
C.	02	2:00	HRC ___	SBPC ___ / DBPC ___	BORGC
D.	03	4:00	HRD ___	SBPD ___ / DBPD ___	BORGD
E.	04	6:00	HRE ___	SBPE ___ / DBPE ___	BORGE
F.	05	8:00	HRF ___	SBPF ___ / DBPF ___	BORGF
G.	06	10:00	HRG ___	SBPG ___ / DBPG ___	BORGG
H.	07	12:00	HRH ___	SBPH ___ / DBPH ___	BORGH
I.	08	14:00	HRI ___	SBPI ___ / DBPI ___	BORGI
J.	09	16:00	HRJ ___	SBPJ ___ / DBPJ ___	BORGJ
K.	10	18:00	HRK ___	SBPK ___ / DBPK ___	BORGK

[*]11. Recovery

		1)	2)	3) 4)
	Stage	Total Recovery Time	HR bpm	BP SBP/DBP
A.	RO Immediate Post-EX	0:00	RHRA ___	RSBPA ___ / RDBPA ___
B.	R1	1:00	RHRB ___	RSBPB ___ / RDBPB ___
C.	R2	2:00	RHRC ___	RSBPC ___ / RDBPC ___
D.	R3	3:00	RHRD ___	RSBPD ___ / RDBPD ___
E.	R4	4:00	RHRE ___	RSBPE ___ / RDBPE ___
F.	R5	5:00	RHRF ___	RSBPF ___ / RDBPF ___
G.	R+ Prolonged Recovery Time	RPROMIN RPRSEC	RHRG ___	RSBPG ___ / RDBPG ___

ID No.			-					1
Visit Type								

12. Did angina occur during study? ETTANG (1) Yes (2) No (3) Uncertain

A. Onset stage ONSTGE
B. Onset time ONMIN : ONSEC
C. Did angina worsen? ANGWORSE (1) Yes (2) No

D. Stage OFFSTGE
E. Time OFFMIN : OFFSEC

F. Offset stage OFFSTGE
G. Offset time OFFMIN : OFFSEC

13. Comments:

PART III: ADMINISTRATIVE MATTERS

14. ETT Technician:

Name: ETTSIG ACIP Staff No.: ETTCRT

15. Research Coordinator:

COMPSIG ACIP Staff No.: COMPCRT

16. Material mailed to the Rest and Exercise ECG Core Lab:

		Yes	No
A.	Form 8E FORM8E	(1)	(2)
	tracings only without diskette ECGTRACE	(1)	(2)
C.	ECG tracings and diskette ECGDISK	(1)	(2)
D.	Date mailed MAILDT		

Day Month Year

ID No.			-				
Visit Type							

Rest and Exercise:

	Stage	Total Exercise Time	_____
A.	Standing at Rest		
B.	01	l:oo	001-060
C.	02	2:oo	061-120
D.	03	4:oo	121-240
E.	04	6:00	241-360
F.	05	8:00	361-480
G.	06	**10:00**	481-600
H.	07	**12:00**	601-720
I.	08	**14:00**	721-840
J.	09	**16:00**	841-960
K.	10	18:00	961-1080

Recovery:

	Stage	Total Recovery Time	Time Range in Seconds
A.	RO **Immedicate Post-EX**		
B.	**R1**	**1:00**	001-060
C.	**R2**	2:oo	061-120
D.	**R3**	3:oo	121-180
E.	R4	4:oo	**181-240**
F.	**R5**	5:oo	241-300
G.	R+ Prolonged Recovery Time	__ __:__ __	__ __ __-__ __ __

Standard ACIP Protocol Worksheet

Instructions:

- Indicate HR and BP at each stage of exercise and for each minute of Recovery until symptoms or ST segment changes normalize.
- Indicate the RPE at each stage of exercise.
- For prolonged recovery > 5:00 minutes, indicate the time of recovery (_:__) as well as HR and BP values.
- If angina occurs, indicate (1) at the stage of occurence, and an (x) at off set:
- If angina worsens as exercise continues, indicate (2).
- If ST segment change > 1.0 mm, indicate an (1) at the stage of onset, and an (x) at offset.

Stage	Speed	Grade	Est. Mets	Total Time	Time/ Stage	HR	BP	Angina	OnsetSTΔ ≥1.0 mm	RPE Scale
Standing Rest						[ ]	[/ 1			
EXERCISE										
1	2.0	0.0	2.5	1:00	1:00	[ ]	[/]	[ ]	[ ]	[ ]
2	2.5	2.0	3.5	2:00	1:00	[ ]	[/]	[ ]	[ ]	[ ]
3	3.0	3.0	4.5	4:00	2:00	[ ]	[/]	[ ]	[ ]	[ ]
4	3.0	7.0	6.2	6:00	2:00	[ ]	[/]	[ ]	[ ]	[ ]
5	3.0	10.5	7.6	8:00	2:00	[ ]	[/]	[ ]	[ ]	[ ]
6	3.0	14.0	9.1	10:00	2:00	[ ]	[/]	[ ]	[ ]	[ ]
7	3.0	17.5	10.5	12:00	2:00	[ ]	[/]	[ ]	[ ]	[ ]
8	3.0	21.0	12.0	14:00	2:00	[ ]	[/]	[ ]	[ ]	[ ]
9	3.1	24.0	13.4	16:00	2:00	[ ]	[/]	[ ]	[ ]	[ ]
10	3.4	24.0	15.1	18:00	2:00	[ ]	[/]	[ ]	[ ]	[ ]
RECOVERY: IMMEDIATE POST-EX				0:00		[ ]	[/]	[ ]	[ ]	
1				1:00		[ ]	[/]	[ ]	[ ]	
2				2:00		[ ]	[/]	[ ]	[ ]	
3				3:00		[ ]	[/]	[ ]	[ ]	
4				4:00		[ ]	[/]	[ ]	[ ]	
5				5:00		[ ]	[/]	[ ]	[ ]	
PROLONGED RECOVERY TIME: _:__						[ ]	[/]	[ ]	[ ]	

Comments:_____

Revised: August 16. 1991

ASYMPTOMATIC CARDIAC ISCHEMIA PILOT

ACIP FORM 10

ANGINA QUESTIONNAIRE

GENERAL INSTRUCTIONS

The Angina Questionnaire should be completed at each of the scheduled visits and sent to the Clinical Coordinating Center along with the Follow-up Contact Form. This form may also be used as a worksheet during the first twelve weeks of medication adjustment when patients are contacted to check on angina level.

ITEM INSTRUCTIONS: Items with instructions outlined below have the symbol [*] preceding the item number on the form.

Refer to Item 5.

STABLE ANGINA: A pattern of angina that is predictably brought on by the activities the patient engages in. It is promptly relieved by sublingual nitroglycerin or prevented by nitroglycerin and other antianginal medication. The frequency and severity of episodes are similar from day to day.

UNSTABLE ANGINA: A changing pattern of angina that has distinctly worsened in severity and frequency in comparison to the patient's previous pattern. The chest discomfort of unstable angina, while similar in quality to stable angina, may be more intense and persist for longer periods of time, and may occur at rest.

Refer to Item 5B.

CANADIAN CARDIOVASCULAR SOCIETY CLASSIFICATION:

I - Ordinary physical activity, such as walking and climbing stairs, does not cause angina. Angina with strenuous, rapid or prolonged exertion at work or recreation.

II - Slight limitation of ordinary activity. Walking or climbing stairs rapidly, walking up hill, walking or stair climbing after meals, in cold, in wind, or when under emotional stress or during the first few hours after awakening may cause pain. Walking more than two blocks on the level and climbing more than one flight of ordinary stairs at a normal pace and in normal conditions.

III - Marked limitation of ordinary physical activity. Walking l-2 blocks on the level or climbing one flight of stairs results in angina.

IV - Inability to carry on any physical activity without discomfort. Angina1 syndrome may be present at rest.

ASYMPTOMATIC CARDIAC **ISCHEMIA** PILOT FORM REV

ACIP Form 10
Rev 1 04/06/92
Page 1 of 1

ANGINA QUESTIONNAIRE

CURCLIN
NEWID
VISIT

Clinic No.			-					
ID No.			-					
Visit Type								

PART I: IDENTIFICATION

1. Patient's NAME CODE: ---------- NAMECODE

2. Contact date: ---------- VISDT
Day Month Year

PART II: ANGINA

3. Has the patient experienced angina within the past 4 weeks (or since the ACIP revascularization procedure if procedure was performed in interval since the last scheduled visit)? -------- ANGDAILY
(1) Yes (2)(3) No Unknown

Skip to Part III.

4. Does angina interfere with usual daily activities? ---- STABLE ---- (1) Yes (2) No

[*] 5. Categorize angina: ---------- CA-TAN G ---------- (1) Stable (2) Unstable

A. How often has the patient had angina *(check ONE from each column):*

	1 Brought on by Physical Activity	2 Unrelated to Physical Activity
None at all	(1)	(1)
1 to 3 times a month	(2) PHYACT	(2) NOPHYACT
1 to 2 times a week	(3)	(3)
≥ 3 times a week but < 1 time a day	(4)	
1 to 3 times a day	(5)	
4 or more times a day	(6)	(6)

[*]B. Current Canadian Cardiovascular Society Classification *(choose one):*
I ---------- (1)
II ---------- (2) ANGCLASS
III ---------- (3)
IV ---------- (4)

Skip to Part III.

Skip to C.

C. Categorize unstable angina (answer *each item):*

	Yes	No	Unknown
1) accelerating angina despite stable therapy ACCELANG	(1)	(2)	(3)
2) angina lasting > 20 minutes ANGGT20	(1)	(2)	(3)
3) angina at rest ANGREST	(1)	(2)	(3)
4) patient hospitalized for above symptoms ANGHOSP	(1)	(2)	(3)

PART III: ADMINISTRATIVE MATTERS

6. Research Coordinator:

Signature: _____ ACIP Staff No.: __ __-__ __ __

CURCLIN

Clinic No.	-
ID No.	-
Visit Type	

NEWID

VISIT

PART I: IDENTIFICATION

1. Patient's NAME CODE: ---------- NAMECODE _ _ _ _ _

2. Contact date: ---------- VISDT _ _ - _ _ - _ _ _ _
Day Month Year

3. Type of contact ---------- CONTACT (1) (2)
Visit Phone

4. Start or increase in open label medication for the control of angina being prescribed at this contact: ---------- INCOPEN (1) (2)
Yes No or None taken
↓

A. If YES, indicate reason: OPENREA

≥ 3 episodes of angina in a week ---------- (1)

< 3 episodes per week, but patient feels too limited by angina and wishes more medication ----- (2)

Personal physician insists ---------- (3)

[*] 5. Notification received to increase the blinded medication? ---------- BLNDNOTE (1) (2) (3)
Yes No Not Applicable
↓
↓

A. Was the new dose level prescribed? ---------- BLNDPRE (1) (2)
Yes No
↓

B. Why wasn't new dose prescribed? BLNDNOPR

Treatment of angina with open label medication increase ---------- (1)

Side effects ---------- (2)

Other ---------- (3)

Specify: _____

6. Is a decrease in ACIP medication indicated because of possible side-effects? ..... DECRSE (1) Yes ↓ (2) No or None taken

7. Which medication: (Check *all* that apply.)

A.	Atenolol open label	DECRATOP	(1)
B.	Nifedipine sr open label	DECRNICP	(1)
C.	**Diltiazem** sr open label	DECRDICP	(1)
D.	Isosorbide dinitrate open label	DECRISOP	(1)
E.	Atenolol blinded	DECRATBL	(1)
F.	Nifedipine sr blinded	DECRNIBL	(1)
G.	**Diltiazem** sr blinded	DECRDIBL	(1)
H.	Isosorbide dinitrate blinded	DECRISBL	(1)

[*]8. Check only those side effects that occur:

CARDIOVASCULAR

A.	Bradycardfa	BRADSE	(1)
B.	Hypotension	HYPOSE	(1)
C.	**Palpitations**	PALPSE	(1)

RESPIRATORY

D.	**Wheezing**	WHEEZSE	(1)
E.	**Dyspnea**	DYSPNSE	(1)
F.	cough	COUGHSE	(1)

CENTRAL NERVOUS SYSTEM

G.	**Depression**	DEPRSE	(1)
H.	Dizziness	DIZZYSC	(1)
I.	syncope	SYNCOSE	(1)
J.	Fatigue	FATIGSE	(1)
K.	Tremor	TREMSE	(1)
L.	Headache	HEADSE	(1)

GASTROINTESTINAL

M.	Diarrhea	DIARRSE	(1)
N.	**Nausea**	NAUSSE	(1)
0.	Anorexia	ANORSE	(1)

PERIPHERAL

P.	**Rash**	RASHSE	(1)
Q.	**Flushing**	FLUSHSE	(1)
R.	**Edema**	EDEMASE	(1)

OTHER

S.	Other	SEOTH	(1)

Specify _____

ID No.			-				
Visit Type							

PART II: MEDICATION PRESCRIBED AT THIS CONTACT

9. Background atenolol or **diltiazem** medication: BACKMED

None ---------- (1)
Atenolol 50 mg qd ---------- (2)
Dfltiazem sr 60 mg bid ---------- (3)

NEWREG

10. Was **the** regimen switched at this contact? ---------- (1) Yes (2) No

↓

A. Why? _____

11. **ACIP** medication

A. Open label medication prescribed at this contact: OPENREG

Regimen D/I ---------- (1) ↓

1. **Diltiazem sr bid:**

OPDIDOS
None ---------- (1)
60 mg ---------- (2)
90 mg ---------- (3)
120 mg ---------- (4)
180 mg ---------- (5)
Other ---------- (6)

2. **Isosorbide Dinitrate bid:**

OPISDOS
None ---------- (1)
20 mg ---------- (2)
40 mg ---------- (3)
60 mg ---------- (4)
80 mg ---------- (5)
Other ---------- (6)

Regimen A/N ---------- (2) ↓ (3) **None**

3. **Atenolol qd:**

OPATDOS
None ---------- (1)
50 mg ---------- (2)
100 mg ---------- (3)
150 mg ---------- (4)
200 mg ---------- (5)
Other ---------- (6)

4. **Nifedipine sr qd:**

OPNIDOS
None ---------- (1)
30 mg ---------- (2)
60 mg ---------- (3)
90 mg ---------- (4)
120 mg ---------- (5)
Other ---------- (6)

ID No.			-				
Visit Type							

11. ACIP medication (Continued)

(*)B. Blinded medication prescribed at this contact: BLNDREG

Regimen D/I ---------- (1) ↓

1. Diltiazem **sr/Placebo** bid: BLDIDOS
   - **None** ---------- (1)
   - **60 mg** ---------- (2)
   - **90 mg** ---------- (3)
   - **Other** ---------- (4)

   A. **Medication code number** DIMEDID
   ___ ___ ___-___ ___ ___-___ ___

2. Isosorbide **Dinitrate/Placebo** bid: BLISDOS
   - **None** ---------- (1)
   - **20 mg** ---------- (2)
   - **40 mg** ---------- (3)
   - **Other** ---------- (4)

   A. Medication code number ISMEDID
   ___ ___ ___-___ ___ ___-___ ___

Regimen A/N ---------- (2) ↓

3. **Atenolol/Placebo** qd: BLATDOS
   - **None** ---------- (1)
   - 50 mg ---------- (2)
   - 100 mg ---------- (3)
   - Other ---------- (4)

   A. Medication code number ATMEDID
   ___ ___ ___-___ ___ ___-___

4. **Nifedipine sr/Placebo qd:** BLNIDOS
   - **None** ---------- (1)
   - **30 mg** ---------- (2)
   - **60 mg** ---------- (3)
   - **Other** ---------- (4)

   A. **Medication** code **number** NIMEDID
   e - W - - -V -

(3) None *or* Not Applicable

12. Was there any unusual adjustment in prescription or a decrease for reasons other than side effects? ---------- (1) Yes (2) No ADJSTPRE

↓

A. Explain: _____

_____

ID No.			-				
Visit Type							

13. Was other medication prescribed in place of ACIP medication for control of angina? ..... (1) (2) OTHMEDS
Yes No
↓

A. Specify: _____

PART III: ADMINISTRATIVE MATTERS

14. Research Coordinator:

Signature: COMPSIG _____ ACIP Staff No.: COMPCRT _ _ _ _ _

ID No.			-				
Visit Type							

ASYMPTOMATIC CARDIAC ISCHEMIA PILOT

ACIP FORM 13

FOLLOW-UP CONTACT FORM

GENERAL INSTRUCTIONS

This form should be completed at each scheduled follow-up contact to report events, procedures, and medical status since the last scheduled follow-up contact or since the ACIP revascularization procedure if procedure was performed in interval since the last scheduled visit. At the four-week contact report all events, procedures, and medical status since the randomization visit. The scheduled follow-up contacts (displayed on the patient appointment schedule) should be completed at 4 weeks, 8 weeks, 12 weeks, 6 months, 9 months, 1 year, 18 months and 2 years after randomization. All medication adjustment contacts between scheduled follow-up contacts are considered unscheduled contacts.

ITEM INSTRUCTIONS: Items with instructions outlined below have the symbol [*] preceding the item number on the form.

Refer to Item 9, Column 3.

Form 11 should be completed at each contact (scheduled or unscheduled) in which: 1) ACIP open label or blinded medication was first prescribed or changed; or 2) notification to increase blinded medication was received: or 3) any medication for control of angina was prescribed.

Refer to Item 10B.

Answer yes if patient has been given open label medication or received a prescription for open label medication at or since the last scheduled contact. Answer yes if open label medication was started at or continued since the last scheduled contact.

Refer to Item 14.

Answer yes if patient has been given blinded medication or received a prescription for blinded medication at or since the last scheduled contact. Answer yes if blinded medication was started at or continued since the last scheduled contact.

ASYMPTOMATIC CARDIAC ISCHEMIA PILOT

FOLLOW-UP CONTACT FORM

CURCLIN
NEWID
VISIT

Clinic No.	| | | - | | |
ID No.	| | | - | | | | | |
Visit Type	| | | |

PART I: IDENTIFICATION

1. Patient's NAME CODE: ---------- NAMECODE _ _ _ _ _

2. Date of contact: ---------- VISDT _ _ - _ _ _ - _ _
   Day Month Year

3. Type of Contact: CONTACT
   In person visit ---------- (1)
   Phone contact ---------- (2)

PART II: MAJOR EVENTS

4. Did any of the following end points occur *since* the last scheduled follow-up contact (or since ACIP revascularizatlon procedure)? ---------- ENDPOINT (1) (2)
   Yes No

Event	Yes	No	DATE OF EVENT Day	Month	Year
A. Death ---------- DEATHEP ----------	(1)*	(2)			
B. HI ---------- MIEP ----------	(1)*	(2)			
C. Rest Angina ---- ANGEP ----	(1)	(2)			
D. Angina requiring increase in medication ---- INCMEDEP ----	(1)	(2)			
E. Cardiac arrest ---------- CARDEP ----------	(1)	(2)	_ _	CARDDT _ _ _	_ _
F. Stroke ---------- STRKEP ----------	(1)	(2)	_ _	STRKDT _ _ _	_ _

Submit appropriate event forms.

ID No.			-				

5. Is there evidence of new or worsening CHF since the last scheduled follow-up contact (or since ACIP revascularization procedure)? ---------- NEWCHF (1) Yes (2) No (3) Unknown

↓

A. Current New York Heart Association Functional Classification: CHFCLASS

- One ---------- (1)
- Two ---------- (2)
- Three ---------- (3)
- Four ---------- (4)

6. Has patient been hospitalized since the last scheduled follow-up contact for a cardiovascular condition or for any cardiovascular complication associated with a noncardiovascular admission7 ------ HOSPCE (1) Yes (2) No (3) Unknown
(Do not include ACIP revascularization procedure.)

↓

Submit Subsequent Hospitalization Form 14 for each admission.

	Date of Admission Day	Month	Year	Hospital
A.	HospADT			
B.	HospBDT			
C.	HospCDT			
D.	HospDDT			

7. Did patient undergo any of the following special procedures since the last scheduled follow-up contact? ---------- PROCS (1) Yes (2) No (3) Unknown
(Do not include ACIP revascularization procedure.)

↓

Event	Yes	No
A. Coronary angiography ---------- ANGIO	(1)*	(2)
B. CABG ---------- CABG	(1)*	(2)
C. PTCA ---------- PTCA	(1)*	(2)
D. Other cardiac revascularization interventional technique ---------- INTER	(1)*	(2)
E. Heart surgery other than CABG ---------- SURG	(1)	(2)

Submit appropriate event forms.

ID No.			-					
Visit Type								

8. Has the patient experienced new onset of any of these symptoms since the last scheduled follow-up contact (or since ACIP revascularization procedure)? ---------- (1) Yes (2) No

NEWSE

	Yes	No
CARDIOVASCULAR		
A. Bradycardia (BRAD)	(1)	(2)
B. Hypotension (HYPO)	(1)	(2)
C. Palpitations (PALP)	(1)	(2)
RESPIRATORY		
D. Wheezing (WHEEZ)	(1)	(2)
E. Dyspnea (DYSPN)	(1)	(2)
F. Cough (COUGH)	(1)	(2)
CENTRAL NERVOUS SYSTEM		
G. Depression (DEPR)	(1)	(2)
H. Dizziness (DIZZY)	(1)	(2)
I. Syncope (SYNCO)	(1)	(2)
J. Fatigue (FATIG)	(1)	(2)
K. Tremor (TREM)	(1)	(2)
L. Headache (HEAD)	(1)	(2)
GASTROINTESTINAL		
M. Diarrhea (DIARR)	(1)	(2)
N. Nausea (NAUS)	(1)	(2)
O. Anorexia (ANOR)	(1)	(2)
PERIPHERAL		
P. Rash (RASH)	(1)	(2)
Q. Flushing (FLUSH)	(1)	(2)
R. Edema (EDEMA)	(1)	(2)

ID No.			-					
Visit Type								

PART III: **MEDICATION**

9. Was the patient contacted since the last scheduled follow-up contact to discuss medication adjustment? (Include this visit if medication is adjusted.) ---------- LVCONTCT (1) Yes (2) No

↓

Contact **Log** for Medication Adjustment

	1) Date: Day	Month	Year	2) Type: Visit	Phone	3)* Form 11 Completed: Yes	No
A.	_ _	CONTADT		CONTACTA (1)	(2)	FORM11A (1)	(2)
B.	_ _	CONTBDT		CONTACTB (1)	(2)	FORM11B (1)	(2)
C.	_ _	CONTCDT		CONTACTC (1)	(2)	FORM11C (1)	(2)
D.	_ _	CONTDDT		CONTACTD (1)	(2)	FORM11D (1)	(2)
E.	_ _	CONTEDT		CONTACTE (1)	(2)	FORM11E (1)	(2)

10A. Background atenolol or **diltiazem** medication: BACKMED

None ---------- (1)
Atenolol **50 mg** qd ---------- (2)
Diltiazem sr 60 **mg** bid ---------- (3)

OPPREV

10B.** Is the patient taking ACIP open label medication? -- (1) Yes (2) No → ***Skip to Item 14.

ID No.			-				
visit **Type**							

11. **ACIP** open label medication prescription at the start of this contact: OPENREG

Regimen D/I ---------- (1) ↓ Regimen A/N ---------- (2) ↓ (3) None

A. **Diltiazem** sr bid:

None ---- OPDIDOS (1)
60 mg ---------- (2)
90 mg ---------- (3)
120 **mg** ---------- (4)
180 **mg** ---------- (5)
Other ---------- (6)
Specify: _____

B. Isosorbide Dinitrate bid:

None --- OPISDOS (1)
20 **mg** ---------- (2)
40 **mg** ---------- (3)
60 **mg** ---------- (4)
80 **mg** ---------- (5)
Other ---------- (6)
Specify: _____

C. Atenolol **qd:**

None --- OPATDOS (1)
SO **mg** ---------- (2)
100 mg _____ (3)
150 **mg** _____ (4)
200 **mg** ---------- (5)
Other _____ (6)
Specify: _____

D. **Nifedipine** *sr* **qd:**

None --- OPNIDOS (1)
30 **mg** ---------- (2)
60 mg _____ (3)
90 **mg** _____ (4)
120 mg _____ (5)
Other ---------- (6)
Specify: _____

12. ACIP staff member's best estimate of **the** proportion of the open label medication ingested since the last scheduled follow-up contact OPENADH (use *Patient Compliance Worksheet attached at the end* **of** *the form to* answer ***this*** *item):* ---------- ___ ___ ___% (1) **Unknown** OPENUNK

If < 90%, answer Item 13.
If ≥ 90%, skip to Item 14.

13. In the opinion of the ACIP staff, why was the proportion of open label **medication** ingested **< 90%?** (Answer each ***item.***)

		Yes	No
A.	Patfent **forgetfulness** ---------- OPENPF ----------	(1)	(2)
B.	Side effects ---------- OPENSE ----------	(1)	(2)
C.	Other ---------- OPENOTH ----------	(1)	(2)

If side effects or other, describe:

_____

_____

ID No.			-				
Visit Type							

BLPREV

*14. Is the patient taking ACIP blinded medication? -------- (1) (2) → ***Skip to Item 18.***
Yes No

15. ACIP blinded **medication prescription at** the start of this **contact:** BLNDREG

Regimen D/I ---------- (1) ↓

A. **Dilitiazem sr/Placebo** bid:
BLDIDOS
None ---------- (1)
60 mg ---------- (2)
90 mg ---------- (3)
Other ---------- (4)
Specify: _____

B. Isosorbide Dinitrate/Placebo bid:
BLISDOS
None ---------- (1)
20 mg ---------- (2)
40 mg ---------- (3)
Other ---------- (4)
Specify: _____

Regimen A/N ---------- (2) ↓ (3) None

C. **Atenolol/Placebo** qd:
BLATDOS
None ---------- (1)
50 mg ---------- (2)
100 mg ---------- (3)
Other ---------- (4)
Specify: _____

D. **Nifedipine sr/Placebo qd:**
BLNIDOS
None ---------- (1)
30 mg ---------- (2)
60 mg ---------- (3)
Other ---------- (4)
Specify: _____

16. **ACIP** staff **member's best** estimate of the proportion of **the** blinded medication ingested since the last scheduled follow-up contact (use ***Patient Compliance Worksheet attached*** at the ***end*** of *the* ***form*** *to answer* ***this*** *item):* ---------- ___ ___ ___% (1) **Unknown**

BLNDADH

BLNDUNK

If < 90%, answer Item 17.
If ≥ 90%, skip to Item 18.

17. In the opinion of the ACIP *staff, why* **was** *the* proportion **of** blinded medication ingested **< 90%? (*Answer each item.*)**

		Yes	No
A.	Patient **forgetfulness** ---------- BLNDPF	(1)	(2)
B.	Side effects ---------- BLNDSE	(1)	(2)
C.	Other ---------- BLNDOT	(1)	(2)

If side effects or other, describe:

_____

_____

ID No.			-				
Visit Type							

18. Have there been any changes in non ACIP study medication at or since the last scheduled follow-up contact? ---------- DELTAMED (1) Yes (2) No

19. Has patient taken-any of the following since the last scheduled follow-up contact? *(Do not include ACIP study medication. Answer each item.)*

		Yes	No	Unknown
A.	Long acting nitrates ---------- LAN	(1)	(2)	(3)
	If **YES**, specify name and dose: _____			
B.	Short acting nitrates ---------- SAN	(1)	(2)	(3)
	If **YES**, specify name and dose: _____			
C.	Beta Blocker therapy ---------- BB	(1)	(2)	(3)
	If **YES**, specify name and dose: _____			
D.	Calcium channel blockers ---------- CCB	(1)	(2)	(3)
	If **YES**, specify name and dose: _____			
E.	Aspirin **(ASA)** ---------- ASA	(1)	(2)	(3)
F.	**Dipyridamole/sulfinpyrazone** ---------- DIPSULF	(1)	(2)	(3)
G.	**Antiplatelet** agents other than **ASA** or **dipyridamole or sulfinpyrazone** ---------- ANTIPLAT	(1)	(2)	(3)
H.	**Anticoagulant** ---------- ANTICOAG	(1)	(2)	(3)
I.	Lipid lowering agent ---------- LIPID	(1)	(2)	(3)
J.	Diuretics ---------- DIUR	(1)	(2)	(3)
K.	ACE inhibitors or other **hypertensives** _____ ACE	(1)	(2)	(3)
L.	Other vasodilators or antihypertensives ---------- OTHRVAS	(1)	(2)	(3)
M.	**Antiarrhythmic agent** ---------- ANTIARR	(1)	(2)	(3)
N.	**Digitalis** ---------- DIGITAL	(1)	(2)	(3)
0.	IV Nitroglycerin ---------- IVNITRO	(1)	(2)	(3)
	If **YES**, specify name and dose: _____			

ID No.			-				
Visit **Type**							

PART IV: PHYSICAL EXAM

20. **Height** ---------- **Not Required**

21. **Weight:** ---------- WEIGHT ___ ___ ___ kg

22. Blood pressure (sitting).

A. Systolic: ---------- SBP ___ ___ ___ mm Hg

B. Diastolic: ---------- DBP ___ ___ ___ mm Hg

23. **Heart Rate:** ---------- HTRATE ___ ___ ___ bpm

24. Findings.

		Yes	No
A. s3:	S3	(1)	(2)
B. **Rales** that do not clear **with cough:**	RLES	(1)	(2)
C. **JVP >** 8 cm of water:	JVP	(1)	(2)
D. Carotid bruit:	BRUIT	(1) ↓	(2)

BRUITR 1. Right ---- (1)(2)
BRUITL 2. Left ----- (1)(2)

E. Peripheral edema:	PEREDEMA	(1)	(2)
F. Hepatomegaly:	HEPATOME	(1)	(2)

25. Are ECC findings available? ---------- ECGFIND (1) Yes (2) No ↓

A. HR ___ ___ ___ **bpm** ECGHRATE

B. Heart block -- HTBLOCK
first degree ---------- (1)
second degree ---------- (2)
third degree ---------- (3)
none ---------- (4)

ID No.			-					
Visit Type								

PART V: ADMINISTRATIVE MATTERS

26. How was the information on this form obtained?

(Answer *each item.*)		Yes	No
A.	From patient interview at Clinical Unit ---------- PTVISIT	(L)	(2)
B.	From patient interview **over telephone** ---------- PTPHONE	(1)	(2)
C.	From patient's personal physician ---------- PERSPHYS	(1)	(2)
D.	From patient's hospital medical record (patient still in hospital) ---------- MEDCORD	(1)	(2)
E.	From a surrogate ---------- SURROGTE	(1)	(2)

↓

Specify surrogate: _____

27. Research Coordinator:

Signature: _____ COMPSIG _____ **ACIP** Staff *No.:* --- __ __ COMPCRT - - - -

ID No.			-					
Visit Type								

ESTIMATION OF PATIENT COMPLIANCE

Clinical Unit Use only - Do NOT Send to CCC.

Date of pill count: ---------- _ _ - _ _ - _ _
Day Month Year

PART I: OPEN LABEL MEDICATION

1. Number dispensed at or since last Follow-up Visit: ____ _ _ _ _ (A)
2. Number pills returned + estimated lost: ---------- _ _ _ _ (B)
3. Number of pills used (subtract A - B): ____ m m _ _ (C)
4. Date pills dispensed: ---------- _ _ - _ _ - _ _
Day Month Year
5. Days since pills dispensed: ____ _ _ _ (D)
6. Number of pills per day: ---------- __ (E)
7. Total number of pills expected to be used ((D) X (E)): - _ _ _ _ (F)
8. Compliance: (C) divided by (F) times 100: ---------- _ _ _ %

PART II: BLINDED MEDICATION

1. Number dispensed at or since last Follow-up Visit: ------ _ _ _ _ (A)
2. Number pills returned + estimated lost: ---------- _ _ _ _ (B)
3. Number of pills used (subtract A - B): ---------- _ _ _ _ (C)
4. Date pills dispensed: ---------- _ _ - _ _ - _ _
Day Month Year
5. Days since pills dispensed: ---------- _ _ _ (D)
6. Number of pills per day: ---------- __ (E)
7. Total number of pills expected to be used ((D) X (E)): - (F)
8. Compliance: (C) divided by (F) times 100: ____ _ _ _ %

ID No.							
Visit Type							

Complete this form only if hospitalization -as for cardiovascular condition or any cardiovascular complication associated with a noncardiovascular admission. Information should be obtained from hospital records and/or patient, family or physician.

Clinic No.					CURCLIN				
ID No.			-				NEWI		
Visit Type					VISIT				

PART I: IDENTIFICATION

1. Patient's NAME CODE: ---------- NAMECODE

2. Admission date: ---------- VISDT
Day Month Year

3. Discharge date: ---------- DISCHDT
Day Month Year

4. Name and address of hospital:

Hospital: _____

Address: _____

_____

5. Diagnosis:

A. Admission _____

B. ICD9 Code ADMCODE

C. Discharge _____

D. ICD9 Code DISCODE

6. Is this form being submitted to report on a hospitalization for a cardiac condition or cardiac complication occurring as a result of an admission for a noncardiac cause? ---------- CARDHOSP
(1) Yes (STOP) No

PART II: MAJOR EVENTS

7. Events during this hospitalization (answer *each item*).

		Definite	No	Suspect
A. MI	MIHOSP	(1)	(2)	(3)
B. Angina	ANGHOSP	(1)	(2)	(3)
C. Congestive heart failure	CHFHOSP	(1)	(2)	(3)
D. Arrhythmia	ARRHHOSP	(1)	(2)	(3)
E. Stroke	STRKHOSP	(1)	(2)	(3)
F. Cardiovascular procedure	PROCHOSP	(1)	(2)	(3)
G. Other	OTHHOSP	(1)	(2)	(3)
		↓		↓

Specify: _____

ID No.			-					

8. Did the patient undergo any of the following tests or cardiovascular procedures?

Submit appropriate forms for each procedure.

		1) Yes	No	2) # Performed
A.	Coronary angiography ANGIO	(1)	(2)	ANGIONBR
B.	PTCA PTCA	(1)	(2)	PTCANBR
C.	*CABG* CABG	(1)	(2)	CABGNBR
D.	Other cardiac revascularization **interventional technique** INTER	(1)	(2)	INTERNBR
	Specify: _____			
E.	Heart surgery other than CABG SURG	(1)	(2)	SURGNBR
	Specify: _____			

PART III: ADMINISTRATIVE MATTERS

9. Research Coordinator:

Signature: _____ COMPSIG ACIP Staff No.: COMPCRT

ID No.	| | |-| | | | |
Visit Type	| | | |

SUSPECT ISCHEMIC EVENT

Complete this form whenever patient has pain of myocardial ischemia lasting longer than 20 minutes or ECC changes or enzyme measurements are suggestive of acute coronary insufficiency, unstable angina or a myocardial infarction.

Clinic *No.*					CURCLIN				
ID No.			-						NEWI
Visit Type					VISIT				

PART I: IDENTIFICATION

1. **Patient's NAME CODE:** _____ NAMECODE _ _ _ _ _

2. Date event occurred: _____ VISDT - - - - - - - - -
Day Month Year

3. Onset of symptoms (military time): ---------- ISCHHR .. ISCMIN ISCUN
Hours Minutes (1) **Unknown**

PART II: EVIDENCE

4. Evidence of event:

		Yes	No
A.	Pain of myocardial ischemia ISCHEV	(1)	(2)

↓

ISCHDUR

1. Duration of pain of myocardial ischemia:
   - **0** - 19 min _____ (1)
   - 20 min-1 hour _____ (2)
   - l-3 hours _____ (3)
   - 4-6 hours _____ (4)
   - ≥ 6 hours _____ (5)

B.	ECG evidence: ECGEV	(1)	(2)
C.	Enzyme evidence: ENZYMEV	(1)	(2)
D.	Angiographic evidence of occlusion: ANGIOEV	(1)	(2)
E.	Other: OTHEV	(1)	(2)

↓

Specify: _____

ID No.			-				

PART III: ECG RESULTS

Were new Q-waves observed?

NEWQ

Yes ---------- (1)
No ---------- (2)
Unknown ---------- (3)

6. Were new ST-T abnormalities observed?

NEWSTT

Yes ---------- (1)
No ---------- (2)
Unknown ---------- (3)

PART IV: ENZYME RESULTS

ENZYMNA

7. Enzyme results not available (1) → *Skip to Item 11.*

	Yes	No
8. Were CK and CK-MB normal? CKNORM	(1)	(2)

↓

LDH enzyme level:
(Record highest value associated with this suspected event.)

	1) Highest Value	2) Upper Limit of Lab Normal Ranee	3) Specify Units
A. LDH: LDHDT (Day Month Year)	LDHMAX	LDHUPPR	LDH UNIT

Skip to Item 11.

9. CK and CK-MB - Upper limit of laboratory normal range:

Total CK	CK-MB		
A) IU/L	B) % or Relative Index	C) or IU/L	D) or ng/ml
CKUPPR	INDUPPR	IULUPPR	NGMLUPPR

ID No.			-				
Visit Type							

LO. Peak CK and CK-MB:

		Total CK		CK-MB			
A) CKDT Date Day Month Year	B) CKTM Military Time Hours Minutes	C) CKPEAK (IU/L)	D) CKNA Not Done	E) % or Relative Index INDPEAK	F) IULPEAK or IU/L	G) NGMLPEAK or ng/ml	H) CKMBN Not Done
_ _ _ _ _ _ _ _	_ _ . _ _	_ _ _ _ _	(1)	_ _.__	- - -	_ _ _	(1)

11. Other objective evidence of ischemia severe enough for hospitalization? ---- (1) Yes (2) No
↓OBJEV

Describe: _____

PART V: ADMINISTRATIVE MATTERS

Submit a narrative summary ≤ 1 double-spaced page' in length, which describes pertinent clinical features. This narrative should be recorded in such a way as to maintain treatment blinding and patient confidentiality.

12. Are the following materials available and are they being submitted with this form? (Answer *each item)*

	1) Available Yes	1) Available No	2) Submitted
A. Required Narrative Summary to CCC. ---------- NARRAVA ----------	(1)	(2)	NARRSUB (1)
B. Required ECG(s) (Include ECG's immediately before event and during convalescence, if available) ---------- ECGAVA ----------	(1)	(2)	ECGSUB (1)

13. Research Coordinator:

Signature: COMPSIG ACIP Staff No.: --- - COMPCRT - - -

FOR CLINICAL COORDINATING CENTER USE ONLY
14. Documents received:
A. Narrative Summary ---------- (1)
B. ECGs ---------- (1)

ID No.			-					
Visit Type								

ASYMPTOMATIC CARDIAC ISCHEMIA PILOT

ACIP FORM 25

CABG SURGERY FORM

GENERAL INSTRUCTIONS

Complete this form for each CABG surgery procedure performed.

ITEM INSTRUCTIONS: Items with instructions outlined below have the symbol [*] preceding the item number on the form.

Refer to Item 8.

Indicate the total number of distal anastomosis sites made during this procedure.

Refer to Item 9.

Indicate the total number of conduits used to perform this procedure.

Refer to Item 15.

A good immediate CABG outcome is defined as discharged from hospital alive with an uncomplicated post operative course (including no post operative myocardial infarction and no cerebrovascular accident) and the complete relief or significant improvement of angina.

CABG SURGERY FORM

CURCLIN
NEWID
VISIT

Clinic No.			-					
ID No.			-					
Visit Type								

PART I: IDENTIFICATION

1. Patient's NAME CODE: ---------- NAMECODE _ _ _ _ _

2. Date of surgery: ---------- VISDT __ __ __ __ __ __
Day Month Year

PART II: PROCEDURE NOTES

3. Why was this CABG performed?

PROCPERF

Protocol Randomization (Revascularization Strategy) ----- (1) → Skip to Item 7.
All others ---------- (2)
↓

4. Check all the reasons for revascularization which were fulfilled at the time of performance of this surgery:

A.	MI	MIPROC	(1)*
B.	Unstable angina	ANGPROC	(1)
C.	Canadian Cardiovascular Society Class IIIo r IV angina	CCSCPROC	(1)
D.	Severe ischemic response on exercise ECG	ECGPROC	(1)*
E.	Failed PTCA	PTCAPROC	(1)*
F.	Coronary anatomy _____	ANATPROC	(1)**
G.	Decision of personal physician	PHYSPROC	(1)**
H.	Clinical decision not specified by **protocol**	CLINPROC	(1)**
I.	Other	OTHPROC	(1)**

↓

Specify: _____

Submit appropriate event and procedure forms.

***PROTOCOL VIOLATION** if surgery performed within twelve weeks of study entry and none of Items A-E is checked.*

5. Indicate surgical priority:

PRIORITY

Urgent ---------- (1)
Elective ---------- (2)

6. Patient's angina1 status at time of surgery:

ANGSTAT

None ---------- (1)
Stable ---------- (2)
Unstable ---------- (3)
Acute MI ---------- (4)

Conduit codes for use in Question 7, Column 2.

A. Saphenous vein(s).
B. Left internal mammary artery.
C. Right internal **mammary** *artery.*
D. Other.

Distal Vessel Quality Codes for Question 7, Column 3.

1. Normal.
2. Mild, diffuse, intimal thickening or plaque formation.
3. Moderate, diffuse, intimal ***thickening or*** *plaque formation with some luminal compromise.*
4. Severe, diffuse, intimal thickening wi *th significant luminal compromise.*
5. Endarterectomy.

7. Arteries grafted: *Indicate coronary artery segment grafted from diagram after instruction page.*

	(1) Segment Code	(2) Conduit Used	(3) Quality of Distal Vessel	(4) Configuration: Sequential Side To Side	Sequential End To Side	Individual
A.	SEGCODEA	CONDUITA	QUALA	(1)	CONFIGA (2)	(3)
B.	SEGCODEB	CONDUITB	QUALB	(1)	CONFIGB (2)	(3)
C.	SEGCODEC	CONDUITC	QUALC	(1)	CONFIGC (2)	(3)
D.	SEGCODED	CONDUITD	QUALD	(1)	CONFIGD (2)	(3)
E.	SEGCODEE	CONDUITE	QUALE	(1)	CONFIGE (2)	(3)
F.	SEGCODEF	CONDUITF	QUALF	(1)	CONFIGF (2)	(3)
G.	SEGCODEG	CONDUITG	QUALG	(1)	CONFIGG (2)	(3)
H.	SEGCODEH	CONDUITH	QUALH	(1)	CONFIGH (2)	(3)
I.	SEGCODEI	CONDUITI	QUALI	(1)	CONFIGI (2)	(3)
J.	SEGCODEJ	CONDUITJ	QUALJ	(1)	CONFIGJ (2)	(3)
K.	SEGCODEK	CONDUITK	QUALK	(1)	CONFIGK (2)	(3)

[*] 8. Total number of bypass grafts: ---------- GRAFTTOT ____

[*] 9. Total number of conduits used: ---------- COND-TOT ____

ID No.							
Visit Type							

CABGTIM

10. Were other procedures done at time of CABG? ---------- (1) Yes (2) No

Yes No

A. Left ventricular aneurysm dissection? LVENTANE (1) (2)
B. Valve procedure ---------- V.ALVPROC (1) (2)

Yes No

1. Repair ---------- REPAIR (1) (2)
2. Replacement ---------- REPLACE (1) (2)

C. Other ---------- OTH.CABG (1) (2)

Specify: _____

11. Any intended vessels not grafted? ---------- NO_GRAFT (1) (2)

Yes No

Refer to the diagram after instruction page.

Intended Vessel(s) Not Grafted

	1	2	3	4	5
A. Distal Site Code _____ (Check all *that apply.*)	DSC1	DSC2	DSC3	DSC4	DSC5
B. Too small --- SMALL1	( )	(1)	(1)	(1)	(1)
C. Diseased --- DISEAS1	(1)	(1)	(1)	(1)	(1)
D. Inaccessible --- INACC1	(1)	(1)	(1)	(1)	(1)
E. Cannot find --- NOFIND1	(1)	(1)	(1)	(1)	(1)
F. Inadequate conduit NOCOND1	(1)	(1)	(1)	(1)	(1)
G. Akinetic segment AKIN1	(1)	(1)	(1)	(1)	(1)
H. Other ---------- OTH1	(1)	(1)	(1)	(1)	(1)
Specify:	_____	_____	_____	_____	_____
	_____	_____	_____	_____	_____

ID No.							
Visit Type							

PART III: **MAJOR EVENTS**

12. Did patient experience any major events prior to discharge after surgery? ---------- MAJOREVT (1) (2) (3)
Yes No Unknown

Answer each item:

		Did Not Occur	Occurred On/R.	Occurred Within 24 Hours	Occurred Prior to Discharge More than 24 Hours After Surgery
A.	Death ---------- DTHCABG	(1)	(2)*	(3)*	(4)*
CARDIOVASCULAR EVENTS					
B.	Non-fatal cardiac arrest ---------- CACABG	(1)	(2)	(3)	(4)
C.	Suspected non-fatal MI ---------- MICABG	(1)	(2)**	(3)**	(4)**
D.	Congestive heart **failure (isolated) or** pulmonary edema (cardiac) ---------- CHFCABG	(1)	(2)	(3)	(4)
E.	Cardiogenic shock ---------- SHKCABG	(1)	(2)	(3)	(4)
F.	Cardiac tamponade ---------- TAMPCABG	(1)	(2)	(3)	(4)
G.	Arterial embolus of extremity **or** loss of pulse requiring treatment EMBCABG	(1)	)	(3)	(4)
H.	Arterial dissection requiring repair DISSCABG	(1)	I:)	(3)	(4)
I.	Arrhythmia requiring continued therapy ARRYCABG	(1)	(2)	(3)	(4)
NEUROLOGIC EVENTS					
J.	TIA _____ TIACA66	(1)	(2)	(3)	(4)
K.	Stroke ---------- STRKCABG	(1)	)	(3)	(4)
L.	Coma ---------- COMACABG	(1)	I:)	(3)	(4)
ALLERGIC **EVENT**					
M.	Hypersensitivity reaction --- ALLGCABG	(1)	(2)	(3)	(4)
PULMONARY EVENTS					
N.	Respiratory failure (includes **ARDS** and non-cardiac edema) ---------- ARDSCABG	(1)	(2)	)	(4)
0.	Pulmonary embolus ---------- PECABG	(1)	(2)	I:)	(4)
RENAL EVENT					
P.	Renal failure requiring dialysis RENLCABG	(1)	(2)	(3)	(4)
PROCEDURAL EVENTS					
Q.	Re-operation for bleeding REOPCABG	(1)	(2)	(3)	(4)
R.	Wound dehiscence ---------- DEHICABG	(1)	)	(3)	(4)
S.	Mediastinitis or wound **infection** INFCABG	(1)	I:)	(3)	(4)
HEMORRHAGE					
T.	Surgical hemorrhage ---------- HEMOCABG	(1)	)	(3)	(4)
U.	Gastrointestinal hemorrhage GICABG	(1)	I:)	(3)	(4)
OTHER **EVENTS** (Do not include study end point or ischemic pain.)					
V.	Other events ---------- OTHCABG	(1)	(2)	(3)	(4)

Specify: _____

**Submit Death Notification Form 15 and Cause of Death Form 16.*
***Submit Suspect Ischemic Event Form 23.*

ID No.			-				
Visit Type							

13. Condition of patient leaving O.R.: PTCOND
Stable (1)
Unstable (2)
Deceased (3)

Submit Death Notification Form 15 to *CCC* within 72 *hours and Cause of Death Form* 16 *within 14 days.*

14. Post-bypass pharmacologic/mechanical support? SUPPORT (1) Yes (2) No

		Yes	No
INOTAGNT	A. **Inotropic** agents > 48 hours	(1)	(2)
PACEMAKE	B. New permanent pacemaker	(1)	(2)
LVENTDEV	C. Left ventricular assist device	(1)	(2)
RVENTDEV	D. Right ventricular assist device	(1)	(2)
PUMP	E. Intra-aortic balloon pump	(1)	(2)

15. Good immediate outcome? OUTCOME (1) Yes (2) No

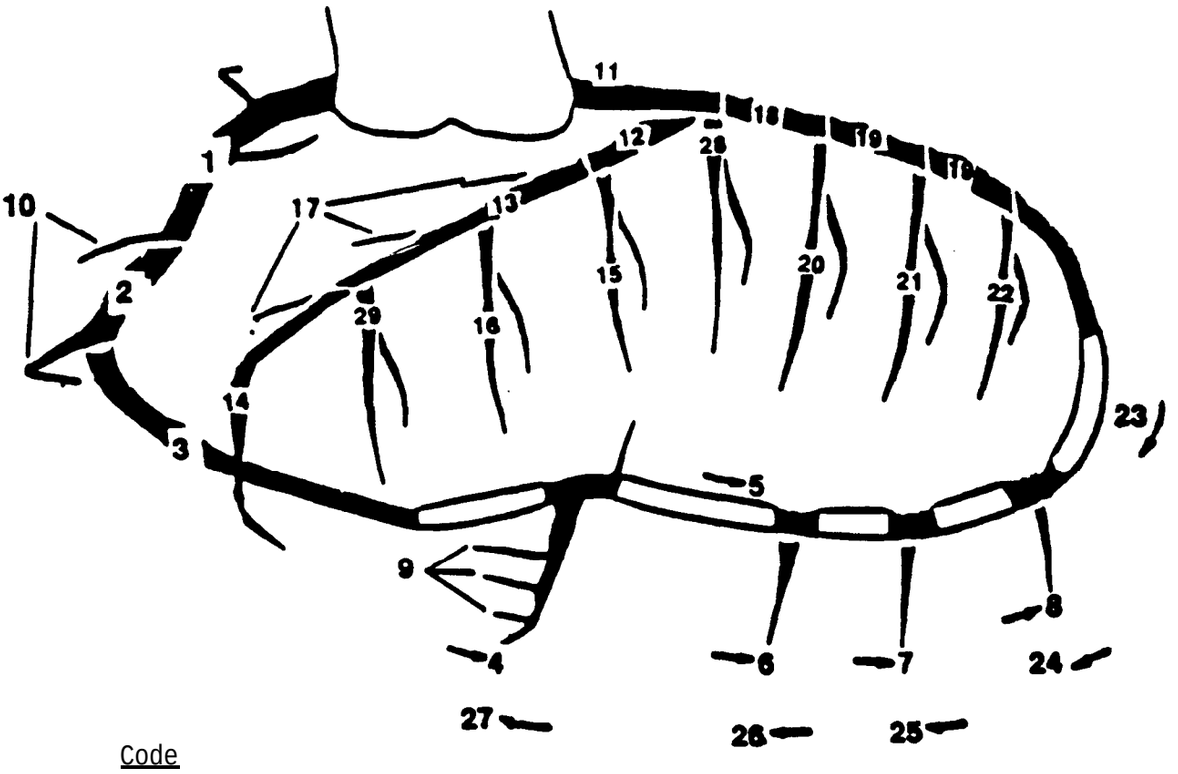
PART IV: ADMINISTRATIVE MATTERS

16. Surgeon:
Name: SURGSIG ACIP Staff No.: SURGCRT

17. Research Coordinator:
Signature: COMPSIG ACIP Staff No.: COMPCRT

ID No.			-				
Visit Type							

ACIP Coronary Artery Diagram



Code

01 Proximal right coronary artery (Prox RCA)
02 Mid-right coronary artery (Mid RCA)
03 Distal right coronary artery (Dist RCA)
04 Right posterior descending artery (RDPA)
05 Right posterior atrioventricular (RPLS)
06 First right posterolateral (1st RPL)
07 Second right posterolateral (2nd RPL)
08 Third right posterolateral (3rd RPL)
09 Posterior descending septal perforators (Inf septal)
10 Acute marginal (Ac marg)
11 Left main coronary artery (LMCA)
12 Proximal LAD artery (Prox LAD)
13 Mid LAD artery (Mid LAD)
14 Distal LAD artery (Dist LAD)
15 First diagonal branch (1st Diag)
16 Second diagonal branch (2nd Diag)
17 First septal perforator (1st Septal)
18 Proximal circumflex artery (Prox CX)
19 Mid circumflex artery (Mid, dist CX)
20 First obtuse marginal branch (1st Ob marg)
21 Second obtuse marginal branch (2nd Ob marg)
22 Third obtuse marginal branch (3rd Ob marg)
23 Circumflex artery AV groove continuation (LAV)
24 First left posterolateral branch (1st LPL)
25 Second left posterolateral branch (2nd LPL)
26 Third left posterolateral branch (3rd LPL)
27 Left posterior descending artery (LPDA)
28 Ramus intermedius (Ramus)
29 Third diagonal branch (3rd Diag)

ASYMPTOMATIC CARDIAC **ISCHEMIA** PILOT

SUSPECTED ISCHEMIC EVENT CLASSIFICATION FORM

ACIP Form 43 FORM
Rev 0 06/11/93 REV

CURE
NEWID
VISIT

Clinic No.	
ID No.	
Visit Type	

PART I: IDENTIFICATION

1. Patient's NAME CODE: NAMECODE
   _ _ _ _ _

2. Date of reported event:
   VISDT
   __ __ - __ __ __ - __ __
   Day Month Year

   Military time: VISHR VISMIN VISUNK
   __ __ : __ __ (1) Unknown
   Hours Minutes

PART II: EVENT CLASSIFICATION

3. Classification decision (check one):
   Final ---------- FINAL (1)
   Pending ---------- PENDING (2)

If FINAL, continue with item 4.
If PENDING, skip to item 6.

4. Classification for event:

	Yes	No
A. Was the history compatible with myocardial ischemia? - CLASS MI	(1)	(2)
B. Did the event meet enzyme criteria for myocardial infarction? - CLASSEN	(1)	(2)
C. Did the event meet ECG criteria for **myocardial** infarction? - CLASSECG	(1)	(2)

D. Classification of event: CLASSEVT
   Myocardial infarction --- (1)
   Other ischemic event ---- (2)
   No ischemic event ------- (3)

5. Did narrative information reveal assignment to (not performance of) revascularization, angina-guided therapy, or AECG plus angina-guided therapy? TRTRVLD ---------- (1) Yes (2) No

Skip to item 7.

6. Specify information required for full committee to complete classification:

	Yes	No
A. **Enzymes** ---------- ENZYMES	(1)	(2)
B. **ECG(s)** ---------- ECGS	(1)	(2)
C. Narrative ---------- NARRAT	(1)	(2)
D. **Other** ---------- OTHINFC	(1)	(2)

State what additional information is required, e.g., ECG dates and times; enzyme assay dates, times and upper limits of normal; etc.

PART III: ADMINISTRATIVE MATTERS

7. **MMCC** member's signature:
   MMCCSIG

8. Date form completed:
   COMPDT
   - m - m - - - -
   Day Month Year

CC USE ONLY

9. Basis for Form 43 Status:
   Full MMCC ---------- (1)
   Two Reviewers Congruent - (2)

ASYMPTOMATIC CARDIAC **ISCHEMIA** PILOT

HOSPITALIZATION CLASSIFICATION **FORM**

CURCLIN
NEWID
VISIT

Clinic No.			-					
ID No.			-					
Visit Type								

PART I: IDENTIFICATION

1. Patient's **NAME CODE:** NAMECODE

— — — — —

2. Date of reported event: VISDT

_ _ - _ _ - _ _ _ _

Day Month Year

PART II: EVENT CLASSIFICATION

3. Classification decision (check one): FINAL

Final ---------- (1)
Pending ---------- (2)

IF FINAL, continue with item 4.

If PENDING, skip to item 6.

4. Classification for event:

Is an ischemic event suspected? ———— Yes (1) No (2) ISCHEVT

Primary reason for hospitalization:

5. Did narrative information reveal assignment to (not performance of) **revascularization**, angina-guided therapy, or AECG plus angina-guided therapy? ---- Yes (1) No (2) TRTRVLD

Skip to item 7.

6. Specify information required for full committee to complete classification:

		Yes	No
A.	Enzymes ENZYMES	(1)	(2)
B.	ECG(s) ECGS	(1)	(2)
C.	Narrative NARRAT	(1)	(2)
D.	Other OTHINFO	(1)	(2)

State what additional information is required, e.g., ECG dates and times; enzyme assay dates, times and upper limits of normal; etc.

PART III: ADMINISTRATIVE MATTERS

7. MMCC member's signature: MMCCSIG

8. Date form completed: CompDT

_ _ - _ _ - _ _ _ _

Day Month Year

CC USE ONLY

		Yes	No
9.	**Form** 43 ----------	(1)	(2)

10. Basis for Form 44 Status:

Full MMCC ---------- (1)
Two Reviewers Congruent - (2)

ASYMPTOMATIC CARDIAC ISCHEMIA PILOT

ACIP FORM 66

BASELINE FORM FOR ANGIOGBAPHIC
ANCILLARY STUDIES

GENERAL INSTRUCTIONS

Complete this form for all patients entered into ACIP Angiographic Ancillary Studies.

ITEM INSTRUCTIONS: Items with instructions outlined below have the symbol [*] preceding the item number on the form.

Refer to Item 4.

FUNCTIONAL CLASSIFICATION: A method of assessing the patient's general cardiovascular disability taking into consideration the symptoms of CHF. Record the class that best characterize the patient's overall level of disability due to congestive heart failure.

1. Patients with cardiac disease but without resulting limitations of physical activity. Ordinary physical activity does not cause undue fatigue, palpitations, or dyspnea.

2. Patients with cardiac disease resulting in slight limitation of physical activity. They are comfortable at rest. Ordinary physical activity results in fatigue, palpitations or dyspnea. Ordinary physical activity includes walking more than 2 blocks on level ground, climbing more than 1 flight of stairs at normal pace, walking uphill, walking or climbing stairs rapidly, walking or stair climbing under adverse conditions (cold, wind, emotional stress).

3. Patients with cardiac disease resulting in marked limitation of physical activity. They are comfortable at rest. Less than ordinary activity causes fatigue, palpitations or dyspnea. Less than normal activity includes walking 1 to 2 blocks on level ground or climbing 1 flight of stairs at a normal pace.

4. Patients with cardiac disease resulting in inability to carry out any physical activity without symptoms of fatigue, palpitations or dyspnea. Symptoms may be present even at rest. If any physical activity is undertaken, these symptoms are increased.

ASYMPTOMATIC CARDIAC **ISCHEMIA** PIMT

BASELINE FORM FOR ANGIOGRAPHIC
ANCILLARY STUDIES

CURCLIN
NEWID
VISIT

Clinic No.			-						
ID No.									
Visit Type	B	L	A	S					

PART I: IDENTIFICATION

1. Patient's NAME CODE: ---------- NAMECODE _ _ _ _ _

2. Randomization date: ---------- _____ VISDT
__ __ Day __ __ __ Month __ __ Year

PART II: MEDICAL HISTORY

3. History of myocardial infarction (MI) ---------- MIHIST (1) Yes (2) No (3) Unknown

A. Date of most recent MI: ---------- MIMON __ __ Month MIYR __ __ Year MIUNK (1) unknown

[*]4. Does patient have a history of congestive heart failure requiring treatment? ---------- CHF (1) Yes (2) No (3) Unknown

A. **Current Functional Classification:** CHFCLASS

One ---------- (1)
Two ---------- (2)
Three ---------- (3)
Four ---------- (4)

ID No.			-					

SMOKER

5. History of cigarette smoking? ---------- (1) Yes (2) No

↓

CURSMOKE

A. Current smoker (within 4 weeks)? ---------- (1) Yes (2) No

	Yes	No	Unknown
6. Family history (parent, sibling, child) of coronary artery disease before age 55? CADB55 ----------	(1)	(2)	(3)
7. History of hypertension requiring medical treatment? HPT ----------	(1)	(2)	(3)
8. History of diabetes? DIABETES ----------	(1)	(2)	(3)

↓

A. Record current therapy: DIABRX

- **Oral medical** ---------- (1)
- **Insulin** ---------- (2)
- **Neither** ---------- (3)
- **Both** ---------- (4)

	Yes	No	Unknown
9. Does patient have a history of hypercholesterolemia (>240 mg/dl or 6.0 mMol/L) HICHOL ----------	(1)	(2)	(3)

↓

A. Does patient know a recent cholesterol level? HICHLVL ---------- (1) yes (2) No

↓

Cholesterol level: ----------1) HCHMG ___ mg/dl
or 2) HCHMMOL __.__ mMol/L

ID No.			-				

10. History of other significant illness:

		Yes	No	Unknown
A.	Cerebrovascular accident, transient ischemic attack or carotid surgery ---------- STROKE	(1)	(2)	(3)
B.	Peripheral vascular disease (claudication, peripheral vascular surgery, or abdominal aneurysm) ---------- PVD	(1)	(2)	(3)
C.	Asthma ---------- ASTHMA	(1)	(2)	(3)
D.	Chronic bronchitis _____ BRONCH	(1)	(2)	(3)

11. Any prior cardiovascular procedures? ---------- HXPRCC (1) Yes (2) No

		Yes	No	Unknown
A.	PTCA ---------- PTCA	(1)	(2)	(3)

If Yes: PTCAMON (Month) _ PTCAYR (Year) (1) PTCAUNK (Unknown)

		Yes	No	Unknown
B.	Other cardiac revascularization interventional technique ---------- OTHTECH	(1)	(2)	(3)

If Yes: Specify: _____

		Yes	No	Unknown
C.	Heart surgery other than CABG -------- HTSURG	(1)	(2)	(3)

If Yes: Specify: _____

PART III: ADMINISTRATIVE MATTERS

12. Research Coordinator:

Signature: _____ COMPSIG ACIP Staff No.: --- COMPCRT

ID No.								