

PSYCHOPHYSIOMGICAL INVESTIGATIONS OF **MYOCARDIAL ISCHEMIA**

PIMI FORM 03

CONFIRMATION OF ELIGIBILITY

GENERAL INSTRUCTIONS

This form should be completed for all potential PIMI candidates for whom a **48-hour** AECG is being performed or was performed for a patient previously considered a candidate for ACIP. These patients have an abnormal screening exercise treadmill stress test and evidence of obstructive coronary artery disease.

If a check mark (✓) is made in any space on this form designated as "STOP," or "**INEL**" 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.

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

REFER TO **ITEM 8B**

Angiograms will not be required to verify coronary artery disease (CAD) if the patient has evidence of CAD from a prior history of myocardial infarction (MI), documented by **ECGs** and serum enzyme assays as defined below.

Q-wave **MI**

ECG findings ▪ new, major Q-waves (at least 40 **msec** duration and 0.1 **mV** amplitude) in at least two contiguous leads.

Enzyme criteria ▪ creatinine kinase at least twice the upper limit of normal; myocardial band positive.

Non-Q-wave **MI**

ECG findings ▪ ST depression or T-wave inversion (compared to baseline) for three days.
Baseline may be either before or after the event.

Enzyme criteria ▪ creatinine kinase at least twice the upper limit of normal; **myocardial** band positive.

CONFIRMATION OF ELIGIBILITY

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

PART I: VISIT IDENTIFICATION

1. Patient's NAME CODE: -----
2. Screening date: -----
 Day Month Year
3. A. Patient consent: ----- (1) Yes (1) No (INEL)
- B. Physician consent: ----- (1) (1) (INEL)
4. Gender: ----- (1) (2) GENDER
 Male Female
5. Ethnic origin: -----
 RACE
 American Indian ----- (1)
 Asian/Pacific Islander ----- (2)
 Black, African American ----- (3)
 Hispanic or Latino ----- (4)
 White, not of Hispanic origin ----- (5)
 Other ----- (6)

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Specify: _____

6. Date of birth: -----
 Day Month Year
- A. Age: ----- AGE

PART II: INCLUSION CRITERIA

7. Abnormal screening exercise tolerance test (ETT): ----- (1) Yes (1) No (STOP)
8. Obstructive Coronary Artery Disease (CAD): ----- (1) ANGCAD (1) (STOP)
- A. Angiographic evidence of obstructive CAD ----- (1) ANGEV (1) (2)
- *B. Prior MI documented by ECG and enzyme criteria (1) PRIORMI (1) (2)

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C. Type of MI ----- Q-wave --- (1) non Q-Wave --- (2)

9. Qualifying 48-hour AECG performed: ----- (1) Yes (1) No (STOP)

ID No.						
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PART III: EXCLUSION CHECKLIST

10. Are any exclusion conditions present? (*Answer each item.*)
- | | <u>Yes</u> | <u>No</u> |
|---|------------|-----------|
| A. Age 81 or greater | (INEL) | (2) |
| B. Pregnancy | (INEL) | (2) |
| C. Myocardial infarction within three months of qualifying ETT | (INEL) | (2) |
| D. PTCA within six months of qualifying ETT | (INEL) | (2) |
| E. Previous cardiac surgery requiring thoracotomy | (INEL) | (2) |
| F. Unstable angina within four weeks of qualifying ETT | (INEL) | (2) |
| G. Noncardiac illness (i.e., renal disease, lung disease) | (INEL) | (2) |
| H. The presence of a noncoronary cardiac disorder which in itself would require surgery or other treatment | (INEL) | (2) |
| I. Persistent congestive heart failure of NYHA Class III or IV on optimal medical therapy | (INEL) | (2) |
| J. Currently on anti-ischemic medication which cannot be discontinued for three days for eligibility assessment | (INEL) | (2) |
| K. Abnormal mini mental state results | (INEL) | (2) |
| L. Neurologic disease | (INEL) | (2) |
| M. ECG findings which interfere with AECG analysis | (INEL) | (2) |
| N. Presence of abnormal baseline ST-segment morphology | (INEL) | (2) |
| O. Inability to discontinue digitalis | (INEL) | (2) |
| P. Inability to discontinue psychotropic agents or antidepressant agents | (INEL) | (2) |
| Q. Inability to discontinue sympatholytics | (INEL) | (2) |
| R. Inability to discontinue angiotensin converting enzyme (ACE) inhibitors | (INEL) | (2) |
| S. Inability to discontinue central acting alpha agonists | (INEL) | (2) |
| T. Inability to discontinue anti-inflammatory agents | (INEL) | (2) |
| U. Inability to discontinue analgesics | (INEL) | (2) |
| V. Inability to discontinue theophylline | (INEL) | (2) |
| W. Inability to discontinue beta-blocker medication (including eye drops for glaucoma) | (INEL) | (2) |
| X. Steroids within four weeks of qualifying ETT | (INEL) | (2) |
| Y. Unable to tolerate nitroglycerin | (INEL) | (2) |
| Z. Active participation in competing protocol | (INEL) | (2) |
| AA. Unreliable | (INEL) | (2) |
| BB. Geographically inaccessible for follow-up | (INEL) | (2) |
| cc. Unable to read or communicate in English | (INEL) | (2) |
| DD. Unable to participate in the opinion of the investigator | (INEL) | (2) |
| 11. Are any "INEL" conditions checked in Part III? | (INEL) | (2) |

ID No.											
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