VA COOPERATIVE STUDIES PROGRAM # 424

Clinical Outcomes Utilizing Revascularization and Aggressive DruG Evaluation

Operations Memo No. 24

Date: August 30, 2000

From: William Boden, MD

Subj: Collection of ECGs and Myocardial Isoenzyme Markers

To: Study Personnel

Thru: Trial Leadership

In an effort to accurately capture data on the occurrence of myocardial infarctions in patients enrolled in the COURAGE Trial, we are now clarifying the required collection times for ECGs and myocardial isoenzyme markers:

Before all percutaneous coronary interventions (PCI) and coronary artery bypass graft (CABG) procedures and within 24 hours after the procedure, obtain a 12-lead ECG, affix Form 5 sticker to the original ECG and send to the West Haven Coordinating Center along with other appropriate Forms (i.e. Form 10 and any other required forms).

In addition, **8 hours after all PCI and CABG procedures and within 24 hours or prior to discharge (whichever comes sooner, * for a total of two samples),** please collect creatine kinase (CK) levels along with CKMB and/or troponin levels (using cardiac-specific troponin [cTNt] or troponin [cTNi], whichever is used in your laboratory). Attach all lab slips to Form 10 and send to the West Haven Coordinating Center.

The diagnosis of an MI for the purpose of determining an endpoint in the COURAGE Trial will include both a total CK > 3X the upper normal limit (UNL) (post-PCI) or total CK > 5X the UNL for the patients post-CABG **plus evidence of abnormal CKMB or troponin activity** (above the UNL for your hospital laboratory).

This is consistent with the protocol and does not require submission to your IRB.