

Operations Memo No. 21



VA COOPERATIVE STUDIES PROGRAM # 424

Clinical Outcomes Utilizing Revascularization and Aggressive DruG Evaluation

Date: April 24, 2000

From: Pamela Hartigan, PhD

Subj: Change in Window for Documenting Objective Evidence of Myocardial Ischemia

To: All Study Personnel

Thru: Trial Leadership

In order to minimize the need to obtain repeat stress tests to document objective evidence of myocardial ischemia during the screening process, we are broadening the window, based on a recommendation from the CSP # 424 Data Monitoring Board.

The NEW study policy will be:

- ◆ All acceptable forms of documentation of myocardial ischemia as outlined on page 32 of the protocol must be within the **previous 180 days (six months) of the date of randomization.**

It is hoped that this change in policy will decrease time delays in the screening process and prevent subjecting patients to unnecessary repeat stress tests and the expense that is incurred.

If there are any questions about the acceptability of a stress test report as evidence of objective ischemia, please contact one of the Study Co-Chairmen.