

## Operations Memo No. 8



VA COOPERATIVE STUDIES PROGRAM # 424

### Clinical Outcomes Utilizing Revascularization and Aggressive DruG Evaluation

Date: July 19, 1999

From: Pamela Hartigan, PhD, Study Statistician at West Haven CSPCC

Subj: Windows for qualifying tests

To: Study Personnel

Thru: Trial Leadership

As we have worked through the first few weeks of patient enrollment it has become clear that some of the windows specified in the protocol may create artificial barriers to enrollment. Specifically the days for catheterization and PCI procedure, as they are written, seem overly restrictive.

The NEW study policy will be:

1. The angiogram should have been done no longer than 90 days prior to randomization.
2. The PCI should be performed no longer than 105 days after the diagnostic angiogram.
3. Although no limits were described for documentation of ischemia in the protocol, the study policy will also be that this documentation should take place within 90 days of randomization.

All of these limits are subject to the restriction that there has been:

- a. No intercurrent event.
- b. The patient is stable and has had no worsening of symptoms since the test was performed.