

Operations Memo No. 1



VA COOPERATIVE STUDIES PROGRAM # 424

Clinical Outcomes Utilizing Revascularization and Aggressive DruG Evaluation

Date: April 8, 1999

From: Pamela Hartigan, PhD, Study Statistician / VA Cooperative Studies Program
Coordinating Center / West Haven, CT

Subj: IRB Submission

To: Study Personnel

Thru: Trial Leadership

We forgot to emphasize to you at the Kickoff meeting that any material you plan to present to the patients, including any advertising going into the clinic areas and the American Heart Association pamphlets, must be approved by your IRB. This also includes the PACE material, both the assessment sheets and the counseling sheets that you will use in counseling the patients for physical activity, nutrition, and smoking.

This does not affect the approval of the protocol, per se, for we said we would use AHA pamphlets and counsel the patients in the protocol. What it does affect, however, is your ability to use these specific materials. You should not use them until your IRB has said OK.

Thanks very much for your attention to these matters and I apologize for not bringing this to your attention before this time.