

Operations Memo No. 2



VA COOPERATIVE STUDIES PROGRAM # 424

Clinical Outcomes Utilizing Revascularization and Aggressive DruG Evaluation

Date: May 19, 1999

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

Subj: Regulatory Documents – where to send what

To: Study Personnel

Thru: Trial Leadership

DOCUMENT	COMMENTS	WHICH HEALTHCARE SYSTEM	WHO NEEDS A COPY?
IRB approval minutes, memo, or letter	Must be signed by the IRB Chairperson (official designee can sign over Chairman's Signature block); approval must be unconditional and must be dated after February 9 th 1999	VA US Non-VA Canada	Albuquerque & West Haven
R&D minutes	As above	VA only	Albuquerque & West Haven
1572	Participating Investigator. All sub investigators must be listed on the 1572	VA US Non-VA Canada	Albuquerque only
CVs	All investigators and sub investigators	VA US Non-VA Canada	Albuquerque only
HPB Form	All Investigators	Canada only	Albuquerque only
Letter of agreement		US Non-VA Canada	West Haven only
Locally approved informed consent	The consent document approved by the IRB	VA US Non-VA Canada	West Haven only
VA Form 10-1223	Subcommittee on Human Subjects	VA Only	West Haven only
Disclosure Statement (MERCK)	Required for distribution of Canadian Investigator's Brochure	Canada	Albuquerque only