

## Operations Memo No. 5



VA COOPERATIVE STUDIES PROGRAM # 424

### Clinical Outcomes Utilizing Revascularization and Aggressive DruG Evaluation

Date: June 16, 1999

From: Pamela Hartigan, PhD, Statistician for COURAGE at CSPCC

Subj: Satellite Sites

To: Study Personnel

Thru: Trial Leadership

1. If the satellite site has a separate IRB we need separate approvals, one from each IRB. If the consent and randomization will all be done at the primary site then we only need approval from the primary site for regulatory purposes, but that the IRB for the satellite site should co-approve.
2. Investigators at a satellite site should be specified as subinvestigators on the 1572.
3. FDA rules for Good Clinical Practice now state that there may only be one primary PI for each site.
4. All satellite sites will use the SAME hospital ID Number as the primary site.
5. Drugs will be shipped to ONE location. This location will be responsible for on-site (primary and satellite) study drug inventory.
6. One pentablot is available for each site. The logistics of sharing the PENTABLET among satellite clinics must be worked out locally. Satellite sites can request the leadership for an additional pentablot in writing, with justification but only a very limited number of these are available.
7. Money will be sent to the PI for the primary site. It is his/her responsibility to see that it is equitably distributed among primary and satellite locations.
8. Supplies (Forms, checklists etc) will be sent to one location. Distribution to the satellite sites is a local responsibility.
9. In general, written data queries will be sent to one location. Distribution to satellite sites, if required, is determined locally. Phone data queries can be made to either location.
10. Randomization: If the angiogram is done ahead of time West Haven can be called from either location (primary or satellite) and the patient randomized over the phone. **But** the correct randomization envelope matching the randomization number has to be retrieved for the satellite site so that number is not reused in some way.

If the PTCA is done only at the primary site and the angiogram will be done at the same time then there is no real problem. The randomization envelopes to be used for this purpose should reside at the primary site.

If PTCA will be done in the same trip to the catheterization laboratory as the angiogram and there are separate cath labs for the satellite sites we will have a separate list at each location.

11. The data forms for each patient should be located where the patient is followed. If a patient is randomized at the primary site and followed at the satellite all screening, baseline, and randomization information should be transferred to the satellite site.