

Department of Medicine

Division of
Cardiovascular Medicine

Division of Cardiovascular Medicine (CVM) Policy for Sponsored and Investigator Initiated Research

The Division of Cardiovascular Medicine is committed to performing sponsored and investigator initiated clinical research at the highest standard of scientific and ethical integrity. The Cardiovascular Clinical Research Unit (CRU) is being established to meet this challenge and to do so while continuing to grow the Division's research programs. The CRU will assure quality, compliance, consistency, economy and institutional transparency to divisional research activities.

Separate documents outlining the CRU Standard Operating Procedures (SOPs) and Procedures for the Oversight and Monitoring of Clinical Trials for the Division of Cardiovascular Medicine Clinical Research Unit are available to faculty for review.

The following policies will be enacted effective on 1/01/08 for all non-government sponsored clinical research:

- All industry sponsored and investigator initiated clinical research conducted in CVM will be centralized to our Clinical Research Unit (CRU), supervised by the CRU Administrator, Betsy Johnson. Dr. Leslie Saxon will serve as the CRU Medical Director.
- All personnel supporting clinical research studies within the Division of Cardiovascular Medicine, such as research nurses, clinical trial coordinators and data managers, will be employed by either HRA or USC and will be managed and directed by the CRU. No other volunteer or paid research staff will be permitted to participate in clinical research within CVM effective 3/01/08. A transition period from 1/01/08-3/01/08 will be utilized to allow for the organized transfer of ongoing studies to the division CRU.
- A separate CRU Support Staff Salary Account will be set up at HRA and monies budgeted for each salary support from each individual project will be transferred to this account as cash is received into the projects. This will allow us to determine the percent effort on a study by study basis.

- A Scientific Review panel of four cardiology faculty and one cardiology fellow will be appointed by Dr. Saxon to review and approve all project proposals on a bimonthly basis. Project proposals, including the protocol, and budgets will be submitted, prior to IRB submission, using the CRU project proposal form. The panel will review the projects to ensure scientific merit, adequate resources (both financial and personnel), proper conduct of the study and a realistic accrual strategy. The panel will also help guard against competitive studies.
- All IRB submissions and HRA contracts will be processed and maintained through the CRU. Dr. Saxon will co-sign all contracts with the Principal Investigator.
- All research study budgets development and budget management will occur through the CRU.
- All screening for patient enrollment in clinical trials will take place through the CRU and screening logs will be kept to document the process. Screening logs will be forwarded to HRA monthly for appropriate billing.
- All ambulatory patients participating in clinical research studies in CVM will be seen in either the out-patient clinics in HCC II, LAC clinics (LAC patients) or the GCRC, depending upon the details of the study. Studies conducted in the GCRC must have the appropriate budget developed.
- All additional research expenditures, from HRA accounts, including Residual Accounts, requested by the study Principal Investigator require the approval of the HRA and the CRU Medical Director.