

Department of Medicine

Division of
Cardiovascular Medicine

Clinical Research Unit

January 17, 2008

Dear CVM Investigators,

As outlined in the CVM Clinical Research Unit (CRU) Policy presented at the December 14, 2007 Faculty Meeting, all new clinical research studies must be reviewed by the CRU Scientific Review Panel. The CRU Scientific Review Panel is comprised of four cardiology faculty members, whose names are listed below for your reference:

- Dr. Leslie Saxon
- Dr. Ray Matthews
- Dr. Tasneem Naqvi
- Dr. Radha Sarma

In order for a new study to be reviewed by the CRU Scientific Review Panel, the PI of the study must submit the CRU Project Proposal Form (please see attached) along with the study protocol, investigator's manual, proposed budgets and any other pertinent information required for the CRU Scientific Review Panel to make its decision.

The CRU Scientific Review Panel will review both industry sponsored and investigator initiated clinical research projects based on the following criteria (which includes, but is not limited to):

1. Scientific Merit
2. Adequate resources (both financial and personnel)
3. Proper conduct of the study
4. Realistic Accrual Strategy (including an assessment of competitive studies)

The CRU Scientific Review Panel will meet bimonthly on Tuesdays from 8:30AM to 9:30AM. (Please see attached meeting schedule for your reference). All CRU proposal forms must be received by 2PM on Tuesday, two weeks prior to the review of your study. Please refer to the attached schedule for a listing of submission deadlines. Exceptions may be made on an individual basis.

Upon receipt of the CRU Project Proposal Form, HRA will be notified of the review date of the study so that they can provide a preliminary budget for review at the CRU Scientific Review Panel meeting at which your study will be discussed. If HRA cannot complete the budget prior to the meeting date for the review of a specific study, the review date may be postponed to the next CRU Scientific

Review Panel meeting, at the discretion of the committee.

Following review of your study, the CRU Scientific Review Panel will inform you of its decision by email within one week of its meeting. The CRU Scientific Panel will issue its decision in one of the following categories:

1. **Approved:** Study is approved. Once your study is approved by the CRU Scientific Review Panel, all IRB submissions, HRA contracts, study budgets and all study related activities will be conducted through the CRU. This is outlined further in the “Division of Cardiovascular Medicine (CVM) Policy for Sponsored and Investigator Initiated Research”.
2. **Deferred:** The CRU Scientific Review Panel feels that although the study is scientifically valid and feasible at our site, there are a few clarifications that need to be made prior to the CRU Scientific Review Panel approving your study. Studies which are deferred will require a letter or email written to the attention of the CRU Scientific Review Panel responding to all concerns raised by the committee. This letter will be placed on the schedule for review at the next CRU Scientific Review Panel meeting.
3. **Denied:** This may be for several reasons and is at the discretion of the CRU Scientific Review Panel. Potential reasons include, but are not limited to:
 - Lack of scientific merit
 - Lack of funding
 - Too many competing protocols.

Please note that you are welcome to attend the CRU Scientific Review Panel meetings on the day your study is being reviewed in order to give a brief synopsis of the study. In addition, a full explanation will be given in letter format as to the decision by the CRU Scientific Review Panel regarding your study.

We look forward to working with you on your current as well as future research studies. Please feel free to contact our office at 323-442-6863 with any questions you may have.

Sincerely,

Leslie A. Saxon
Chief, Cardiovascular Medicine

Betsy Johnson
Administrator, Clinical Research Unit

Attachments:

1. CRU Project Proposal Form
2. CRU Scientific Review Panel Meeting Schedule