

## **CIRT Ancillary Study Submission and Review Procedures**

Investigators are encouraged to propose and conduct ancillary studies. Ancillary studies refer to studies that are distinct from the main CIRT trial, but propose questions and test hypotheses that are congruent with the goals and purposes of CIRT. Such studies may require tests or data that are not routinely obtained in the main CIRT protocol, or may involve analyses of trial data in ways not planned in the CIRT protocol. Ancillary studies may involve some or all CIRT subjects and clinical sites, depending on the eligibility criteria of the study, sample size needed, or interest of the participating CIRT investigators.

Such studies will enhance the value and productivity of CIRT, and help ensure the continued interest of the diverse group of investigators who are critical to the success of the trial as a whole. These studies provide an exceptional opportunity for investigators, either within or outside of CIRT, to conduct additional projects at minimal cost. In general, ancillary studies will require additional funding from the NIH or other sources.

### **Application Review Process**

To protect the integrity of CIRT, all ancillary studies must be reviewed and approved before access to CIRT data, samples, or participants is permitted. New ancillary study proposals should be sent to the CIRT Ancillary Studies Committee (ASC), which includes membership from the National Heart Lung and Blood Institute. Ancillary study forms can be obtained by calling or emailing the CIRT Coordinating Center ([855-437-9330](tel:855-437-9330); [cirt@partners.org](mailto:cirt@partners.org)) or accessing the CIRT website ([theCIRT.org](http://theCIRT.org); click the “About CIRT” Tab, scroll to bottom “Ancillary Studies”). Complete ancillary study applications will be submitted to the ASC for review. Ancillary study proposals will be reviewed by the ASC on an as needed basis.

The ASC will review the proposal and make a recommendation to the CIRT Steering Committee (SC). Preliminary approval/disapproval will then be made by the SC with a final recommendation for approval/disapproval made by the CIRT Data and Safety Monitoring Board (DSMB). Then investigators will receive a letter of approval/disapproval.

The following specifications should be noted while planning for submission of an ancillary study proposal:

- All CIRT ancillary studies must be independently funded by the investigator or by sources obtained by the investigator.
- At least one CIRT investigator from the DCC must be involved in each proposed study, either as a primary investigator or a collaborator.

- Proposed studies should not have a negative impact on the main trial and should comply with the CIRT publication policy ([theCIRT.org](http://theCIRT.org)).
- Ancillary studies should not confer undue burden upon the DCC, site personnel, or participants enrolled in the main CIRT trial.
- Analysis involving post-randomization outcome data will not be permitted until the completion of the trial.
- All main trial data will reside at the DCC.
- All data analyses will be conducted at the DCC.
- If DCC resources are to be used, arrangements must be made in advance with the DCC Principal Investigator. In general, costs associated with ancillary study data management at the DCC must be budgeted into each ancillary study.

All proposed ancillary studies must be submitted to the ASC in time for review, circulation to appropriate committees, and to obtain clearance prior to submission to a funding agency. Studies submitted for approval less than 60 days prior to a funding application deadline may not receive timely approval.

During the review process, highest priority will be given to studies which:

- do not interfere with the main CIRT objectives,
- have the highest scientific merit,
- produce the least burden on CIRT participants,
- have objectives closest to those of CIRT,
- require the unique characteristics of the CIRT cohort, and
- provide opportunities for more junior investigators to serve as the PI of a project.

## Acknowledgement of Terms of Collaboration

Investigators with approved ancillary studies will report to the Chair(s) of the ASC and the CIRT SC every year regarding the status of study funding, initiation and terminations dates, success of data collection. By submitting an Ancillary Study proposal for CIRT, investigators agree that:

- Data analysis for all ancillary studies will be conducted at the CIRT Data Coordinating Center in Boston.
- Data analysis and/or publication involving post-randomization outcome data will not be permitted until the main trial is complete. If an investigator feels that a proposed analysis and/or publication can be conducted without affecting the randomized portion of the trial, or having a deleterious impact on the conduct of the overall trial, he or she may appeal to the CIRT ASC, SC, and DSMB.
- Data analysis and/or publication of data collected prior to randomization (during the trial run-in phase) is permissible. However, abstracts and manuscripts must be reviewed by the CIRT ASC and Publications Committee (PC) prior to publication, and will be forwarded to the DSMB for review prior to publication if either committee has concerns about the impact of the findings on the conduct of the main CIRT trial. The DSMB reserves the right to suspend publication if they believe the findings will have an adverse impact on the conduct of the main trial.
- All oral and written abstracts, manuscripts, and other public presentations of CIRT data must be provided to the ASC and CIRT Publications Committee (PC) 20 business days prior to submission for publication or presentation.
- A written progress report on ancillary studies will be made once a year to the ASC and to the SC.

I, \_\_\_\_\_, as principal investigator of the CIRT ancillary study entitled \_\_\_\_\_

\_\_\_\_\_, have read and will abide by the above CIRT Ancillary Study Submission and Review Procedures.

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date