As of December 2010, the IRB submission process has gone electronic. All protocol submissions are required to be completed through the Children's Hospital Electronic Research Portal (CHeRP). This application allows researchers to complete all required IRB protocol forms online and move protocols through all required reviews electronically, including scientific review.

In accordance with the requirements set forth by the CCI, the Cardiology Scientific Review Committee is now only accepting proposals submitted through CHeRP. The members of the Cardiology SRC have decided to continue to meet collectively once a week to review all new research proposals. Once Scientific Review is complete, the Scientific Review letter and review form will be uploaded in the CHeRP system by the SRC administrator.

Submission Requirements: Review and approval by the SRC are necessary for all protocols that that are to be submitted to the IRB, including retrospective chart/database reviews. The SRC is also willing to review and provide feedback on proposals that may not require IRB approval (e.g. quality improvement projects) if an investigator wishes. The Committee will review up to 5 protocols per meeting. Protocols will be reviewed based on the order in which they are received.

Submission to the Scientific Review Committee requires preparation of a structured project outline, which should be no more than 2 pages in length (1 page is adequate for many studies). In addition to the elements of the sample protocol, all outlines should include a list of pertinent references from the literature. Depending on the protocol, the template and examples provided may not be entirely appropriate. Please inquire if the appropriate protocol format is not clear.

For prospective studies, a copy of the full research protocol or detailed research plan (if applicable) must be submitted to the SRC along with the project outline and literature review.

Applicants are encouraged to discuss the analysis plan and statistical methods with Dr. Kimberlee Gauvreau prior to submission.

CHeRP Submission Process:

Below are step-by-step instructions for requesting Scientific Review for a new research proposal:

- 1. Log-in to CHeRP: <u>http://rc-cherpprod/CHERP</u>
- 2. Click "Create new IRB protocol", on the left hand side of your page.
- 3. Complete the **General Information** page and save it.
- 4. This will assign your new protocol an initial IRB number in the system
- 5. Once saved, you can click "Exit" at the top of the page
- 6. This should bring you back to the summary page
- 7. On the left hand side, there should be an icon "**Request Scientific Review**". If you click this a new window opens
- 8. Here is where you can upload the SRC summary, study protocol, study survey, etc. Upload anything you want the Scientific Review Committee to look over and review. You can also enter comments for the committee members.
- 9. Once this is done, confirm the request and click OK.
- 10. An automated email is then sent to the SRC administrator who can then log in and save the materials you uploaded and distribute then to the SRC members for review.

If you have any questions regarding the scientific review process or requirements, please contact Amanda Erlwein at Amanda.Erlwein@cardio.chboston.org or at4-1805.