**Social Work Scientific Review (SWSR) Committee**

**Information for Investigators**

This document is intended to provide guidance to social workers who are submitting human subjects research protocols to the IRB, and who wish to use social work scientific review rather than departmental review. The IRB requires scientific review to assure that the scientific merit of the research is sufficient to justify any burden on the participants. The committee needs to assure, for example, that all the proposed measures are necessary, that the aims are appropriate, the literature review is complete, and that the study is designed to meet the aims. The review criteria are listed on the standard worksheet that is completed along with the first review. The review has also served the purpose of promoting the quality of the research that we do (and this pertains to everyone, no matter how much experience they have). The attitude of the committee in reviewing protocols is not to create roadblocks but to assure that the proposed project will result in a high quality final product (publication, instrument, grant proposal, etc). This should benefit both the participants (whose time and efforts are well spent) and the investigator. Protocols are also reviewed for potential “red flags” that might not be scientific concerns but could affect review at the IRB level.

There are two types of protocols: research protocols that entail the collection of new data and chart reviews. For the chart reviews, we have an internal document that needs to be completed (see appended) so that the committee can review that the effort is well spent and again that the effort will lead to a high quality final product, useful pilot data, and so forth.

Because the primary goal of the review process is to promote high quality for all projects, investigators should feel free to contact the committee as they are developing the protocol if they have questions. It is also often a good idea to seek bio-statistical support in preparing the protocol if the analyses are not simple and straightforward.

Social Work Scientific Review committee members:

* Elizabeth Wharff, PhD (chair)
* Elizabeth Boskey, PhD MPH (chair)
* Moira Harrison, MSW (coordinator)
* Colleen Hayden, PhD (reviewer)
* Yudy Muneton-Castano, PhD candidate (reviewer)
* Kim O’Brien, PhD (reviewer)
* Samantha Schneider, PhD (reviewer)
* Christina Sellers, PhD (reviewer)

All research protocols, including chart reviews, must receive approval from the Social Work Scientific Review committee prior to being submitted to the Committee on Clinical Investigation.

Research Protocols:

Protocols should be submitted through the Children`s Hospital eResearch Portal (CHeRP)

[CHeRP](http://rc-cherp.tch.harvard.edu/CHERP/Rooms/DisplayPages/LayoutInitial?Container=com.webridge.entity.Entity%5bOID%5bD5B53DDEA721C24FB812D58D201BF463%5d%5d)

Step 1: Create an IRB submission in CHeRP. Complete the general information (under General Protocol Information tab). Under the Protocol and Appendices tab, upload the research protocol (Part B) and any accompanying documents.

Step 2: Select the submission from your CHeRP IRB inbox. Once in the submission workspace, you will have the ‘Request Scientific Review’ activity available if applicable. When you execute this activity, the submission will transition to the ‘Scientific Review’ state. The Scientific Review Coordinator for Social Work (Moira Harrison) will receive email notification of your request and the protocol will appear in her CHeRP IRB inbox. **Submissions are due by the 20th of the month** (or the next working day, if the 20th falls on a weekend or holiday).

Step 3: **Protocols will be reviewed during the 1st week of the following month**. The primary reviewer assigned to the protocol will email a worksheet and detailed review of the protocol to you within two weeks. The Scientific Review process takes place outside of the CHeRP system.

Step 4: To respond to feedback, you are invited to meet with the primary reviewer to discuss any changes, issues etc. Once the protocol has been modified, email an updated version of the protocol to the primary reviewer. Please use track changes. You should also include a separate document that outlines your response to each review item, and the location in the protocol. The committee will not need to review the changes, which are at the discretion of the primary reviewer and committee chair. **All correspondence should cc Moira Harrison.**

Step 5: Once the primary reviewer has approved of the submission, Moira will upload all documentation (e.g. final protocol, Scientific Review correspondence, worksheets) and complete the review process. The investigator will be notified that Scientific Review is complete. At this time, the protocol is transitioned to ‘Draft’ state and the investigator can once again make changes to the CHeRP submission form before submitting to the IRB.

Step 7: After Scientific Review is complete, the investigator must submit the protocol for IRB review. In the submission workspace, you will have the ‘Submit to the IRB’ activity available if applicable.

Step 8: When the investigator submits the protocol to the IRB, the protocol is first sent to Social Work Department leadership, the submission automatically proceeds to the IRB.

**Outline for Scientific Protocol**

(Template form provided by SWSR Coordinator)

**TITLE:**

**A. Specific Aims/Objectives**

**B. Background and Significance**

**C. Preliminary Studies**

**D. Design and Methods**

**(1) Study Design**

**(2) Patient Selection and Inclusion/Exclusion Criteria**

**(3) Description of Study Treatments or Exposures/Predictors**

**(4) Definition of Primary and Secondary Outcomes/Endpoints**

**(5) Data Collection Methods, Assessments, Interventions and Schedule (what assessments performed, how often)**

**(6) Study Timeline (as applicable)**

**E. Adverse Event Criteria and Reporting Procedures**

**F. Data Management Methods**

**G. Quality Control Method**

**H. Data Analysis Plan**

**I. Statistical Power and Sample Considerations**

**J. Study Organization**

**K. References**

Chart Reviews (Template provided by PSR Coordinator):

Chart reviews are reviewed in a similar manner to new protocol submissions. However, please obtain the Scientific Background (Chart review) template form from the SWSR coordinator before submitting.

Similar to new protocol submissions, chart reviews should be submitted for scientific review via CHeRP. Keep in mind, chart reviews are labeled as New Research Activity Limited to Excess Human Biological Material and/or Review of Health Information on Patients in CHeRP and are typically IRB exempt. Chart reviews will be reviewed by the full committee and adhere to all the same deadlines as new protocols.

Unlike research protocols for which patients must be consented, the chart review procedure in CHeRP does not require submission of a scientific plan or consent forms.

Amendments:

The question often arises about whether scientific review is needed for amendments to an approved protocol. If the amendment involves the addition of a scientific aim, scientific review is required and you should contact the committee to request review. If the amendment involves a relatively minor change in procedure, addition of a measure, etc. that does not modify the aims of the study, the investigator can simply submit the request to the IRB through CHeRP.

Amendments are reviewed by the whole committee on a case-by-case basis. Some amendments may simply be reviewed offline by a single committee member (often the primary reviewer for the original protocol). This is at the discretion of the chair of the committee. Committee members will NOT have access to any documents in CHeRP. All amendment review documents must be sent via email to the PSR coordinator for distribution.

Once an amendment has been approved, it is up to the PI to document it appropriately in CHeRP. The amendment form will ask if scientific review was required, obtained, and to upload proof of review. The PI may upload any correspondence with reviewers (e.g. email exchange) or may upload the primary reviewer’s letter and any subsequent response from the PI. The PI may then submit the amendment to the IRB.