



Scientific Review Requirements for CARDIOLOGY

DEPARTMENT/DIVISION AUTHORIZED SIGNORS

1. **Department Chair/Division Chief:** Tal Geva, MD
2. **Authorized Signors:** Tal Geva, MD
T.P. Singh, MD, MSc

DEPARTMENT/DIVISION SCIENTIFIC REVIEW REQUIREMENTS

as of January 2020

1. Summary provided by Department Chair/Division Chief:

Purpose of Scientific Review Committee: The Committee for Clinical Investigation (CCI) has mandated that all hospital departments develop internal processes for assessing the scientific aspects of clinical research studies conducted by members of the department prior to submission to the CCI. The Department of Cardiology responded to this mandate by establishing the Scientific Review Committee (SRC). The SRC is comprised of members representing various divisions within the department, and convenes weekly to review research protocols submitted by faculty, fellows, and staff. The SRC review is focused on the scientific question(s) and methodology of each study, and is intended to provide constructive feedback aimed at encouraging optimization of study conception and design, with the ultimate goal of helping investigators make the most of each research opportunity. While considerations of safety and protection of human subjects are under the purview of the CCI rather than the SRC, the SRC does consider and address aspects of the protocol that may be problematic from a human subjects perspective.

Meeting Schedule: The Scientific Review Committee meets each Wednesday, pending submission of at least 1 project before noon on the preceding Wednesday. The Committee will review up to 5 protocols per meeting. Protocols will be reviewed based on the order in which they are received.

Committee Members: The Scientific Review Committee reviews each new protocol prior to IRB submission. Committee members include T.P. Singh, MD, MSc (Chair); Jean Connor, DNSc; Kimberlee Gauvreau, ScD; Lynn Sleeper, ScD; Dominic Abrams, MD; Melissa Smith-Parrish, MD; Sarah Pickard, MD; Jacob Hartz, MD; Michelle Gurvitz, MD; Kathy Jenkins, MD; Lisa Bergersen, MD; and Meena Nathan, MD. The SRC administrators are Amanda Erlwein and La Tina Watson. A quorum of at least 6 members is required for the meeting to take place.

Submissions Requirements: Review and approval by the SRC are necessary before submission to the CCI for all protocols that require the signature of the Chairman of Cardiology, and for retrospective chart/database reviews. Case reports do not require review. Three-year re-writes and most protocol amendments do not require SRC review.

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). A protocol template is attached. All outlines should include a list of pertinent references from the literature. Please inquire if the appropriate protocol format is not clear.

For prospective studies, a copy of the full research protocol (if applicable) must be submitted to the SRC along with the project outline and literature review. Aside from the full protocol, it is not necessary to submit other forms required by the CCI, including consent forms.

For studies supported by the Clinical and Translational Study Unit, the CTSU prefers that protocols are first reviewed and approved by the SRC.

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

For any questions concerning the format or design of the proposal, please contact one of the Committee members.



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- Protocols should be submitted electronically via CHERP

Review Process: Two members of the SRC review each protocol in detail. Each protocol undergoes biostatistical review by Dr. Kimberlee Gauvreau and Dr. Lynn Sleeper. The protocol is reviewed according to the content areas listed on the SRC review forms. All members review the project outline. The protocol is discussed among members present at the meeting; comments submitted in advance by members not present are considered as well. By consensus, one of the following decisions is reached:

1. **Approved:** The proposal is approved for submission to the CCI, along with the signed SRC letter, without resubmission to the SRC. The Committee may or may not suggest changes or clarifications to the protocol. The applicant's responses to the recommendations listed in the SRC letter must be addressed explicitly in a cover letter to the CCI. Although the recommendations do not necessarily need to be incorporated into the protocol, the rationale for the response should be stated in the letter to the CCI.
2. **Request for clarification:** The SRC requests clarification of points outlined in the response letter before it will release an approval.
3. **Not approved:** Changes must be made and the project must be resubmitted to the Committee for re-review prior to approval.

The decision will be communicated to the primary investigator by letter within 1 week of the meeting.

Occasionally, the Committee will ask the investigator(s) to discuss the proposal during the SRC meeting in an effort to clarify questions or potential concerns, with the hope of reaching a more appropriate and favorable decision.

On occasion, a member of the SRC may approach the investigator with suggested modifications or clarifications without issuing a formal decision. In such cases, the intention of the committee is to allow expedited resubmission of a protocol that does not contain sufficient information in one or more respects to complete an adequate review.

If there are questions about the SRC response letter, please contact the Committee chair or any member.

Resubmission: Protocols that are not approved must be modified or clarified and resubmitted to the SRC. If the requested changes or modifications are not clear to the applicant, he/she should seek clarification from an SRC member prior to resubmission. The required elements of a resubmission are the same as for initial submission. In addition, investigators must submit a cover letter to SRC specifying changes made in response to the initial review, in a point-by-point manner, along with the modified outline and literature review. In some cases of simple clarification, an administrative decision on the revised proposal will be made without full re-review. Generally, the proposal will be reviewed by the entire committee, with the same primary reviewers if possible.

2. **Submissions requiring scientific review as described above *prior* to CCI/IRB submission:**
 - New Protocol Submissions
 - Medical Record Review
3. **The following requirements must be submitted with CCI application**
 - Letter of approval from SRC
 - Completed SRC review committee form



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- Pertinent correspondence: PI responses to concerns/questions, and any follow-up concerns/questions from the reviewer

OTHER SCIENTIFIC REVIEWS*

* The following reviews may replace the Department/Division scientific review *as permitted* by the Chair/Chief.

1. **General Clinical Research Center (GCRC)**: if study uses GCRC services (7 East, CAT/CR, GCRC Laboratory, or any other GCRC resources), scientific review and approval must be obtained from the GCRC Scientific Advisory Committee. See GCRC for requirements. (The GCRC prefers that protocols are first reviewed and approved by the SRC.)
2. **Neonatology Intensive Care Unit (NICU)**: if study uses the NICU on 7 North, scientific review and approval must be obtained from the Harvard-wide Neonatal Research Review Committee (HNRRC). See Division of Newborn Medicine for HNRRC requirements.
3. **Hematology/Oncology Patients**: if study includes Hematology/Oncology patients, scientific approval must be obtained from the Pediatric Scientific Review Committee (PSRC). See Division of Hematology/Oncology for PSRC requirements.