

CTSA Consortium Consensus Scientific Review Committee (SRC) Working Group Report on the SRC Processes

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Introduction

This report reflects the consensus of the Clinical and Translational Science Awards (CTSA) Consortium Scientific Review Committee (SRC) Consensus Working Group, responding to the charge to propose a framework for scientific review processes of human participant research protocols at CTSA institutions. The objectives of the proposed SRC process are to assure the scientific validity and feasibility of human research protocols and to uphold institutions' missions of promoting excellence in research. The Working Group envisions this as a committee process, and the term SRC is used throughout, but it is understood that the exact configuration of review will vary according to institutional circumstances. In any case, there was strong consensus on the requirement for the SRC process, criteria for protocol selection for review, and criteria for the process of review as described in this report.

Research involving human participants must comply with well-recognized ethical and regulatory precepts and processes.¹ An important ethical requirement is that a research project involving humans must have a scientifically valid study design and analytic plan while being operationally feasible. This fundamental concept is essential to providing a reasonable chance of generating new knowledge. Human studies that are improperly designed, or cannot achieve their proposed aims (e.g., because of inadequate sample size) are, by definition, unethical as they impose risks and burden on study subjects without a likely benefit to the participants or society. Given the breadth of the issues that must be adjudicated by an institutional review board (IRB) in approving a study, and given the specialized expertise and discussion that may be needed to judge study design, plan, and feasibility, a focused SRC review should be conducted prior to, but integral to, full IRB review. This should help ensure that a study meets acceptable standards of scientific rigor and feasibility. With an SRC process in place, the quality of research will be more directly assessed and supported, while the work of the IRB made more efficient.

This approach of having SRC assessment prior to full IRB review is aligned with the IRB mandate to assure ethical conduct of human research. The exact relation and interaction of the SRC, particularly with an IRB, will vary based on individual institutional structures and functions related to human participant research.

Even though some variations due to institutional circumstances (e.g., differences in protocol submission procedures and specific roles of SRC members) might be necessary, the SRC process described in this report should be part of the institutional review process for human research protocols.

Despite the important intent, a potential detriment to the overall clinical research enterprise would be if the SRC process degraded institutional efficiency and timeliness. To promote assessment of such an effect and for efficiency, institutional information technology infrastructures should facilitate SRC processes and communication among the SRC, IRB, and the principal investigator (PI; see IT recommendations in Appendix 1). To detect potentially deleterious effects, institutions should monitor the SRC process for burden of implementation, effect on protocol quality and feasibility, and efficiency of the review process (i.e., time for SRC and IRB review, net investigator time to make revisions). Specific metrics will need to be tested in an anticipated pilot study and reported separately. The informatics infrastructure should facilitate automated capture of time-based metrics.

Institutional Support for the SRC Process and Roles of CTSA

Institutions with National Institutes of Health (NIH) sponsored CTSA should have study design and statistical consultation available for investigators to provide clinical research education and design assistance for new investigators and others needing help. In particular, CTSA should provide such assistance to those funded by the CTSA, such as pilot awards, T, and K awards, even prior to being referred to the SRC and IRB. Institutional policies should include submission of reviewer feedback from that review to the SRC and/or IRB. Institutions may choose to have pre-SRC review of all protocols (including those not funded by a CTSA) to address the needs of PIs who need study design and related assistance prior to, or during, the SRC process. An example of such a process is provided in *Figure A.1A*, Scientific Review at CTSA Institutions (for the full *Figure A.1*, see Appendix 2).

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Multisite Research

In many cases for multisite clinical studies, external funders complete a full peer-review of protocols before engaging study sites. In these cases, the SRC screening process will determine whether there was prior adequate peer review. Because multisite clinical studies may use a central IRB (including reliance and other centralized models) rather than depend on individual institutional review, given the link of SRC and IRB review, SRC review may not be necessary at each study site. In these cases, the SRC related to the central or relied-upon IRB should be responsible for reviewing scientific feasibility. However, although this single SRC process would assess scientific quality and general feasibility, policies at local institutions should include an assessment of local operational feasibility of the study site, available resources, and determination that the PI has the necessary skills, experience, and time to successfully complete the study. On the occasion that the relied-upon IRB does not have a SRC, local institutional policies should include a SRC process to ensure scientific validity.

Criteria for Selection for SRC Review

All human participant research should be considered for review by a SRC prior to IRB submission. However, the degree of review will vary based on the type of research, its needs, and institutional factors. We suggest a multipath approach to review that will start with determining whether a research protocol is potentially exempt from SRC review. This determination should be based on such features as whether it has already undergone substantial peer review, whether it was an investigator-initiated study that has not had extensive vetting, and other factors (See *Figure A.1B*). SRC Review Process. For the full *Figure A.1*, see Appendix 2).

For example, SRC review will be appropriate for protocols that have not already received full peer review, which would include (but not be limited to) investigator-initiated projects, pilot projects, clinical trial protocols generated by those supported by T or K awards or other trainees, by foundations, or by pharmaceutical, and biotech companies. If a protocol has not received adequate peer review, it should not be exempt from SRC review (Path 1 in *Figure A.1B*). These protocols either proceed directly to the SRC for review, or prior to full review, to the SRC screener. The screener of the SRC may return the protocol to the PI for minor revisions (e.g., clarification and/or responses to SRC review points) or for major revisions (i.e., recommendation for study design assistance). Once initial questions for the PI are addressed, the protocol is sent to the SRC to determine whether it is ready for IRB review. With SRC approval, the protocol will proceed to the IRB. If the protocol is still not ready for IRB review, the protocol will be returned to the PI with additional comments and suggestions, and resubmitted to the SRC once revisions are made.

Although research protocols with prior adequate peer review should be considered for exemption from SRC review, some protocols may raise a specific concern that needs to be addressed by the PI (Path 2 in *Figure A.1B*). In this regard, it should be noted that review of a research *proposal*, for example, by NIH, is not necessarily the same as review of a research *protocol* from the SRC perspective; the former often does not have the details of study processes and analysis. Prior adequate review must be of the *protocol*. When warranted, exemptions based on prior adequate review will limit redundant reviews, duplication of effort, delays, and bureaucratic burden. Protocols determined as exempt from SRC review will be submitted directly to the

IRB (Path 3 in *Figure A.1B*). Types of research protocols that will usually meet criteria for exemption will have already had significant scientific and feasibility review, as determined by the SRC chair and/or an equivalent person based on institutional policies. Examples of protocols that could potentially be exempt from SRC review may include:

- Research protocols that have been subjected to scientific review by a CTSA process, such as for pilot awards or protocols generated by K or T awardees that have been reviewed for quality and feasibility;
- Research approved for federal funding (e.g., NIH, Department of Defense, Centers for Disease Control, Agency for Healthcare Research and Quality, Food and Drug Agency, Patient-Centered Outcomes Research Institute) that has gone through a peer-review process of its scientific validity and feasibility, including review of the research *protocol*;
- Research approved for funding by industry, foundations, or other organizations, when the funding entity uses an adequate peer review mechanism for scientific validity and feasibility of the protocol;
- Research that qualifies for expedited IRB review;
- Research that qualifies for exemption from IRB review.

Such expectations notwithstanding, the IRB and/or Institutional Officials may forward to the SRC any protocol that otherwise potentially qualified for exempt and/or expedited handling, or was previously reviewed.

Roles of SRC Members

As embodied in an SRC, the process outlined in this document is envisioned as requiring six or more functions, including: a chair, a coordinator, medical/scientific reviewers (probably a minimum of three), a statistician, and content experts as needed. The chair and reviewers should have active research careers and have demonstrated scholarly accomplishments in the form of grants and publications. A chair and/or reviewer who is not actively engaged in research should be considered if he or she has a past history of conducting research. Involvement in institutional IRB and/or CTSA is beneficial, but not a requirement. Emphasis should be placed on having reviewers with diverse skill sets and clinical backgrounds. The following general criteria should be followed when considering candidates for SRC membership:

1. Has the requisite expertise,
2. Is not a research team member of the study subject to review,
3. Has no conflict of interest,
4. Is available to perform the review in a timely manner, and
5. Is willing to undertake the task.

The roles of the proposed SRC members are as follow:

- **Chair:** The role of the chair (or his or her designee, with oversight) is to screen studies referred to the SRC by the IRB (or other referral source) to determine whether there is sufficient evidence of prior peer review and whether the protocol has all necessary components as defined in the Protocol Review Form (see Appendix 3). The chair leads the SRC meeting discussion, to ensure that all reviewers' opinions are represented and, when necessary, helps resolve conflicting viewpoints. The chair participates in drafting communication on the SRC's decision to PIs and reviews PIs, responses. In some circumstances, to help clarify concerns, the chair will meet with the PI to help clarify issues. If necessary,

the chair will direct the PI to consultative services to help with study design and protocol development.

- **Coordinator:** The coordinator works closely with SRC members, the IRB, and PIs to facilitate communication, ensure documentation of SRC communications, and distribute the outcome of the SRC's deliberations. Additionally, the coordinator is responsible for scheduling and attending SRC meetings, taking minutes, and assisting the chair in drafting the report of the SRC's decision for the PI.
- **Medical Reviewer:** A medical/scientific reviewer evaluates protocols for scientific merit using (but not limited to) criteria listed in the Protocol Review Form in Appendix 3. The reviewer attends SRC meetings and presents their review to the SRC for discussion.
- **Statistician:** A statistician reviews protocols and provides necessary feedback to ensure the appropriateness, adequacy, and alignment of study components. The components that are reviewed by the statistician include:
 1. The study design including specific aims, approach, and methods,
 2. The sample size and measurement design so that it has the power for the hypothesis(es) to be tested while controlling for inferential error rates,
 3. The plans for ensuring data quality,
 4. The statistical analysis plan, including plans for minimizing bias and handling of patient withdrawals and dropouts,
 5. Identification of personnel essential for research success. The statistician also attends SRC meetings and presents his or her reviews to the SRC for discussion.
- **Content Experts:** In reviewing protocols, the SRC may need the assistance of faculty members, or other reviewers who have specific expertise relevant to the disease, condition, or research methods under consideration. Also, the SRC may need to go outside the institution to find a reviewer who has no conflict of interest. These questions may concern the relevance of the proposed study to the field, the relationship of the proposed study in reference to other ongoing research within the institution's clinical program, or other technical issues beyond the expertise of SRC members. The role of the expert reviewer is to review the study in advance of the SRC meeting, to present their review during the meeting, and to address specific questions posed by the SRC. When a need for a content expert is identified by the SRC chair, the primary medical/scientific reviewer in consultation with the chair, or the SRC, the coordinator will contact the relevant department chair or division chief and ask for assistance in identifying a willing and available expert. If this results in a delay of more than a week, the PI should be notified that the SRC review will be delayed while an expert reviewer is identified. Once identified, the expert will be invited to the next SRC meeting, at which time the protocol will be discussed. The SRC recommendation will be communicated to the PI and the IRB. In the rare instance of an extended delay, the SRC may elect to review the protocol without the content reviewer and instead, forward questions to the PI.

SRC Application Process

A SRC review process is intended to ensure that human research protocols meet acceptable standards of scientific rigor and feasibility prior to IRB review. Institutions should have standard

policies that govern coordination with the IRB that (1) facilitate the review process, and (2) allow the IRB access to the SRC review of protocols (see Appendix 4 for examples of communication from the SRC regarding protocol review status).

The medical reviewer ensures that while assessing protocols for scientific merit and operational feasibility based on the definitions given for the criteria within the form, at minimum, the core criteria on the Protocol Review Form are met (see Appendix 3). Each category on the form is to be categorized by the reviewer as: present/acceptable, present/not acceptable, or absent (see Appendix 3). To facilitate the review process, the reviewer's assessment should be available for all members to view prior to meeting and discussed when the committee meets.

In summary, an example of an application process is as follows:

- PI submits study protocol to the IRB for the initial screening process.
- If appropriate, the IRB forwards the submitted protocol to the SRC where it is recorded and added to the list of protocols pending review.
- SRC chair or an institutional screening designee conducts preliminary assessment of the study to determine whether it meets criteria for SRC review. The process should be transparent and logical to all involved.
- While the submitted protocol is undergoing assessment to determine the path to review (see *Figure A.1B*), the PI should be notified that this is underway.
- The PI should be promptly informed of the outcome of the assessment.
- Protocols that are scheduled for review will then be assigned a statistical reviewer and medical/scientific reviewer(s). If necessary, review by a content expert also will be assigned.
- All protocols scheduled for SRC review should be available for reviewers at least three business days prior to the meeting. All SRC members should be notified at that time and members told of their review assignments.
- All protocols will be reviewed by SRC reviewers based on predetermined criteria to make a preliminary determination of scientific validity prior to meeting. Reviewers should use the Protocol Review Form (see Appendix 3) to make and record their assessment.
- All communications and referencing documents during the application process should be shared using a secure content management system.

SRC Process

Scientific Review Committee meetings are to be conducted regularly (e.g., weekly or biweekly) as long as there is a quorum and protocols for to review. The frequency of SRC meetings should be based on the number of protocols submitted for review in order to avoid delays in the review process. A quorum, may be defined as (at minimum) three medical/scientific reviewers, one statistical reviewer, the chair, and the coordinator being present. If there are protocols for the SRC to review and a meeting cannot be convened at the regularly scheduled time, an alternate time may be proposed and agreed upon within the same week. If at least three medical/scientific reviewers are not available, the meeting would be rescheduled. If the chair of the SRC is not available for a scheduled meeting, the chair would nominate a deputy chair for his or her absence.

Recommendations should be made by majority vote. If a reviewer is unable to attend, but has reviewed the relevant

information, their input would be considered in the deliberations of the meeting. However, only those members present for the majority of the meeting and present for critical deliberations would vote. There should be an attempt to achieve consensus in all decisions.

Potential SRC Actions

Potential SRC actions include:

1. the protocol is returned to the PI for further action or revisions,
2. the protocol is returned to the PI for further action for substantial revision, potentially with a recommendation to seek assistance from experts in study design, statistics, or other, or
3. the protocol is forwarded to the IRB without further requirement for action by the PI.

Examples of SRC Correspondence

If a PI indicates that a protocol had prior peer review, he or she should provide supporting and related information prior to review. The PI should be contacted after the initial screening if there are any questions and/or it is determined that the protocol will undergo SRC review (see Notice of Scientific Review in Appendix 4). After the SRC convenes, recommendations should be sent to the PI and the IRB. The Notice of Scientific Review letter, recommendations, and committee meeting attendance would serve as meeting minutes. Minutes should be confidential and available to SRC and IRB members, and other institutional personnel as per institutional policy.

Example Response Process for SRC Reviews

If the protocol is returned to the PI for clarification or modification, the PI should submit an item-by-item response, along with applicable tracked-change documents, to the SRC office.

The revised protocol should be made available to all SRC assigned reviewers. The assigned reviewers and chair should determine if the revised protocol adequately addresses all concerns and questions of the SRC, if it needs to be discussed at the next convened SRC meeting, or if there are concerns remaining that need to be returned to the PI for further clarification and/or action. If the SRC requires further action by the PI, he or she should be notified immediately and should revise the protocol as necessary per the SRC comments and then re-submit for review. If appropriate, the PI should be given the opportunity to attend the reconvened SRC. At any time during this process, the PI may contact the SRC chair for assistance and guidance. This is noted in the Notice of Scientific Review letter (see Appendix 4) that is forwarded to the PI. The SRC chair may also contact the PI and/or study coordinator at any point in the process for clarification or information if this would help review.

Conclusion

This document is the result of the CTSA Consortium SRC Consensus Working Group's discussions, draft documents with iterative revisions, and final consensus. While an attempt to provide statements on a wide range of scientific and feasibility review, it is understood that this consensus document will leave some structures, processes, and procedures unspecified and left to the discretion of institutions. It is hoped that this report will provide a conceptual and procedural framework for SRC processes, criteria for selection for review, and criteria for the content review that can be applied in multiple institutions as a way to improve the quality and ethical compliance of their human participant research. The purpose of this consensus document is to provide a framework for rigorous scientific assessment in order to reinforce the mission of promoting research excellence in human participant research.

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1. Title 45 Code of Federal Regulations (CFR), Part 46 Protections of Human Subjects. U.S. Department of Health and Human Services Web site. <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.111>. Published Effective July 14, 2009. Revised January 15, 2009. Accessed February 5, 2015.

Appendix 1. CTSA Consortium Scientific Review Committee (SRC) Consensus Working Group Information Technology (IT) Infrastructure Needs Assessment and Recommendations

Overview

A needs assessment was conducted September–December 2014 with the SRC Consensus Working Group to determine best practices in IT infrastructure to support the project and data management of the recommended SRC process. The results of this assessment indicated that there is significant variation between both IT infrastructures and SRC processes among institutions. Variations in IT infrastructure ranged from institutions utilizing email and paper to maintain SRC and/or IRB processes, to others utilizing enterprise solutions such as, Click®, SharePoint, or similar home-grown electronic content/process management applications. Due to these variations, finding a single IT solution to support the key functions for all institutions conducting clinical research was not recommended.

Recommendations

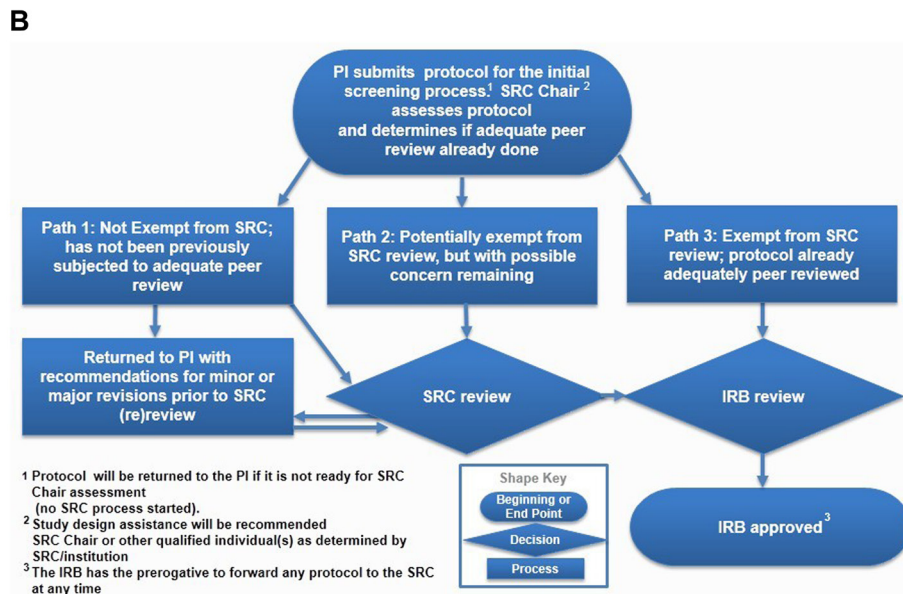
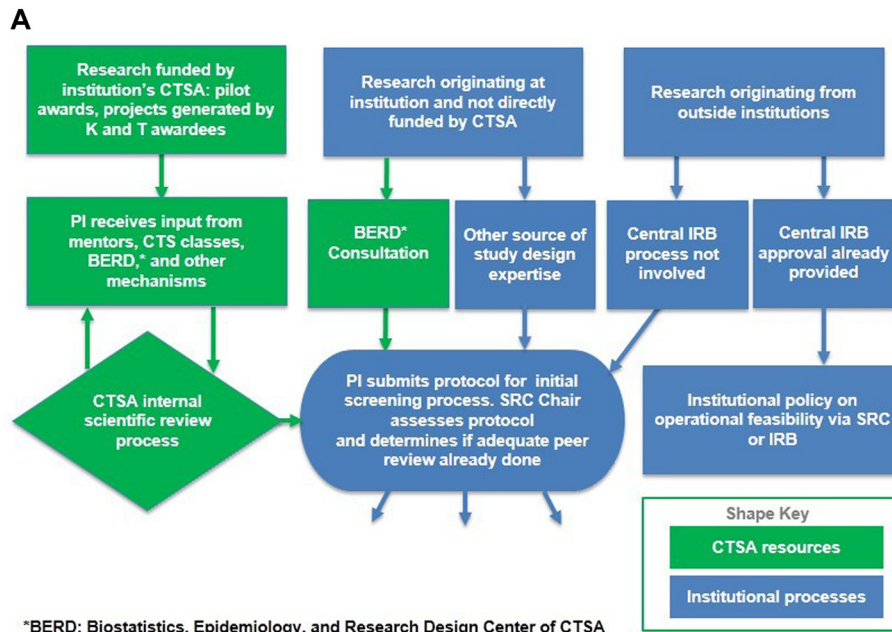
Both a project management system to support the workflow of the SRC (e.g., communication between SRC staff, submission of protocols, time stamping key points in the workflow, etc.), and a data management system (e.g., to support data entry, quality control, and collection of evaluation metrics) was recommended by the Working Group. The following IT solutions provide both project and data management capabilities.

If institutions use Click® IRB to support the IRB review process, the suggested approach is to explore the “auxiliary review” functionality of the system. This would allow for communication between the IRB and SRC, as well as the ability to have all documents submitted and reviewed in one place. Adding an additional SRC module option could be explored, which would be an additional charge.

Institutions that already have an existing electronic, home-grown project and data management system in place could create institutional policies and processes to collect the recommended metrics within their existing workflow.

Appendix 2. Figure A.1 (A). Scientific Review at CTSA Institutions and (B). Scientific Review Committee (SRC) Review Process Combined

Figure A.1. (A) Scientific Review at CTSA Institutions. (B) Scientific Review Committee (SRC) Review Process Combined.



Appendix 3. Scientific Review Committee Protocol Review and Monitoring Criteria Protocol Review Form
Scientific Reviewer Comments—(Page 1 of 3)

Title: _____

Principal Investigator: _____ Reviewer: _____

Type of Support (check all that apply): Type of funding and/or protocol support/assistance prior to SRC submission.

- | | | |
|---|---|---|
| CTSA Pilot <input type="checkbox"/> | Small industry support <input type="checkbox"/> | Investigator-initiated <input type="checkbox"/> |
| CTSA K Awardee <input type="checkbox"/> | Large industry support <input type="checkbox"/> | NIH or other federal support <input type="checkbox"/> |
| CTSA T Awardee <input type="checkbox"/> | Multi-center <input type="checkbox"/> | Study section review <input type="checkbox"/> |
| CTSA funded <input type="checkbox"/> | Single-center <input type="checkbox"/> | Protocol review <input type="checkbox"/> |
| Foundation support <input type="checkbox"/> | FDA approved <input type="checkbox"/> | Other source (specify) _____ |
| Company initiated <input type="checkbox"/> | | |

Comment: _____

Translational: Study has clinical impact versus exploration.

- Present/Acceptable Present/ Not Acceptable Absent

Comment: _____

Objectives: Clearly stated specific aims aligned with well-defined endpoints and appropriate study design.

- Present/Acceptable Present/ Not Acceptable Absent

Comment: _____

Scientific Merit/Background and Rationale: Justification for conducting the study; results of similar or pilot data; current literature cited

- Present/Acceptable Present/ Not Acceptable Absent

Comment: _____

Design: Clearly describes: how stated objectives will be achieved, methods to acquire data, and strategies to overcome anticipated barriers. Addresses randomization, minimization of bias, patient follow-up, and blinding (if applicable).

- Present/Acceptable Present/ Not Acceptable Absent

Comment: _____

Eligibility Criteria: Specific inclusion/exclusion requirements and stratification factors (if applicable).

- Present/Acceptable Present/ Not Acceptable Absent

Comment: _____

Outcome Characteristics and Endpoint Definitions: Clearly defined primary and secondary endpoints/outcomes.

Present/Acceptable Present/ Not Acceptable Absent

Comment: _____

Statistical Analysis and Sample Size: Appropriate and adequate study design statistical analysis plan. Prospective analysis plan, including sample size justification to achieve study objectives and plans to minimize missing data.

Present/Acceptable Present/ Not Acceptable Absent

Comment: _____

Data Management: Practices and procedures in order to manage data analysis, quality, cleaning, and storage.

Present/Acceptable Present/ Not Acceptable Absent

Comment: _____

Principal Investigator and Study Site Qualifications and Resources: Has the necessary skills, experience, time, and resources to ensure that the study can be successfully completed, including identification of personnel to provide statistical computations and statistical expertise. A plan to register protocol with clinicaltrials.gov.

Present/Acceptable Present/ Not Acceptable Absent

Comment: _____

Overall Assessment:

Forward to IRB for consideration Forward to IRB with comments Return to PI with comments

Comment: _____

Summary: Please summarize below, at end of committee discussion, what changes you request or questions you want conveyed to the PI: _____

Appendix 4. Examples of Communication from SRC: Protocol Review Status

Example One: Notice of Review

This email is to inform you that your new protocol submission, IRB # _____, entitled “_____” was forwarded to Scientific Review Committee (SRC) Chair for possible review. Once the Chair has determined whether SRC review is necessary, we will inform you of the decision. Please refer to our website for more information on the SRC and IRB processes and feel free to contact our office with any questions you may have.

Example Two: Letter to Inform PI of Study Selection

This email is to inform you that your new protocol submission, IRB # _____, entitled “_____” has been selected to be reviewed by the institutional Scientific Review Committee (SRC). It is scheduled for review by the SRC on [date].

The SRC was established to reinforce the institutional mission in promoting research excellence. The SRC reviews selected clinical research proposals to ensure that they meet an acceptable standard of scientific rigor and merit prior to IRB review. For more information about the SRC, please visit the IRB website.

You will be notified about the outcome of SRC review of your protocol and will be sent communication regarding any necessary changes to the protocol.

If you have administrative questions regarding this matter please contact me at (XXX) XXX-XXXX.