Office of Research and Innovation

VCU SRC Written Policies and Procedures

Scientific Review Committee (SRC) Overview

Scientific Review Committee (SRC) Overview
I-1. Mission and Purpose
I-2. Membership
I-3. Review Criteria
I-4. Communications
I-5. Reviewer Form
Section I: Scientific Review Committee (SRC) Overview

WPP #: I-1

Title: Mission and Purpose

Effective Date: 08-01-2016

Revision History:

Policy and Procedures

VCU is committed to ensuring that human subject research conducted at the institution is scientifically sound and feasible:

The Scientific Review Committee (SRC) at Virginia Commonwealth University provides study design, analytic planning and operational feasibility review of clinical research before review by the IRB.

The SRC’s mission is to ensure that all research projects involving humans at Virginia Commonwealth University meet acceptable standards of scientific rigor and feasibility without obstructing institutional efficiency and timeliness. The SRC is directly linked to the goals and strategies of VCU’s Quest for Distinction, Theme II which aims to “Attain distinction as a fully integrated urban, public research university through contributions in human health, research, scholarship and creative expression that advance knowledge and enhance the quality of life.”

Formation of an effective SRC will place VCU in alignment with the NIH NCATS vision of the future that currently is being adopted by other leading research universities.

The SRC reserves the right to amend the current WPP’s and add new WPP’s as circumstances merit.

Purpose

The SRC is an integral part of the VCU system of research that involves living human beings that operates under the office of the Vice President for Research and Innovation.

The SRC functions in collaboration and in cooperation with all other entities of that office dedicated to human research. Its primary purpose is to assure the quality of research proposals being submitted to the IRB for full board review.

The structure and function of the SRC are addressed in other documents labelled as SRC-WPPS.

Definitions

VCU Quest for Distinction: a strategic plan that embodies Virginia Commonwealth University’s commitment to advancing knowledge and student success—a dual commitment that is distinctive among research universities on the road to becoming a premier urban, public research university.

References

Quest for distinction:  http://quest.vcu.edu/  (last accessed 05-11-2016)
Section I: Scientific Review Committee (SRC) Overview

Effective Date: 08-01-2016

Title: Membership

Revision History:

Policy and Procedures

The SRC members and leadership will be defined as:

A. **Quorum:** A quorum will usually consist of the actual or virtual participation of the SRC Chair or Associate Chair, one Core member, the Statistician (or designee) and the Executive Director (or designee).

B. **SRC Chair and Associate Chair:** the SRC Chair and Associate Chair are appointed by the Vice President for Research and Innovation and are re-appointed on an annual basis. They are charged with providing oversight of the SRC and be the liaison between the SRC and other stakeholders, i.e. IRB leadership and CCTR leadership, Chairs and Deans, etc. Responsibilities include, but are not limited to:

- determining if a protocol meets the requirements for a SRC review
- leading the SRC meeting discussions
- participate in assigning the primary and secondary reviewers for each protocol identified
- available to be a reviewer
- determine if reviewers from outside of the SRC are needed
- resolving conflicting viewpoints
- achieving consensus on SRC response
- approve the final communication with the PI
- evaluating the responses from the PI
- meet with the PI and provide consultative resources/services, or mentoring as needed

C. **Core Member:** charged with providing leadership within the SRC and will have the background and experience to be appointed as a future SRC Chair or Associate Chair. Responsibilities include, but are not limited to:

- ability to demonstrate scholarly accomplishments in the form of publications or grants
- ability to represent the VCU SRC internally and externally
- extensive mentoring experience

D. **Ad Hoc SCR Member:** chosen for their research and content expertise. They have the scientific expertise to provide thorough and rigorous SRC reviews as requested. They are chosen to ensure that the breadth of human subject research conducted at VCU is represented. Ad hoc members are selected with the expectation that they may evolve into the cadre of core members. Designated ad hoc members may be either be present face-to-face or virtually for the SRC meeting. Responsibilities include, but are not limited to:
• active actual or virtual participation during assigned meetings
• availability to provide SRC reviews as requested

E. **SRC Statistician:** charged with reviewing all protocols that meet the criteria for a SRC review providing the feedback needed to ensure that the protocol includes appropriate adequacy and alignment. Responsibilities include, but are not limited to:

• active actual or virtual participation during assigned meetings
• providing an analytical report on the following: the study design (including specific aims, approach and methods), sample size and measurement design to ensure power achieved for hypothesis testing while controlling for inferential error rates, the plans for ensuring data quality and the statistical analysis plan

F. **SRC Executive Director:** is charged with working with directly with the SRC Chair, IRB Staff, the PI’s and SRC members to facilitate communication, ensure document dissemination, scheduling and attending SRC meetings, documenting the SRC process and collecting and evaluating the required metrics. This position will also manage the development, launching and maintenance of SRC initiatives. Responsibilities include, but are not limited to:

• planning, scheduling, documenting and attending all SRC meetings
• ability to represent the VCU SRC internally and externally
• ensure that communications between the SRC, IRB and the PI are clear and provide in a timely manner
• recommend program revisions as needed while monitoring the program and assessments
• provide quarterly reports to the SRC, IRB and other stakeholders and requested
• collaborate regularly with other CTSA hubs
• ensure that practices and initiatives are consistent with University and CTSA policies and guidelines
• maintain and update the policies

**References**

Section I: Scientific Review Committee (SRC) Overview

Title: Review Criteria

Effective Date: 08-01-2016

Revision History:

Policy

The SRC will review protocols that are submitted to the VCU IRB that either meet SRC inclusion criteria or upon request by interested parties including, but not limited to: University leadership, IRB leadership, Department Chairs, funding entities, Principal Investigators, SRC members, etc. The protocols will be reviewed as outlined:

A. Exempt protocols: SRC review only by request

B. Expedited protocols: SRC review only by request

C. Full Board protocols: Will usually undergo automatic SRC review if the following criteria are met:

1. The protocol is not industry sponsored
2. The protocol did not have a comprehensive scientific review from the Massey Cancer Center
3. The protocol did not receive a scientific peer review from the funder (just the proposal was evaluated)
4. The FDA did not review and approve the protocol
5. The protocol is funded by: The VCU CCTR (K, T and endowment funds), internal department funds, or other internal funding
6. The protocol is not funded
7. By request

References

### Section 1: Scientific Review Committee (SRC) Overview

<table>
<thead>
<tr>
<th>WPP #:</th>
<th>I-4</th>
</tr>
</thead>
</table>

**Title:** Communications

**Effective Date:** 08-01-2016

**Revision History:**

---

**Policy**

The VCU SRC believes that prompt and effective communication between the PI and the SRC is a priority.

A. The PI and the IRB will be notified in a timely manner if an SRC review will be required for a protocol

B. If the protocol is not determined to require an SRC review, the usual IRB protocol review process will commence

C. If an SRC review is required, the PI and the IRB will be notified when the review will take place and which SRC members will be conducting the review. It is considered appropriate for the PI and the reviewer(s) to have direct contact during the review process as found necessary

D. The findings and recommendations of the assigned SRC reviewers will be presented at the assigned SRC meeting for discussion. The meeting quorum has final adjudication over the determinations

E. Protocols will be rated as “acceptable” or “unacceptable” by the SRC quorum

F. “Acceptable” protocols are defined as needing no protocol modifications or minor scripted modifications as per reviewers comments and SRC quorum vote

G. “Unacceptable” protocols are defined as needing protocol modifications or minor scripted modifications as per reviewer’s comments and SRC quorum vote. It is acceptable to meet with the PI to discuss the modifications
### Policy Statement

The SRC is committed to providing thorough and consistent reviews to the PI and study team. SRC reviews will evaluate the following protocol components: objectives, scientific merit/background rationale, design, population to be studied, eligibility criteria, outcome characteristics and endpoint definitions, statistical analysis and sample size, data and safety monitoring plan, data management, qualifications of the PI and the study site and an overall assessment based on quorum discussion.

The reviews of the protocol components will be summarized in a letter that will be sent to the PI and the IRB in a timely manner.

**EXAMPLE OF A REVIEW FORM (version 6, June 3, 2016)**

VCU Scientific Review Committee (SRC) Protocol Review and Monitoring Criteria Protocol Review Form

<table>
<thead>
<tr>
<th>Title of Protocol:</th>
<th>Reviewer(s):</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PI and Study Team Members:</strong></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Type of Support (check all that apply):</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CCTR/CTSA</strong></td>
<td><strong>INTERNAL VCU</strong></td>
</tr>
<tr>
<td>□ Pilot/CTTR Endowment</td>
<td>□ Departmental/ School Funds</td>
</tr>
<tr>
<td>□ K Award</td>
<td>□ Presidential Research Quest (PeRQ)</td>
</tr>
<tr>
<td>□ T Award</td>
<td>□ Other internal pilots</td>
</tr>
<tr>
<td>□ Other CCTR Funding</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The study (check all that apply):

<table>
<thead>
<tr>
<th>□ Funder completed a scientific, peer review of the protocol</th>
<th>□ Massey competed a scientific peer review of the protocol</th>
<th>□ Will be required to register with clinicaltrials.gov</th>
<th>□ This is a student or trainee project in which activities will be carried out by that individual under PI supervision</th>
<th>To which IRB is this being submitted?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>□ VCU IRB</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>□ NCI Central</td>
</tr>
</tbody>
</table>
peer review of the protocol □ Has a community partner

□ Exempt
□ Expedited
□ Clinical Investigation (Indicate phase) _____
□ Exception from Informed Consent for Planned Emergency Research
□ Emergency Use of Investigational Drug, Biologic or Device
□ Treatment Use (Expanded Access to Investigational Product for Treatment Use)
□ Center or Institute Administrative Grant Review

This box will be filled out by the SRC Executive Director or designee before assigned to reviewers

1. **OBJECTIVES**: Clearly stated specific aims and hypothesis.
   - □ Present/Acceptable
   - □ Present/Not Acceptable
   - □ Absent
   - □ Not Applicable
   Comments: __________________________________________________________________________________________
   __________________________________________________________________________________________

2. **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
   - □ Not Applicable
   Comments: __________________________________________________________________________________________
   __________________________________________________________________________________________

3. **DESIGN**: Clearly describes: how stated objectives will be achieved, identification of how the methods to acquire research data align with standard of care data collection, strategies identified to overcome anticipated barriers. Addresses randomization, minimization of bias, patient follow-up, and blinding (if applicable).
   - □ Present/Acceptable
   - □ Present/Not Acceptable
   - □ Absent
   - □ Not Applicable
   Comments: __________________________________________________________________________________________
   __________________________________________________________________________________________

4. **POPULATION STUDIED**: Scientific justification provided for including or not including vulnerable and limited or non-English speaking participants.
   - □ Present/Acceptable
   - □ Present/Not Acceptable
   - □ Absent
   - □ Not Applicable
   Comments: __________________________________________________________________________________________
   __________________________________________________________________________________________
5. **ELIGIBILITY CRITERIA:** Specific Inclusion/Exclusion requirements and stratification factors (if applicable).

- □ Present/Acceptable
- □ Present/Not Acceptable
- □ Absent
- □ Not Applicable

Comments: 
__________________________________________________________________________________________
__________________________________________________________________________________________
__________________________________________________________________________________________

6. **OUTCOME CHARACTERISTICS AND ENDPOINT DEFINITIONS:** Clearly defined primary and secondary endpoint/outcomes.

- □ Present/Acceptable
- □ Present/Not Acceptable
- □ Absent
- □ Not Applicable

Comments: 
__________________________________________________________________________________________
__________________________________________________________________________________________
__________________________________________________________________________________________

7. **STATISTICAL ANALYSIS AND SAMPLE SIZE:** (The SRC statistician will also be contributing to this topic) 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
- □ Not Applicable

Comments: 
__________________________________________________________________________________________
__________________________________________________________________________________________
__________________________________________________________________________________________

8. **DATA AND SAFETY MONITORING PLAN:** Appropriate DSMP and oversight (EX: DSMB, external auditing) in place as appropriate for the study related risks. Study related risks have been minimized.

- □ Present/Acceptable
- □ Present/Not Acceptable
- □ Absent
- □ Not Applicable

Comments: 
__________________________________________________________________________________________
__________________________________________________________________________________________
__________________________________________________________________________________________

9. **DATA MANAGEMENT:** Practices and procedures in order to manage data analysis, quality, cleaning and storage.

- □ Present/Acceptable
- □ Present/Not Acceptable
- □ Absent
- □ Not Applicable

Comments: 
__________________________________________________________________________________________
__________________________________________________________________________________________
__________________________________________________________________________________________

10. **PRINCIPAL INVESTIGATOR AND STUDY SITE QUALIFICATIONS AND RESOURCES:** Has the necessary skills, experience and reasonable study recruitment plan to ensure that the study may be successfully completed, including the identification of personnel to provide statistical computations and statistical expertise. PI time and resources will be determined/evaluated by the division or department chair.
Overall Assessment: The protocol was assigned to the (date and time) SCR meeting and the following consensus was reached:
- Forward to the IRB for consideration (fully accepted/no changes)
- Forward to the IRB for consideration (accepted with minor changes)
- Return to PI with comments (PI required response)
- Return to PI with recommendations (PI response/face-to-face meeting with core member, CCTR Research Innovator, or reviewer is required)

Summary: The communication to the IRB and the PI should include the following:

---

How long did it take for the primary reviewer to complete the review? __________
How long did it take for the secondary reviewer to complete the review? __________
How long did it take for the SRC to complete the review and arrive at a consensus? __________

This box will be filled out by the SRC Executive Director or designee AFTER the SRC meeting.

References: