The Office of Human Research Ethics

The University of North Carolina at Chapel Hill

Understanding the Scientific Review Committee (SRC)

Introduction

Before a study reaches the IRB, it often undergoes scientific review, because ethical review depends on sound science. If a study lacks scientific merit, it may expose participants to unnecessary risk without meaningful benefit. The Scientific Review Committee (SRC) helps ensure that studies are methodologically sound, feasible, and justified – laying the foundation for ethical approval.

Simply put, scientific review is a cornerstone of the 111 Criteria that "Risks to subjects are minimized by using procedures that are consistent with sound research design."

Learning Objectives

In this video, we'll take a closer look at the UNC Scientific Review Committee and how it works with the IRB to support our shared mission of protecting human research participants.

We'll cover…

- What the SRC is, why it exists, and the types of studies the SRC reviews.
- Then we'll discuss how the SRC reviews a study and who is making the review decisions.
- And finally, we'll walk through the SRC Review Process, including how they communicate their reviews to the IRB.

In 2016, UNC adopted an official policy regarding Scientific Review. According to the policy, "All biomedical research at UNC-Chapel Hill involving procedures that pose **greater than minimal risk** must undergo scientific review to ensure protocols are scientifically sound before IRB submission."

The UNC SRC focuses on scientific merit, while the UNC IRB safeguards participant rights and welfare, together supporting excellence and integrity in research, a partnership in which the SRC serves as a gatekeeper of sorts, establishing a firm foundation upon which the IRB can then justify its determinations regarding risk to participants

When biomedical protocols involve oncology patients, the Lineberger Oncology Protocol Review Committee conducts the scientific review. All other biomedical protocols are reviewed by the UNC Scientific Review Committee. In many respects, the two committees operate similarly. For today's training we will focus on the SRC.

What Types of Studies Does the SRC Review?

Not all studies require SRC review. Typically, it's reserved for investigator-initiated research, clinical trials, or studies with complex methodologies. Exempt studies and other minimal risk research proposals that do not come to the full board for approval are evaluated for scientific merit by the IRB staff, chairs, and vice chairs. In addition, the UNC SRC does not review most multi-site industry-sponsored trials, because the study protocol has already been rigorously developed by the Sponsor and other agencies before UNC joins as a study site.

Here is a representative list of the types of studies that the SRC reviews:

- Studies involving greater than minimal risk, where potential harm or discomfort exceeds that of daily life or routine medical exams.
    - For instance, a study requiring a CT scan would require SRC review, while a standard hearing test would likely not.
- Use of experimental drugs or devices
- Invasive procedures
    - Studies involving surgeries, biopsies, or other procedures that penetrate the body or involve significant intervention. For instance, collecting a liver biopsy for research purposes would require SRC review. Collecting blood from healthy adults by finger stick to evaluate blood glucose levels would not.
- Novel interventions
    - Testing new therapies, technologies, or methodologies not yet validated in the clinical setting when those tests pose greater than minimal risk to participants
- Studies involving vulnerable populations
    - Such as children, people who are pregnant, or individuals with diminished decision-making capacity

FDA IND/IDE reviews or NIH study section evaluations do not satisfy the UNC policy for SRC review under most circumstances.

What Does the SRC Evaluate?

We've talked about the types of studies the SRC will review. What are they looking for in those studies?

The SRC members will ask:

- Is the research question clear and important? (relevance)
- Is the study design appropriate to answer that question? (study design)
- Are the statistical methods valid? (statistical methods)
- Is the study feasible given the resources and timeline? (feasibility)
- Does the research contribute meaningfully to the field?

Typically, the SRC answers these questions before the IRB reviews the study. After the SRC completes its review, the protocol moves forward to the IRB for ethical and regulatory evaluation. This sequencing allows the IRB meetings to focus on consent, risk-benefit balance, participant protections, and regulatory compliance.

For IRB members, SRC review offers three key benefits:

- **Confidence**: You can have a good deal of confidence that the scientific method and protocol have been vetted.
- **Efficiency**: You spend less time untangling design flaws.
- **Focus**: You can concentrate on ethical issues, knowing the study design is appropriate to achieve the study aims.

The SRC's contribution to the review process does not replace the IRB's responsibility and final authority for study approval.

Who Serves on the SRC?

The UNC SRC is comprised of researchers from diverse disciplines, including dentistry, neurology, pulmonology, pediatrics, infectious diseases, women's health, genetics/omics, psychiatry, endocrinology, epidemiology and biostatistics. Members are selected for their expertise in designing and conducting studies within their respective fields. They bring deep domain knowledge to the table and have many years of experience overseeing, conducting, and evaluating biomedical research.

SRC Review Process/Lifecycle

The SRC review process begins when investigators submit a protocol, preferably using a UNC-approved protocol template. Investigators who are new to the process can get

assistance with protocol writing by using a free online tool called Protocol Builder or by consulting with the UNC TraCS Proposal Development Team.

The process requires a protocol that is separate from the investigator's grant application and/or IRBIS application. This is because a grant is a brief, largely persuasive document designed to convince a funder to support a new project. It is typically heavy on the "why" and less detailed on the "how" parts of the project.

A protocol is a complementary document that flips this dynamic on its head, delving much deeper into the 'how' elements. It is the document that most helps investigators carry out their science in a rigorous and reproducible fashion.

The UNC SRC meets every Monday morning to review protocols. Once a complete protocol is submitted, it generally is assigned to a Primary, Secondary, and Biostatistical Reviewer for the next meeting agenda.

These reviewers focus on the following:

- **Background and rationale** – literature review of this topic and explanation of how this study fills a gap in scientific knowledge
- **The study design** – is it adequate to achieve study aims?
- The protocol should have a **complete statistical analysis plan.**
- The protocol should contain **measurable study outcomes.**
- Details about patient **visit procedures and timelines**
- Participant **inclusion and exclusion criteria** should be clearly detailed.

Reviewers compile their comments into a single document and the SRC coordinator return it to the investigator, usually within a few days after the meeting.

The investigator will have three possible actions:

- Make minor edits then go on to the IRB, no further review is required
- Return the revised protocol to the 3 SRC reviewers for final sign off
- Return the revised protocol to the full SRC committee for re-review and consideration

What Happens if SRC Identifies Issues That Require Significant Revisions?

If the SRC identifies concerns—say, unclear endpoints or underpowered sample sizes—it provides feedback to the investigator. The investigator then revises the protocol before it reaches the IRB. This process improves the quality of submissions for IRB review.

How are the SRC reviews communicated to the IRB?

When the study is ready for IRB review, the investigator uploads with their IRBIS application the following information:

- The SRC Cover Letter indicating the SRC gate is "open," and the protocol can be submitted to the IRB.
- The reviewer comments and the investigator's responses to those comments.
- The revised protocol.

It is important to know that the SRC does not have the authority to "stop" a protocol from going forward to the IRB. Their role is evaluative and advisory. Typically, the SRC will review a protocol twice when necessary; after that, they send the investigator on to the IRB. **The IRB retains final responsibility and authority for approving a protocol.** For this reason, it is important for IRB members to review the SRC's comments and the investigator's responses, so they have a clear understanding of the issues that were raised, and whether they were adequately resolved.

Summary

The Scientific Review Committee is a vital partner for the IRB. By ensuring scientific integrity, it empowers the IRB to focus its attention more fully on ethics and participant protections. IRB members can lean into the SRC as a reliable resource for information; but, final approval for a study rests in the IRB's hands.

Thank you for your dedication—and as always, reach out to your board analyst or chair with any questions.