Scientific Review Committee (SRC) Charter
Purpose

The purpose of the Robert H. Lurie Comprehensive Cancer Center Scientific Review Committee is to evaluate all new and ongoing clinical trials for scientific merit, institutional priority and ongoing progress. All clinical trials approved by the SRC have access to CCSG-supported resources.

Membership

The Robert H. Lurie Comprehensive Cancer Center’s Deputy Director appoints committee members in consultation with the SRC chairs. Committee membership is as follows:

Leadership: The SRC includes 1 chair and 2 co-chairs.

Members: Membership consists of 16 voting members and 5 alternates. At a minimum, membership includes representatives from Northwestern Medicine’s medical oncology, radiation oncology, surgical oncology, and biostatistics, pharmacy, and social sciences groups. Ad hoc reviewers will be used in the event that expertise that is not represented on the committee is needed to adequately review a protocol. Ad hoc reviewers will vote only on protocols they review.

Non-voting members: Each meeting has an administrative coordinator. Other non-voting members representing clinical research interests may attend meetings but may not vote.

Appointment Term: Members are appointed for 2-year renewable terms. The Deputy Director and the committee chairs review membership annually.

Authority and Responsibility

Review for scientific merit: The SRC reviews new clinical trials to ensure that they are scientifically sound. Review focuses on the:

1. Background and rationale,
2. Objectives,
3. Adequacy of the study design to meet primary endpoints,
4. Statistical plan,
5. Feasibility/Ability to complete the trial as proposed, and
6. Adequacy of data and safety monitoring plan of the protocol.

The committee conducts a comprehensive scientific review of all clinical trials derived or supported from institutional sources, as well as those that have not received review by an external NCI-approved peer review committee as described online at http://cancercenters.cancer.gov/PoliciesResources/PoliciesResources. Externally reviewed studies are approved by the SRC chairs via expedited review.

Prioritization of trials: Priority is initially set by the Disease Team within the context of their trial portfolio, and is communicated to SRC upon protocol submission. The SRC has final authority to set priority. The SRC members who are reviewing the protocol will provide a score using the NIH CSR Merit descriptors [see below]. The scores will be taken in consideration to assist in any decisions that the Cancer Center may make on additional function through the Lurie Clinical/Translational Resource Allocation Committee (LCTRAC) mechanism.
1 - Exceptional exceptionally strong with essentially no weaknesses
2 - Outstanding extremely strong with negligible weaknesses
3 - Excellent Very strong with only some minor weaknesses
4 - Very Good Strong but with numerous minor weaknesses
5 - Good Strong but with at least one moderate weakness
6 - Satisfactory some strengths but also some moderate weaknesses
7 - Fair some strengths but with at least one major weakness
8 - Marginal A few strengths and a few major weaknesses
9 - Poor Very few strengths and numerous major weaknesses

Ongoing progress monitoring: The SRC reviews all clinical trials for progress. Accrual is monitored at least annually in accordance with the Research Oversight System’s Accrual Policy. The committee has sole authority to close studies not meeting minimum accrual requirements. Special consideration is given to studies involving rare diseases, as it is understood that minimum accrual requirements often do not apply to these studies. These rare disease trials are exempt from the SRC closure policy. Based on the National Institutes of Health (NIH) definition, a rare disease is generally considered to have a prevalence of fewer than 200,000 affected individuals in the United States or an incidence of fewer than 150 per million per year (i.e., 15 per 100,000 per year), roughly corresponding in the U.S. to 40,000 new cases per year or fewer.

All pediatric cancers are considered rare by this definition. Trials that recruit a molecular subset of common diseases may also be considered rare. The SRC will consider other data in support of a rare disease designation (e.g., information pertaining to a particular sub-type or category of disease) on a case by case basis.

Externally-peer reviewed studies, such as R01s or other federally funded trials are also given special consideration and may not be closed if external funding support is ongoing.

While studies that have a rare disease designation may be exempt from closure, the SRC will still evaluate these trials for progress. The SRC may request or require the accrual goals be changed or make other recommendations as are appropriate.

Review of protocol revisions: The SRC reviews all protocol revisions for studies that required full initial scientific review. Revisions or amendments that affect eligibility, sample size, treatment design, endpoints, statistical plans, or that impact patient safety must be formally reviewed by the SRC at a full committee meeting. All other revisions and amendments will be eligible for an administrative approval by the Chair, Co-Chairs, or their designees.

Exclusions: The SRC does not evaluate or prioritize studies dealing with healthy human subjects, population science studies, medical record reviews, or banking/registry protocols.

Procedures and Administration

Meetings: The panel meets twice monthly at regularly scheduled times. Additional meetings may be called with agreement of the chairs and the majority of committee members. Each meeting will be called to order by the chair or co-chairs. The meeting agenda will include new protocols (including each disease team’s research portfolio study prioritization list), protocol
revisions, and other relevant business. Studies are reviewed for ongoing progress monitoring at quarterly sub-committee meetings.

Committee support: The Robert H. Lurie Comprehensive Cancer Center employs a full-time staff member who provides administrative support to the SRC. The SRC Coordinator is responsible for distributing review materials, creating meeting agendas and minutes, writing and distributing protocol review letters, and communicating other committee decisions. The SRC coordinator processes approval of items that qualify for administrative approval.

Quorum: 50% of members must be present to hold a meeting. Attendance must include at least 2 physicians and 1 biostatistician.

SRC approval types:

Any cancer relevant trial must be submitted through the SRC Coordinator for processing.

There are 3 categories of SRC review, including full, administrative, and prioritization review.

1. Full review – required for all interventional and observational trials involving cancer patients that have not been previously reviewed and approved by an NCI approved peer-review agency. Examples include investigator-initiated trials, industry sponsored trials, or SPORE trials (or other trials generated from federal grants) that have not been reviewed through the NIH. Full review includes, at a minimum, 1 primary reviewer (an MD or PhD, depending on the aims of the trial), a biostatistician, and a pharmacy reviewer, when applicable. Investigator-Initiated trials also require a secondary reviewer (an MD or PhD, depending on the aims of the trial).

2. Administrative review – required for correlative/lab-based studies involving cancer patients and any observational studies. The SRC chair, co-chair, or an assigned designated reviewer conducts expedited reviews by performing a high level check of the study’s scientific merit as defined on the first page of this document. The reviewer may refer a protocol for full review if they feel it is appropriate.

3. Prioritization review – studies that have undergone external peer-review, such as NCTN studies. The SRC chair, co-chair, or an assigned designated reviewer conducts an administrative review that focuses on study prioritization.

All retrospective chart reviews and tissue/biospecimen repository protocols with no hypothesis are exempt from review. Their status will be confirmed by the SRC coordinator during entry into the clinical trial management system.

SRC votes: The SRC review process has the following possible outcomes:

Approved. Comments or suggestions may be made, incorporated into protocol, and followed-up on as is necessary, but no formal response is necessary.

Approved with contingencies. Response and/or Revisions required prior to approval, confirmation of response/revisions required.

• The review of responses and/or revisions may be conducted administratively, by the Chairs.
• The individual reviewer(s) that requested the response/revision must confirm the responses and/or revisions.

**Hold for re-review.** Substantial revisions to the protocol are required. The full committee must re-review this study at another SRC meeting.

**Reject.** There are fundamental flaws in the study, the study does not align with Robert H. Lurie Comprehensive Cancer Center priorities, or it is not feasible to conduct the study. The study may not move forward.

**Self-evaluation:** SRC monitors performance through assessment of SRC approval times. These are reported to the SRC bi-annually.