Scientific Review Committee (SRC) Frequently Asked Questions (FAQs)

What is the Scientific Review Committee (SRC)? When and why must a project be approved by the SRC?

As part of its designation as a National Cancer Institute (NCI) Comprehensive Cancer Center, the Lurie Cancer Center is required to maintain a comprehensive review and monitoring system. This system includes the Scientific Review Committee (SRC). All new cancer-relevant studies must receive SRC approval prior to IRB submission. The exception to this would be if a study has already undergone review by another NCI-approved peer-review body (see next question). Cancer-relevant research may include retrospective reviews, lab-based research, industry, and investigator-initiated trials (IITs). Cancer center sign-off in eIRB is dependent upon SRC approval.

The SRC will review projects to:

- Evaluate the scientific soundness
- Confirm the relevance to Cancer Center goals
- Ensure the appropriate usage of a Data and Safety Monitoring Plan (DSMP)

This review is different from the NU IRB review of projects in that the IRB reviews to ensure the protection and safety of human research subjects.

Could my study be exempt from SRC review?

The NCI provides a list of approved peer-review bodies. This list can be found at http://cancercenters.cancer.gov/documents/fundorg.pdf. If your study has undergone review and approval by one of these entities, it will likely be considered exempt from SRC review. Studies that are usually exempt from review include NCI cooperative group-sponsored studies and those funded by a federal grant.

Is my study considered cancer-relevant? Will SRC approval be required for my study?

Although it would be difficult to list every possible scenario in which a study would be considered cancer-relevant, in general, this means that it involves cancer patients, uses data, tissue, or blood specimens from cancer patients, or will lead to findings that may be significant to cancer patients. If an Investigator is unsure if a study is considered to be cancer-relevant, please contact the CRO Scientific Review Coordinator, Anne McDermott, to determine if the study must be submitted for SRC review and approval.

When is a Letter of Intent (LOI) required and what do I need to include in it?

All Northwestern University (NU) Investigators interested in initiating interventional studies at NU must first complete and submit an LOI. An LOI is not required for any non-interventional study. If a New Protocol Submission Form (NPSF) and/or a New Protocol Submission Packet (NPSP) have been submitted to the CRO for a NU interventional IIT before an LOI has been approved for the protocol, the SRC will contact the PI to request that they first complete an LOI for the study and hold the NPSP until the LOI is approved. These studies will not be reviewed or approved by the SRC until an LOI has first been approved by the SRC.
A LOI must be submitted on the [LOI template](#) and should include details about the following study criteria:

- Concept Title
- Primary and Secondary Objectives
- Study Phase
- Design and Rationale
- Study Population
- Correlative Studies
- Treatment Details
- Statistics
- Feasibility Assessment
- Financial Support
- IND Involvement
- Publication Plan

**How do I submit my study for SRC review and approval?**

The Principal Investigator (PI) must submit a new protocol submission packet (NPSP) to the CRO Scientific Review Coordinator, **Anne McDermott**, via e-mail. This packet must include:

- New Protocol Submission Form (NPSF)
- Copy of the protocol
- Copy of the Informed Consent Form (ICF) (if applicable) in editable word form
- Copy of the Grant (if applicable)

**What is the review process like?**

The committee reviews new protocols twice a month (1st and 3rd Wednesdays). The schedule is posted on the website. The SRC review letter is typically sent to the PI within one week of review. Each project will receive one of the following review outcomes after initial review:

- **Approve** - No revisions/minor revisions, proceed to IRB
- **Response and/or Revisions Required Prior to Approval**
  - To be confirmed administratively
  - To be confirmed by original reviewers
- **Held for Re-Review**
  - Substantial revisions required, will be sent to another meeting once addressed
- **Rejected**
  - Fundamental flaws with study design and/or methods – may not be resubmitted for review.

**How long will this take?**

The average project is SRC approved in 30 days or less. Submission of a complete protocol, and all required documents (NPSF, grant, protocol, ICF) will ensure the most efficient processing. Please promptly respond to questions and requests from the Scientific Review Coordinator or other reviewers—this will help everything move more quickly!
What specifically will the SRC want to see? What should I include in my protocol to help ensure that it will be approved?

The PI should refer to the templates for protocol development on the CRO website. These templates do not necessarily have to be followed precisely, but the finished protocol should include details for all applicable sections. Studies with missing and/or inadequate sections may not be considered complete for submission purposes and will be returned to the PI for further development prior to SRC review.

Additional resources are available for cancer-relevant research:

- The CRO employs a Medical Writer, Ashlee Drawz, who is able to assist at any stage during the protocol development process. Ashlee can also pre-review studies prior to SRC submission and provide feedback and writing/editing assistance. For all interventional studies initiated by NU or CMH investigators, it is strongly recommended to contact Ashlee during study planning and protocol development. She can be reached via email or phone (312-695-0902).
- All studies being submitted for SRC review should have clearly stated objectives and a corresponding statistical analysis plan for each objective. Statistical support for cancer-relevant studies is provided by the Lurie Cancer Center’s Biostatistical Core under the direction of Alfred Rademaker, PhD. Please contact Dr. Rademaker to request assistance and ensure appropriate statistical planning prior to SRC submission.

When is the next meeting? When am I required to submit a project in order to get it reviewed?

The full meeting schedule through calendar year 2012 with corresponding due dates is available here. In general, deadlines are approximately 2 weeks prior to the meeting date to allow time for assignment of reviewers and distribution of review packets.

Every effort will be made to review all submitted studies at the next available meeting; however, when availability on the agenda is limited, review of submitted studies will be scheduled according to the Lurie Cancer Center prioritization rating guidelines.