Guidance on SRC Review Requirements

To fulfill NCI requirements, all cancer-relevant projects must still be routed through the SRC, but certain research will be exempt from full board review and/or eligible for administrative review.

What’s Considered ‘Cancer-Relevant’ Research?

Cancer-relevant research can generally be defined as any research that could potentially benefit a cancer patient and may include retrospective reviews (e.g. ‘chart’ studies, lab-based research, industry, investigator-initiated trials (IITs), and NCTN trials.

All cancer-relevant research of any kind must be still submitted to the Scientific Review Coordinator in order to track project information in Northwestern Oncology Trial Information System (NOTIS) and report information about the research to the NCI.

Accrual data for cancer-relevant research of any kind must also be updated in NOTIS at least annually, from the time the study is formally open to accrual.

What Kind of Review is Required?

Submission-only
- Retrospective Chart Reviews
- Tissue or biorespository trials with no hypothesis
- Observational trials with no hypothesis

Expedited approval required (review by SRC Chair/Co-Chair or designee via e-mail)
- Lab based studies
- Any previously externally peer-reviewed studies, including all National Cancer Trial Network (NCTN) studies and any Investigator-Initiated Trials (IITs) that were previously approved by another institution with a NCI approved Protocol Review and Monitoring System (PRMS) will not need to be approved by our SRC. Documentation of institutional PRMS approval must be provided when the study is initially submitted.

Full Board Approval Required
• Required for all interventional cancer-relevant trials taking place at any Northwestern entity and Lurie Children’s Hospital
• SRC approval for all investigator-initiated trials are required prior to IRB submission.

**Does SRC Review Revisions?**

Revisions for all cancer-relevant interventional trials not previously reviewed (e.g. pharmaceutical trials and IITS) must also be reviewed by the SRC. Generally, revisions that affect eligibility, sample size, change in treatment design, endpoints, statistical plan, or impact patient safety must be reviewed at a full meeting. Any other revision will be eligible for an expedited approval by the SRC Chair, Co-Chairs or their designees.

**Does SRC Review Informed Consent Forms?**

No. The NPSF asks investigators to submit an informed consent form (ICF) so we have a copy on file, but this is not reviewed by the SRC. ICFs undergo formal review by the NU IRB.

**Do Letters of Intent Require SRC Review?**

The LOIs for trials that are developed with the plan of applying for a CTEP drug are required to be submitted for formal SRC review. If a CTEP drug will not be used, the SRC is available to review LOIs if the PI is interested in getting scientific input from the SRC. However, this will not be mandatory for most LOIs as the expectations are that all LOIs will undergo review and approval at the disease team level. An additional approval at the SRC level is not required, but may be requested.