Clinical Research Unit (CRU) Review Requirements

Does this study involve cancer patients and undergoes CRG and SCI review?

Yes → CRU review is not required

No →

Does the study require obtaining an Informed Consent (including informed consent with a waiver of documentation) from study participants?

Yes → Risk-Based CRU review required

No → CRU review is not required

Does the study have industry or government funding or is there an IND or IDE or is this a Registry?

No →

Yes →

CRU review will ensure the following:
- Scientific validity review completed
- Budget feasibility
- Operational feasibility
- Cohort availability
- Available vs. needed FTE%
- Competing studies

Note: Other required reviews and/or intake processes (e.g., MCHRI, CRSO, OPRCS, CTRU) are limited to certain feasibility aspects, such as operational feasibility within LPCH, SHC, or the CTRU, or for required vs. available CRC time. If the study will undergo any of these reviews, the CRU review should be limited to non-reviewed items.

A Full Review may be conducted by 1 or more Faculty Reviewers, the Operational Lead and other specialty roles as appropriate. The review may take place during periodic meetings, ad-hoc meetings, over email, or a combination.

Perform a full CRU review

Perform a limited CRU review

A Limited Review may be conducted by the Operational Lead alone or Operational Lead + 1 Faculty Reviewer. The review may take place over email exchange.

Note: For a scientific review of a complex and/or multi-disciplinary study, the CRU may escalate the review SoM to SADR.

Related Links:
Sample Reviewer Form
Criteria for Scientific Review