**Relying Investigator Checklist and Guidance**

As Principal Investigator (PI) at the University of Chicago **(Relying Institution)** for a study that may be overseen by an external IRB, you should be aware of your responsibilities. Once you have agreed to collaborate with an investigator at another institution and intend to use an external IRB for oversight of this study:

**Prior to Submitting Protocol In AURA**

You should contact the UChicago BSD IRB Reliance Team ([IRBReliance@bsd.uchicago.edu](mailto:IRBReliance@bsd.uchicago.edu)) to:

Discuss whether ceding IRB oversight to an external IRB is appropriate.

Provide UChicago BSD IRB Reliance Team with details about the study (including your study team’s role), the proposed reviewing IRB, and the lead investigator’s name and institution.

* + - Obtain a copy of the study-wide protocol and template consent documents(s), which will help facilitate the discussion with the UChicago BSD IRB Reliance Team.

**During Consideration of Protocol**

If UChicago BSD-IRB agrees to cede review to an external IRB, you will be asked to submit a CIRB protocol in the [AURA-IRB](https://aura.uchicago.edu/) electronic system and upload documents received, including lead site IRB approval, protocol narrative, site-specific consent form if applicable, and any other relevant materials. During this time you will also be asked to provide in AURA-IRB the following:

* The names and roles of all key study personnel on the local study team
* Any management plans for potential conflicts of interest (COI) relevant to the study that will be ceded to the external IRB, including any new or altered management plans put in place throughout the lifespan of the study. If a copy of a finalized management plan is needed, you may reach out to the IRB Director.
* Work with the Lead Study Team and the UChicago BSD IRB Reliance team to incorporate locally required language into the consent template to be used by the local study team, such as institutionally required compensation for injury language, local study team contact information, and additional costs that subjects may incur that differ from those identified in the template consent form.

Please note that the study may not proceed at the University of Chicago until it reaches the ‘CIRB Approval Acknowledged’ state.

**Throughout the Course of Study**

Be aware of the study communication plan (typically outlined in grant or protocol narrative). Promptly respond to questions or requests for information from the Lead Study Team (or their designee) as well as from the Reviewing IRB.

Participate, as required, in conference calls regarding a study as requested by the Lead Study Team, Reviewing IRB, or the UChicago BSD IRB Reliance Team.

Become familiar with the reportable event policy of the Reviewing IRB to ensure that you appropriately report protocol deviations, noncompliance, significant subject complaints, subject injuries, unanticipated problems, or other events required by the Reviewing IRB to be reported and within the timeframes required.

Ensure that all local reviews and sign offs that, in addition to IRB approval, are in place before a study is activated, such as coverage analysis, department approvals, data use agreements, material transfer agreements, ancillary committee reviews (e.g., [CTRC,](https://www.uchicagomedicine.org/cancer/research/clinical-research-support/protocol-review-and-monitoring) [IBC](https://researchsafety.uchicago.edu/about/committees/ibc-saibc/), [RADRAC](https://biologicalsciences.uchicago.edu/radrac-home), [NERC](https://www.uchicagomedicine.org/health-care-professionals/nursing/nursing-research)).

Notify UChicago BSD IRB of any staff changes via personnel change amendment so they can confirm their training is current and help ensure any relevant COI management plans are communicated to the Reviewing IRB.

Notify the lead PI of:

* + - Any reportable events that occur locally, according to regulations and the Reviewing IRB’s policy.
    - Any changes (including those related to funding and personnel) in accordance with the Reviewing IRB’s policies and procedures for timing and content of such submissions.
    - Any management plans, including any updates to these plans, as relevant to the study.
    - Any applicable information for continuing review progress reports in accordance with the Reviewing IRB’s policies and procedures for timing and content of such submissions.

Follow all determinations of the Reviewing IRB.

Only implement changes of protocol, including local variations, after the Reviewing IRB has approved them, except in cases where a change is required to avoid an apparent immediate hazard to participants. Utilize the ’Updating CIRB Study’ function in AURA-IRB and ensure that all members of the UChicago study team have access to relevant study documents.

Provide access to study records for audit by UChicago Office of Clinical Research and BSD IRB, the Reviewing IRB’s institution, and other regulatory or monitoring entities upon request.