**Overall Principal Investigator/Lead Study Team Guidance and Checklist**

As the Overall Principal Investigator for a study for which research activities involving human subjects will be overseen by a single IRB for all or most sites, you should be aware of your additional responsibilities in assuming that role. Once you have agreed to collaborate with investigators at another institution(s) and intend to use a single IRB for oversight of this study:
**Prior to New Protocol or Amendment Submission:**

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

* + Discuss whether UChicago BSD IRB can act as the single IRB for all or some institutions participating in this study or whether another external IRB would be appropriate. If the protocol lacks federal funding or a requirement by sponsor/funder to utilize a single-IRB, provide clarification as to why reliance is being sought.
	+ Identify who will act in the role of the Lead Study Team (e.g., your own study team, a coordinating center, or both). The Lead Study Team assumes additional responsibilities when single IRB review will be used.
	+ Provide details about the study, including the study-wide protocol and template consent document(s), which will help facilitate the discussion with the UChicago BSD IRB Reliance Team.
	+ Identify all sites that will be engaged in human subjects’ research and thus need IRB coverage.

**During Consideration of the IRB Reliance Request:**

[ ]  Submit a reliance request to the UChicago BSD IRB via electronic [AURA-IRB](https://aura.uchicago.edu/) submission. Include all relevant documentation associated with this request, including but not limited to:

* [Local Site Context Form](https://dtdxsaqq5q4.cloudfront.net/sites/biologicalsciences/files/2022-12/Local%20Site%20Context%20Form%20vNov22.docx)
* [Relying Site Personnel List](https://dtdxsaqq5q4.cloudfront.net/sites/biologicalsciences/files/2023-06/Relying%20Site%20Master%20Personnel%20List%20-%205.26.23.xlsx)
* Documentation of Human Subjects Protections Training (e.g. [CITI](https://about.citiprogram.org/series/human-subjects-research-hsr/), [OHRP training](https://www.hhs.gov/ohrp/education-and-outreach/human-research-protection-training/human-research-protection-foundational-training/index.html))
* Reliance Agreement
	+ [IRB Authorization Agreement](https://dtdxsaqq5q4.cloudfront.net/sites/biologicalsciences/files/2022-10/IRB%20Authorization%20Agreement%20ver%20Oct%202022.docx)
	+ [SMART-IRB Agreement](SMART%20IRB%20Cede%20and%20Letter%20of%20Acknowledgement%20Template)
	+ Master Reciprocal Agreement
	+ [Individual Investigator Agreement](https://dtdxsaqq5q4.cloudfront.net/sites/biologicalsciences/files/2022-10/Individual%20Investigator%20Agreement%20ver%20Oct%202022.docx)
* [Site-Specific Consent Form](https://biologicalsciences.uchicago.edu/sites/biologicalsciences/files/2019-06/Site%20Specific%20UofC%20CF%20template.doc) (If applicable)

[ ]  Develop a Communication Plan with collaborators across the lifetime of the study (i.e. regular conference calls, site initiation procedures, and training materials, communicating study changes).

[ ]  Promptly respond to questions or requests for information from study teams and IRB/Human Research Protection Program personnel at institutions who are relying on the single IRB.

**If the UChicago BSD IRB agrees to serve as Single-IRB for the study, you will be responsible for the following throughout the lifespan of the study:**

[ ]  Participate in conference calls regarding this study as requested. Follow the study Communication Plan.

[ ]  Promptly respond to questions or requests for information from study teams and IRB/Human Research Protection Program personnel at institutions who are relying on the single IRB.

[ ]  Provide the Site Investigators with the IRB policies of the Reviewing IRB. This includes, but is not limited to, policies for reporting unanticipated problems, noncompliance, and subject complaints.

[ ]  Provide participating Relying Site Study Teams with the IRB-approved versions of all study documents (e.g., consent and authorization forms, protocol, recruitment materials).

[ ]  Prepare and submit IRB applications on behalf of all sites, including initial reviews, local amendments, personnel updates, local reportable events, and study-wide information for continuing review.

[ ]  As part of preparing the IRB application, the Lead Study Team (or designee) must:

* + - Have a mechanism in place to obtain and organize information from Relying Sites regarding local variations in study conduct, such as recruitment materials and processes, consent process and language, and subject identification processes.
		- Assist Relying Sites in ensuring consent documents follow the Reviewing IRB’s template form and include applicable site-specific required language from each Relying Institution.
		- Maintain site-specific consent forms for all relying sites, as applicable. This will include ensuring each site-specific consent form is updated at the time of an amendment or continuing review (as necessary).

[ ]  Notify Relying Site Investigators of all UChicago BSD IRB determinations (i.e. approvals) and communications, including those for initial review, continuing review, amendments, and reportable events.

[ ]  Promptly report to the Relying Site Investigator/Team any unanticipated problems involving risks to subjects or others research-related subject injuries, or significant subject complaints that are related to or may affect subjects participating in the research (i.e., the specific study or studies ceded to the Reviewing IRB) at the Relying Institution.

[ ]  Collect information from relying sites at the time of continuing review via [Relying Site Continuing Review Form](https://dtdxsaqq5q4.cloudfront.net/sites/biologicalsciences/files/2020-07/Relying%20site%20continuing%20review%20form.pdf) in advance of BSD IRB continuing review deadline. Please note that for any site(s) for whom this form is not complete prior to continuing review approval by BSD IRB, relying site participation in this research will end.

[ ]  Provide access to study records for audit by the Relying Institution, the UChicago BSD IRB, and other regulatory or monitoring entities upon request.

[ ]  Follow all requirements of the Relying Institution regarding ceded review, such as ensuring administrative requirements for documenting ceded review have been met before study activation occurs at a Relying Institution.