## GENERAL INFORMATION

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<td>RR Number:</td>
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<td>UU IRB Number (if available):</td>
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<td>Date of Consultation:</td>
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<td>Name of Person Completing the Checklist:</td>
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<td>Names of Consultation Attendees:</td>
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## RELIANCE CONDITIONS

**Determine if the study under consultation requires SIRB review.**
- Must meet the definition of human subject research at all sites requesting SIRB review
- Must be non-exempt research
- NIH-funded or subject to the Common Rule

*If the study is non-exempt, but does not require SIRB review by federal rule or regulation, what is the impetus for seeking IRB reliance?*

**Comments:**

**Determine who will be performing SIRB responsibilities.**

*This may include one of the following situations:*
- The UUIRB is the SIRB
- An external IRB is the SIRB
- A multi-lateral agreement is sought, allowing any IRB who has signed the agreement to act as the SIRB in any given situation.

**Comments:**

**Determine how many studies or possible studies the reliance relationship will apply to.**

**Comments:**

**Determine how many UU investigators the reliance relationship will apply to.**

**Comments:**

**Determine how many external investigators and research sites the reliance relationship will apply to.**

*A single investigator may be responsible for activities at multiple sites (e.g., one investigator for a study conducted at UU and VA, or UU and PCH). Reliance may need to be established between multiple institutions for one investigator if the institutions are separate legal entities and/or have separate FWAs.*

**Comments:**
**Determine preliminarily if there are any specific institutional, community, or HRP concerns with the proposed reliance relationship.**

This may include one of the following:

- Conflict of interest
- HIPAA privacy requirements
- Confirmation of investigator training and qualifications
- Ancillary committee reviews
- Concern regarding specific, sensitive or vulnerable populations to be included
- Specific state laws and institutional policies affecting the research

**Determine if there are any existing master agreements that would cover this reliance relationship.**

SMART IRB, IRB Choice, commercial IRBs, NeuroNEXT, NCI CIRB, etc.

**Determine if there are any timing issues with using the SIRB model as proposed, e.g., pending grant funding, FDA determinations pending, finalizing the protocol, etc.**

**Determine the ERICA site model that is best suited for the reliance relationship (if UU is the SIRB).**

- Standard model = all site information is maintained as part of the main application
- Site-Control model = sites have own access and own workspaces separate from the main application

**Determine if any external individuals will require ERICA access.**

ERICA access should be given with discretion. If an external study team needs access, the site PI and a lead study coordinator can be given access; all others should function outside of ERICA.

Studies using the site-control model will need access for at least one individual at each site.

**Determine if study personnel have completed the SIRB Education Modules.**

This is required for study personnel at the University of Utah and its Affiliate Institutions. This is optional for all other study personnel.