INSTITUTIONAL REVIEW BOARD
THE UNIVERSITY OF UTAH

Reliance Consultation Checklist

Version: 26 April 2018

GENERAL INFORMATION

RR Number:	
UU IRB Number (if available):	
Date of Consultation:	
Name of Person Completing the Checklist:	
Names of Consultation Attendees:	

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 as 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:

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Determine preliminarily if there are any specific institutional, community, or HRP concerns with the proposed reliance relationship. *This many 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*	Comments:
Determine if there are any existing master agreements that would cover this reliance relationship. *SMART IRB, IRB Choice, commercial IRBs, NeuroNEXT, NCI CIRB, etc.*	Comments:
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.	Comments:
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*	Comments:
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.*	Comments:
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.*	Comments: