



WORKSHEET: RELIANCE AGREEMENT EXTERNAL IRB

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The purpose of this worksheet is to provide support for IRB staff conducting Pre-review. The worksheet is to be used. It does not need to be completed or retained.

IRB Number:	
Protocol Name:	
Investigator:	
Reviewing IRB:	

Eligibility for Relying on an External IRB using its own Template IAA (if applicable)

- The research is minimal risk. The IRB staff member may agree to an external review subject to a signed IRB Reliance Agreement.
- The research is greater than minimal risk and the reviewing institution is accredited by AAHRPP. The IRB staff member may agree to an external review subject to a signed IRB Reliance Agreement.
- The research is greater than minimal risk and the reviewing institution is not accredited by AAHRPP and the IRB Director or Associate Director has agreed to the external review subject to a signed IRB Reliance Agreement.

The Reliance Agreement includes the following (All must be checked)

- Statement naming and containing contact information for the reviewing and relying institutions and indicating that the University of Miami will rely on the external IRB for review and oversight of the proposed human subject research. Contact information may be provided in a separate document.
- Statement that reviewing IRB will follow written procedures.
- If federally funded or supported, FWA numbers for reviewing and relying IRBs are included on the agreement. (N/A if individual investigator agreement)
- The review conducted by the external IRB will comply with the requirements of University of Miami's FWA.
- The reviewing IRB will follow written procedures for making notifications to the investigator, appropriate individuals at the relying institution, and regulatory authorities.
- The reviewing IRB will notify appropriate individuals at the University of Miami of an intention to report (1) an unanticipated problem involving risks to subjects or others; (2) serious or continuous non-compliance, and (3) suspensions and/or terminations of approval of research activities. The notification will include a copy of the report and the University of Miami will be afforded adequate time and opportunity to suggest edits to the report.
- The agreement describes which institution/IRB will be responsible for compliance with the Federal Privacy Rule (HIPAA)
- The agreement does not have an expiration date.
- The agreement allows the University of Miami to review minutes of full committee decisions involving this research.
- The University of Miami remains responsible for compliance with the reviewing IRB's determinations and the terms of the University of Miami's OHRP-approved FWA.

Reliance Agreement Does not Include the following (All items must be checked)

- Requirement for insurance coverage unless the requirement is mutual.
- Indemnification unless the indemnification is mutual.

Agreement specified requirements of the University of Miami – The research cannot start until:

- Yes No The University of Miami documents that investigator meets the University of Miami's requirements for Principal Investigator (HRP-103 p.4)
- Yes No The PI or the University of Miami must notify the reviewing IRB if an investigator has a related financial interest in the research and provide the management plan.



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Comments: