

**WORKSHEET: AUTHORIZATION AGREEMENTS**

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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:	

Complete this section if UM site is relying on an External IRB - One must be checked

- ☐ The research is minimal risk. The IRB staff member may agree to an external review subject to a signed IRB Authorization 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 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 Authorization Agreement.

The following criteria must be met for all Authorization Agreements (All must be checked)

- ☐ Statement indicating which institution is conducting the review and which institution is relying on the review.
- ☐ Contact information for the reviewing and relying institutions is included or provided as a separate document.
- ☐ Identification of the research covered by the agreement.
- ☐ 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)
- ☐ Statement indicating the review conducted by the reviewing IRB will comply with the terms of the relying IRB's FWA.
- ☐ Statement indicating 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 relying IRB 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 relying IRB will be afforded adequate time and opportunity to suggest edits to the report.
- ☐ Requirement for relying institution will provide to the reviewing institution information related to local context
- ☐ Requirement for relying institution to provide information to the reviewing institution about financial conflicts of interest
- ☐ Requirement for relying institution to provide information to the reviewing institution relating to investigator qualifications and institutional training requirements.
- ☐ The agreement describes the responsibilities of each institution/IRB for compliance with the Federal Privacy Rule (HIPAA)
- ☐ The agreement requires the relying institution to report related financial interests to the reviewing IRB/institution.
- ☐ The agreement allows the relying IRB to review minutes of full committee decisions involving this research.
- ☐ A statement indicating that the relying IRB will be responsible for compliance with the reviewing IRB's determinations.
- ☐ The agreement does not have an expiration date.

Authorization 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.

Comments:



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