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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:** |  | |
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| **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. | |
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| **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. | |
| Review of the research will be conducted in accordance with relevant regulations, including but not limited to 45 CFR 46 and FDA 21 CFR 56. | |
| 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 (COI) including management plans specific to the research. | |
| Requirement for post approval monitoring or for cause audits process upon request by the reviewing IRB. | |
| Requirement for relying institution to provide information to the reviewing institution relating to investigator qualifications and institutional training requirements. | |
| Requirement for relying institution to report non-compliance, participant complaints, protocol deviations or other events. | |
| The agreement describes the responsivities 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 relevant IRB records, including but not limited to IRB Meeting minutes of full committee decisions, approved protocols, consent documents and other records that document the reviewing IRB’s determinations involving this research. | |
| A statement indicating that the relying IRB will be responsible for compliance with the reviewing IRB’s determinations and with the terms of its OHRP-approved Assurance.. | |
| If the research involves pregnant women, fetuses, and neonates; or prisoners, information indication which organization is responsible for obtaining any additional approvals from the Department of Health and Human Services (DHHS).  If the research is funded by the National Institute of Health (NIH) and involves Genomic Data, information indication which institution is responsible for meeting the additional requirements of the NIH Genomic Data Sharing Policy. | |
| If the research requires additional regulatory requirements, for example, those of Department of Defense (DoD) or Department of Justice (DoJ), information for which organization is responsible for ensuring those requirements are met during review of the research. | |
| The agreement does not have an expiration date. | |
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| **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. | |
| UC | |
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| Comments: | |
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