|  |
| --- |
| 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 UC Davis 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 UC Davis’ 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 UC Davis of an intention to report (1) an unanticipated problem involving risks to subjects or others; serious or continuous non-compliance, and suspensions and/or terminations of approval of research activities. The notification will include a copy of the report and UC Davis will be afforded adequate time and opportunity to suggest edits to the report.  |
| [ ]  The agreement will remain effective as long as the proposed research will be subject to IRB oversight.  |
| [ ]  The agreement allows UC Davis to review minutes of full committee decisions involving this research.  |
| [ ]  UC Davis remains responsible for compliance with the reviewing IRB’s determinations and the terms of UC Davis’s OHRP-approved FWA.  |
|  |
| **Reliance Agreement Does not Include the following (All items must be checked)** |
| [ ]  Requirement for insurance coverage. |
| [ ]  Indemnification unless the indemnification is mutual.  |
| UC |
| **Agreement specified requirements of UC Davis** |
| **Yes** [ ]  No [ ]  UC Davis must ensure that investigator meets UC Davis requirements for Principal Investigator (HRP-103 p.4) |
| **Yes** [ ]  No [ ]  UC Davis must notify the reviewing IRB of any findings related to the investigator. Enter specific findings here, if any:       |
| **Yes** [ ]  No [ ]  The PI/UC Davis must notify the reviewing IRB of related financial interests of the UC Davis investigator and/or UC Davis research staff in the research and provide the management plan.  |
| **Yes** [ ]  No [ ]  Other:       |
| **Yes** [ ]  No [ ]  Other:       |
|  |
| Comments:       |
|  |