

WORKSHEET: Authorization Agreement Review

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The purpose of this worksheet is to provide the review criteria for Rutgers IRB Reliance Administrator when assessing a request to engage in a reliance agreement with an external institution/organization.

IRB Number _____ [Rutgers eIRB+ Protocol Number]

1. Considerations for Reliance (Check if "Yes")

- ☐ The Rutgers Principal Investigator (PI) meets the requirements as set forth in 1.002 (HRP-103) MANUAL Investigator Manual. **(The proposed Rutgers PI must meet the requirements. If PI criteria is not met, do not proceed with reliance review.)**
- ☐ Rutgers is a sub-contracted site and IRB approval for the overall study has been provided by the external institution/organization.
- ☐ The request is mandated by the funding agency per Single IRB or Cooperative Research requirements.
- ☐ The request is mandated by the study sponsor or funding agency in order for the Rutgers site to participate in the research.
- ☐ The Rutgers University site is collaborating with the main research site for the study and receiving of identifiable information. (Note a Data Use or Material Transfer Agreement may also be required.)
- ☐ Engagement for both sites (Rutgers University and the external institution/organization) has been confirmed. (Review 3.208 (HRP-311) - WORKSHEET - Engagement Determination)
- ☐ Special permission of the Institutional Official.
- ☐ The Rutgers authorization agreement template has been provided for signature. **(Authorization agreement templates other than the Rutgers template, may require additional review by the Rutgers Institutional Official or designee and consultants from other offices. Agreement terms should be reviewed to determine if this is required).**

2. External Institution/Organization (Check if "Yes")

- ☐ The external institution/organization has a current IRB/IORG registration and/or Federal wide Assurance (FWA) (when applicable) with the Office for Human Research Protections (OHRP) and/or the Food and Drug Administration (FDA). **(If the external institution/organization has an FWA and is relying on the Rutgers University IRB to serve as the IRB of Record, it should be confirmed if the external institution/organization applies the FWA covers the research)**
- ☐ The external institution/organization has AAHRPP accreditation.
- ☐ Describe how the IRB or EC communicates its decisions to relying organizations. The IRB or EC may communicate directly with each relying organization and its researchers, communicate via a lead or overall study PI or via a Coordinating Center.
- ☐ The process for a relying organization to communicate directly with the IRB or EC (IRB or EC Chair) when necessary to discuss questions, concerns or obtain interpretation of determinations
- ☐ The external institution/organization has confirmed willingness to either serve as the IRB of Record or cede review to the Rutgers IRB.
- ☐ The external institution/organization has provided contact information for the Organization Official or designee and IRB contacts.
- ☐ The external institution/organization is located domestically.
- ☐ The external institution/organization is located internationally.
- ☐ The external institution/organization has a mechanism for COI review and will provide any applicable management plans relevant to the research to the Reviewing IRB.
- ☐ The external institution/organization has appropriate structure and composition to conduct review of the research and complies with applicable laws. This includes ensuring the IRB is properly constituted; members are appropriately qualified- Information about the qualifications and expertise of researchers and research staff, including research workload, which may be provided in any number of ways. It need not necessarily include specific information about each member of the research team; that members do not participate in the review of the studies in which they have a conflict of interest.

3. Authorization Agreement (Check if "Yes")

The authorization agreement includes information to address the following:

- ☐ Review of research will be conducted in accordance with relevant regulations, including but not limited to 45 CFR 46 and FDA 21CFR 56.
- ☐ Relevant IRB records, including but not limited to, IRB Meeting Minutes, approved protocols, consent documents and other records that document the Reviewing IRB's determinations, will be made available to the Relying Institution upon request.
- ☐ Information indicating that research activities at Relying Institution will be conducted in compliance with the Reviewing IRB's determinations and with the terms of its OHRP-approved Assurance.

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- ☐ COI policies and procedures, including management plans specific to the research.
- ☐ Reporting of non-compliance, participant complaints, protocol deviations or other events.
- ☐ Researchers' and research staff qualifications and expertise to conduct the research.
- ☐ Post approval monitoring or for cause audits process upon request by the Reviewing IRB.
- ☐ Terms for terminating the reliance agreement and timeline for transferring IRB oversight of active protocols.
- ☐ If the research involves pregnant women, fetuses, and neonates; or children; or prisoners, information indicating 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 Institutes of Health (NIH) and involves Genomic Data, information indicating 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.

4. Local Site Requirements:

How general information about other organizations or research sites is collected and made accessible to the review IRB or EC. Information should include:

- ☐ Whether ancillary reviews must be completed prior to IRB or EC review in order for the IRB or EC to determine the criteria for approval are met
- ☐ Whether the relying organization requires any site-specific language in approved consent documents such as local contracts for research participants' questions or compensation for injuries
- ☐ If the study site is located in another state or country, information about whether there are any laws, regulations or policies relevant to the site. (e.g. age of majority; circumstances that affect the age of consent; who can be a legally authorized representative)
- ☐ Describe which organization is responsible for maintaining and updating the general information.

5. Study specific Information

Describe how study-specific information is collected. It is not necessary for each researcher on a study to provide duplicate copies of study-wide information, such as the study protocol or investigator brochure. Instead, researchers at each local site may complete a short, abbreviated, application limited to the site-specific information. Examples of information the organization may consider collecting include:

- ☐ Information about what laws and regulations related to human participant protections are directly relevant to the study (for example, DHHS, DoD, FDA) and whether the sponsor is requiring compliance with ICH-GCP (E6) for the study.
- ☐ Information about resources at the local research site, including space, equipment, and personnel, which may be provided in any number of ways. For example, if the research organization has an existing process for verifying resources, the reviewing IRB can accept that, and does not need to conduct additional review
- ☐ Information about the process of recruitment and consent at the local site, including any local recruitment materials; who will obtain consent at the local site; the location of the consent discussion; the language spoken by participants; and the language spoken by the person obtaining consent.
- ☐ When relevant to the specific study, information about the local population. Information about the local population may include information about race/ethnicity, languages, religious affiliations; and whether the research involves discrete and insular communities and sensitive areas of inquiry.
- ☐ Plans to protect the confidentiality of information, such as the method for secure storage of records.
- ☐ If not managed centrally by a pharmacy at the organization, study-specific information about plans for storage, handling and dispensing of drugs and medical devices. If managed centrally by the organization, no additional information is needed for each study.

6. Adding External Sites:

- ☐ Describe the process for adding study sites. IRBs or ECs may consider reviewing requests to add study sites using the expedited procedure as a minor change to the study if the site will be following the same protocol that has already been reviewed and approved

7. Submission of Amendments:

- ☐ Describe the process for review of amendments, unanticipated problems involving risks to subjects or other, or noncompliance and for conducting continuing review. Policies and procedures should identify who is responsible for submitting information related to each of these reviews and whether the relying organizations may submit changes directly to the IRB or EC or through a PI or coordinating center.