|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **The purpose of this form is to record information about the Authorization Agreement established with another institution/organization. If there is more than one Authorization Agreement with another institution/organization, indicate so in the fields below, and describe nuances for those agreement in the spaces provided[[1]](#footnote-1).** | | | | | | | | | | | | |
| **Institution:** | |  | | | | | | | | | | |
| **Institutional Official:** | |  | | | | | | | | | | |
| **FWA number:** | |  | | | | | | | | | | |
| **FWA expiration date:** | |  | | | | | | | | | | |
| **FWA information:** | | (attach any relevant documentation, if applicable) | | | | | | | | | | |
| **IRB Registration information:** | | (attach any relevant documentation, if applicable) | | | | | | | | | | |
| **IORG number:** | |  | | | | | | | | | | |
| **IRB roster:** | | Attach separately | | | | | | | | | | |
| **Tribes, states or non-US locations in which this institution conducts FWA-approved research:** | |  | | | **Age of Majority:** | | |  | | | | |
|  | | | **Age of Majority:** | | |  | | | | |
|  | | | **Age of Majority:** | | |  | | | | |
| **Relevant tribal, state, or non-US laws, regulations, or policies:** | | Attach separately any relevant descriptions of tribal, state, or non-US laws, regulations, or policies that are not identified below, such as circumstances that would affect age of consent and who can serve as a Legally Authorized Representative. | | | | | | | | | | |
| **Quality Control**  **Describe the IRB quality control mechanisms in place to ensure the integrity of the IRB-review process at this site.** | | | | | | | | | | | | |
| **Quality control mechanism:** | | **AAHRPP Accredited** | | | | **Established QA/QI Program** | | | | | | |
| **OHRP IRB Self-Assessment** | | | | **Other** | | | | | | |
| **If other, describe:** | | | | | | | | | | |
| **Status:** | |  | | | **Date of most recent review:** | | | | |  | | |
| **Agreements and Communication** | | | | | | | | | | | | |
| **Authorization Agreement 1** (Attach agreement separately)**:** | | **Effective Date:** | | |  | | **Expiration Date:** | | | | |  |
| **Notes:** | | |  | | | | | | | |
| **Authorization Agreement 2** (Attach agreement separately)**:** | | **Effective Date:** | | |  | | **Expiration Date:** | | | | |  |
| **Notes:** | | |  | | | | | | | |
| **Communication plan:**  If not described in the Authorization Agreement, indicate the plan for communicating with this site. | |  | | | | | | | | | | |
| **Consent form instructions:**  Provide site-specific information that must be included in consent forms used at this site. | |  | | | | | | | | | | |
| **Recruitment material instructions:**  Provide site-specific content or procedural information regarding the recruitment process. | |  | | | | | | | | | | |
| **Route RNIs to this institution for review when they are the sIRB?:** | | **Yes** - RNIs will be routed directly to the sIRB for multi-site studies  **No** -RNIs will be routed locally before being sent to the sIRB for review | | | | | | | | | | |
| **Staff members who will serve as points of contact for this institution:** | | | | | | | | | | | | |
| **Name:** |  | | **Name:** |  | | | | **Name:** |  | | | |
| **Role:** |  | | **Role:** |  | | | | **Role:** |  | | | |
| **Phone:** |  | | **Phone:** |  | | | | **Phone:** |  | | | |
| **Email:** |  | | **Email:** |  | | | | **Email:** |  | | | |
| **Eligibility and Reliance** | | | | | | | | | | | | |
| **This institution is eligible to be a participating site on a multi-site study.** | | | | | | | | **Yes** | | | **No** | |
| **This institution is eligible to be a single IRB of record on a multi-site study.** | | | | | | | | **Yes** | | | **No** | |
| **This Institutional Profile is currently active.** | | | | | | | | **Yes** | | | **No** | |

1. This document satisfies AAHRPP elements I-9, II.5.B [↑](#footnote-ref-1)