|  |
| --- |
| **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)