**Template Letter of Acknowledgement (Flexible Implementation)**

IRB Review will be ceded under the [**SMART IRB Agreement**](https://smartirb.org/agreement/) **Version 3.0**. Questions regarding this reliance arrangement should be directed to SMART IRB institutional [Points of Contact](https://smartirb.org/participating-institutions/).

|  |  |
| --- | --- |
| Reviewing IRB Institution |  |
| Relying Institution |  |
| Research Study Title(s): |  |
| Reviewing Institution PI |  |
| Relying Institution Site Investigator |  |
| **This Letter of Acknowledgment was completed by the following institutional representatives (Name, Role, Date):** |
| Reviewing Institution POC/Designee |  |
| Relying Institution POC/Designee |  |

 **Flexible Implementation Apply**

*[please outline terms as mutually agreed and delete the options that do not apply; we recommend the reviewing IRB POC and relying institution POC work together to agree on flexible implementation]*

**1. Standard Operating Procedures:
(Default) SMART IRB SOPs Will Apply**

The Participating Institutions will follow the SMART IRB SOPs with respect to the identified research.

**Reviewing IRB SOPs Will Apply**

The Participating Institutions will follow the Reviewing IRB SOPs *[Insert link here]* with respect to the identified research.

**Other Mandated SOPs Will Apply**

The Participating Institutions will follow the *[Insert SOP here]* for this research.

**2. HIPAA Determinations and Actions:
(Default if HIPAA Applies) Relying Institution or Third Party Will Provide Determination**

The Relying Institution or third party will make any HIPAA determinations or perform any HIPAA Actions in connection with this research on behalf of the Relying Institution **Reviewing IRB Will Provide Determination**The Reviewing IRB will review in accordance with 45CFR164.512(i)(1)(i) and (i)(2) a request for HIPAA Waiver/Alteration of Authorization in Connection with the Research.

**Relying Institution will make any HIPAA determinations or perform any HIPAA Actions as the Reviewing IRB does not as a matter of policy or otherwise, review requests for HIPAA waivers/alterations**

The Relying Institution(s) will make determinations for themselves as to what pathway under the HIPAA Privacy Rule (authorization / alteration or waiver of authorization / Limited Data Set) is applicable and required for them to use/disclose PHI for the identified research. If a Relying Institution determines that authorization is required, it must use a freestanding authorization form that is separate from (not merged into) the study consent provided by the Reviewing IRB.

**(Default if HIPAA does not apply) Not Applicable**The Ceded Research does not fall under HIPAA Privacy Rule, OR Relying Institution is NOT a HIPAA Covered Entity.

**3. HIPAA Authorization Language and Consent Forms:**
**(Default) Relying Institution Will Provide Notification**
The Relying Institution notify the Reviewing IRB of any required HIPAA authorization Language. If no such language is provided at the time this arrangement is executed, the Reviewing IRB will provide the HIPAA authorization form/language. The Reviewing IRB as necessary will permit the use and disclosure of Protected Health Information.

**Reviewing IRB Will Provide HIPAA Authorization Language/Forms**
The Relying Institution notify the Reviewing IRB of any required HIPAA authorization Language. If no such language is provided at the time this arrangement is executed, the Reviewing IRB will provide the HIPAA authorization form/language. The Reviewing IRB as necessary will permit the use and disclosure of Protected Health Information.

**Not Applicable**

The Ceded Research does not fall under HIPAA Privacy Rule, OR Relying Institution is NOT a HIPAA Covered Entity

**4. Conflicts of Interest:
(Default) Relying Institution Will Perform Conflict of Interest Analyses Under Their Policies (Default)**

The Relying Institution will perform their own analyses under their relevant policy with respect to disclosure and management of their Research Personnel’s conflicts of interest in connection with the identified research. The Reviewing IRB may impose additional prohibitions or conflict management requirements.

**Reviewing IRB Will Perform Conflict of Interest Analyses Under Their Policies**

The Relying Institution will provide the Reviewing IRB with relevant information to enable the Reviewing IRB to perform their own analyses under their relevant policy with respect to disclosure and management of their Research Personnel’s conflicts of interest in connection with the identified research.

**5. For-Cause Audits:
(Default) Reviewing IRB Will Conduct Any IRB-Initiated, For-Cause Audits or Investigations (Default)**

The Reviewing IRB will conduct any audits or investigations it initiates of matters relating to the Ceded Review of the identified research.

**Relying Institution Will Conduct Any IRB-Initiated, For-Cause Audits or Investigations**

The Relying Institution will conduct any audits or investigations it initiates of matters relating to the Ceded Review of the identified research.
 **6. IRB Notifications (of Decisions, Changes, Lapses in Approval, Problems, Noncompliance)
(Default) Reviewing IRB Will Provide Notification Directly**

The Reviewing IRB will notify the Overall PI, Site Investigator(s) and Relying Institution(s) of decisions, changes, lapses in approval, problems, and noncompliance.

 **Reviewing IRB Will Provide Notifications Through Another Party**

The Reviewing IRB will provide notifications through [NAME OF NOTIFYING PARTY (e.g., the Lead Study Team)] to the Overall PI, Site Investigator(s), and Relying Institution(s) of decisions, changes, lapses in approval, problems, and non-compliance.

**7. IRB-Initiated External Reporting:
(Default) Reviewing IRB Will Draft and Submit Reports To External Recipients (Default)**The Reviewing IRB will notify the Overall PI (or designee), the Site Investigator(s), and involved Participating Institution(s) whether the identified research is accepted for Ceded Review and, if accepted, the designation of the Reviewing IRB and Relying Institutions.

**Relying Institution Will Draft and Submit Reports To External Recipients**The Reviewing IRB will notify the Overall PI (or designee), the Site Investigator(s), and involved Participating Institution(s) whether the identified research is accepted for Ceded Review and, if accepted, the designation of the Reviewing IRB and Relying Institutions.

**Participating Institutions Will Jointly Draft and Submit Reports To External Recipients**The Reviewing IRB will notify the Overall PI (or designee), the Site Investigator(s), and involved Participating Institution(s) whether the identified research is accepted for Ceded Review and, if accepted, the designation of the Reviewing IRB and Relying Institutions.

**Plan for Conduct of IRB-Initiated Audits or Investigations Will Be Determined on Case by Case Basis**The Reviewing IRB and the Relying Institution will agree upon a plan for the conduct of any IRB-initiated audit or investigation of a matter relating to the Ceded Review of the identified research on a case-by-case basis at the time the matter arises.
 **8. Congruence of Federal Grant Applications/Contract Proposals:
(Default) Reviewing IRB Will Provide Notification**
The Reviewing IRB will review the congruence of any federal grant application(s) or contract proposal(s) supporting the identified research submitted to the IRB (when required by federal regulations or oversight agencies).

**Another Party Will Review Congruence**
The Reviewing IRB will delegate responsibility for review of the congruence of any federal grant application(s) or contract proposal(s) supporting the identified research to [INSERT RESPONSIBLE PARTY FOR REVIEW HERE].

**9. Financial Agreements:
(Default) Reviewing IRB/Institution Will Not Charge Relying Institution For Review Costs**

The Relying Institution will not be responsible for financial support of the costs of review of the identified research. The Reviewing IRB may charge the sponsor or other third parties for those costs.

**Reviewing IRB/Institution Will Charge Relying Institution For Review Costs**

The Reviewing IRB and the Relying Institution will enter a separate agreement under which the Relying Institution will provide financial support to the Reviewing IRB for the costs of review of the identified research.

 **10. Quality Assurance/Quality Improvement (“QA/QI” Function or Program):
(Default) Program Access Required**Each Participating Institution must have or have access to a human subjects research QA/QI program or service (or an alternate means of monitoring) that can conduct and report to that institution the results of for-cause and not-for-cause audits of the institution’s and its Research Personnel’s compliance with human subjects protections and other relevant requirements.

**Program Access Not Required**Participating Institutions engaged in or conducting the identified research are not required to have or have access to a human subjects’ research QA/QI program or service.

**11. Insurance:
(Default) Insurance Required**Each Non-Public Participating Institution must maintain insurance coverage of sufficient type(s) and in reasonable amount(s) to cover its activities with respect to the identified research, including coverage of its IRB/IRB members when acting as a Reviewing IRB. Participating Institutions may request from one another an insurance certificate or equivalent documentation of the relevant coverage (including any sponsor-provided coverage).

**Insurance Not Required**Each Participating Institution is not required to maintain insurance to cover its activities with respect to the identified studies.

**12. Indemnification:**
**(Default) Version 3.0 Indemnification Required**

If the Participating Institutions are signatories of the optional Version 3.0 SMART IRB Agreement Indemnification provision, this will apply for this research.

**Indemnification Agreement Not Required**

Indemnification agreements or other contractual arrangements for allocation of liability are not required with respect to the identified research.

**Separate Indemnification Agreement Required**

Participating Institutions will enter a separate indemnification agreement or other contractual arrangement for allocation of liability among them with respect to the identified research.