**Letter of Acknowledgement (Default Implementation)**

IRB Review will be ceded under the [**SMART IRB Agreement Version 3.0**](https://smartirb.org/agreement/). 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/IRB# |  |
| Relying Institution Site Investigator/IRB# |  |
| **This Letter of Acknowledgment was completed by the following institutional representatives (Name, Role, Date):** |
| Reviewing Institution POC/Designee  |  |
| Relying Institution POC/Designee  |  |

**Default Implementation Applies**

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

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

**2. (If HIPAA Applies) HIPAA Determinations and Actions: Relying Institution Will Provide Determination**

The Relying Institution or a third party named by Relying Institution will make any HIPAA determinations or perform any HIPAA Actions in connection with the research.

**3. (If HIPAA Applies) HIPAA Authorization Language and Consent Forms: Relying Institution Will Provide**
If HIPAA applies, the Relying Institution provide the Reviewing IRB with its own HIPAA language to be inserted into the informed consent document(s), or the Relying Institution will provide a separate HIPAA Authorization. The Reviewing IRB is under no obligation to ensure HIPAA Authorization language meet the requirements of 45 CFR 164.508(b) and (c).

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

The Relying Institution will perform their own analyses under their relevant policy(ies) 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.

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

The Reviewing IRB 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)**

The Reviewing IRB will notify 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: Reviewing IRB Will Provide Notification**
The Reviewing IRB/Reviewing IRB Institution will draft external reports to federal human subjects research regulatory authorities regarding unanticipated problems involving risks to human subjects or others; serious and/or continuing noncompliance with the Federal Policy, other applicable federal human subjects protection regulations or policies, and/or the FDA Clinical Investigation Regulations, as applicable, or with the requirements or determinations of the Reviewing IRB; and/or any suspensions or terminations of IRB approval. The Relying institution will have the opportunity (no fewer than five (5) business days, whenever possible) to review and comment on the draft report before it is sent to external recipient(s).

**8. Congruence of Federal Grant Applications/Contract Proposals: 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).

**9. Financial Agreements: Reviewing IRB/Institution Will Not Charge Relying Institution(s) 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.

 **10. Quality Assurance/Quality Improvement (“QA/QI” Function or Program): Program Access Required**Participating Institutions 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.

**11. Insurance: Required**Participating Institutions 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.

**12. Indemnification: SMART IRB Version 3.0 Indemnification**

If theParticipating Institutions are signatories to the optional Version 3.0 SMART IRB Agreement Indemnification addendum, this will apply for this research.