



Purpose of Form: This form documents the terms by which participating institutions will follow for the identified research. This form is intended to be validated by Reviewing IRB POC and Relying Institution POCs.

Implementation Checklist and Documentation Tool

Reviewing IRB Institution	
Relying Institution	
Research Study Title(s)	
Reviewing Institution PI	
Relying Institution Site Investigator	
SMART IRB Agreement Terms	<input type="checkbox"/> Default Implementation Applies <input type="checkbox"/> Flexible Implementation Applies (as outlined below)
This Implementation Checklist was completed by the following institutional representatives (Name, Role, Date):	
Reviewing Institution POC/Designee	
Relying Institution POC/Designee	



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Reviewing IRB

1. Notification of Acceptance or Declination of Ceded Review *Section 3.2.3*

(DEFAULT) OPTION 1 – Reviewing IRB Will Provide Notification
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. This can be accomplished through the [SMART IRB Reliance System](#) or another mechanism.

OPTION 2 – Another Party Will Provide Notification

will notify the Overall PI and 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.

OPTION 3 – Reviewing IRB Determination Mandated By External Group

The Participating Institutions are members of / participants in

and must follow its requirements and procedures for ceding IRB review and determining the Reviewing IRB with respect to the identified research.



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2. Standard Operating Procedures (“SOPs”)
Section 3.4.2

- (DEFAULT) OPTION 1 – SMART IRB SOPs Apply**
Participating Institutions will follow the SMART IRB SOPs

- OPTION 2 – Reviewing IRB SOPs Apply**
Participating Institutions will follow the Reviewing IRB SOPs, which are available at:

- OPTION 3 – Other SOPs as mandated by External Group**
Participating Institutions are members of / participants in

and must follow the

Standard Operating Procedures which are available at:



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3. HIPAA Determinations and Actions

Sections 4.4, 4.4.2, 4.4.3

(DEFAULT IF HIPAA APPLIES) OPTION 1 – Relying Institution or 3rd Party 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.

OPTION 2 – 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.

OPTION 3 – Relying Institution(s) 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) OPTION 4- Ceded Research does not fall under HIPAA Privacy Rule regulations, OR Relying Institution is NOT HIPAA Covered Entity

No HIPAA determinations or actions are required for the Relying Institution to use/disclose PHI.



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**4. HIPAA authorization
Language and
consent forms**
Sections 4.4.1

- (DEFAULT IF HIPAA APPLIES) OPTION 1 – Relying Institution will provide Reviewing IRB with its own HIPAA language to be inserted into the informed consent documents OR 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).
- OPTION 2 – Reviewing IRB will Provide and Insert HIPAA Authorization Language into the Informed Consent Document(s)** on behalf of the Relying Institution meeting the requirements of 45 CFR 164.508(b) and (c) as necessary to permit the use and disclosure of PHI.
- OPTION 3– Reviewing IRB will Provide separate HIPAA Authorization Form** on behalf of the Relying Institution meeting the requirements of 45 CFR 164.508(b) and (c) as necessary to permit the use and disclosure of PHI.
- (DEFAULT IF HIPAA DOES NOT APPLY) Not Applicable – HIPAA does NOT apply, or the Relying Institution is NOT a HIPAA Covered Entity**



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5. Conflict of Interest
Sections 5.8 and 6.6

- (DEFAULT) OPTION 1 – Relying Institution Will Perform Conflict of Interest Analyses of their Research Personnel 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 Relying Institution’s resulting determinations, prohibitions, management plans, and any updates will be provided to the Reviewing IRB. Note that the Reviewing IRB has the right to impose additional prohibitions or conflict management requirements.

- OPTION 2 – Reviewing IRB will Perform Conflict of Interest Analyses of the Relying Institution’s(s’) Research Personnel Under Its Policies**
The Reviewing IRB will apply its institution’s own policies with respect to disclosure and management of the Relying Institution’s(s’) Research Personnel’s conflicts of interest in connection with the identified research. The Reviewing IRB will notify the Relying Institution(s) of the IRB’s resulting determinations, prohibitions, management plans, and any changes thereto. Note that the Relying Institution(s) may propose additional prohibitions or conflict management requirements to the Reviewing IRB for approval.

- OPTION 3 – Relying Institution and Reviewing IRB have Agreed on an Alternate Plan for Conflict of Interest Analyses**



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<p>6. IRB notifications (of Decisions, Changes, Lapses in Approval, Problems, Noncompliance) <i>Sections 5.8, 5.9, 5.10, 5.11</i></p>	<p><input type="checkbox"/> (DEFAULT) OPTION 1 – Reviewing IRB Will Provide Notifications Directly 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.</p> <p><input type="checkbox"/> OPTION 2 – Reviewing IRB Will Provide Notifications Through Another Party The Reviewing IRB will provide notifications through</p> <p>to the Overall PI, Site Investigator(s), and Relying Institution(s) of decisions, changes, lapses in approval, problems, and non-compliance.</p>
<p>7. IRB-Initiated Audits and Investigations <i>Sections 5.12 and 6.13</i></p>	<p><input type="checkbox"/> (DEFAULT) OPTION 1 – 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.</p> <p><input type="checkbox"/> OPTION 2 – Relying Institution(s) Will Conduct Any IRB-initiated, For-Cause Audits or Investigations The Reviewing IRB will request Relying Institution conduct any IRB-initiated audits or investigations of matters relating to the Ceded Review of the identified research.</p> <p><input type="checkbox"/> OPTION 3 – Reviewing IRB and Relying Institution(s) Will Jointly Conduct any IRB-Initiated, For-Cause Audits or Investigations The Reviewing IRB and the Relying Institution will jointly conduct any IRB-initiated audits or investigations of matters relating to the Ceded Review of the identified research.</p> <p><input type="checkbox"/> OPTION 4 – Plan for conduct of IRB-initiated audits or Investigations Will Be Determined on a 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 and at the time the matter arises.</p>



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**8. IRB-Initiated
External Reporting**
Sections 5.4.1.2

(DEFAULT) OPTION 1 – Reviewing IRB Will Draft and Submit Reports to External Recipients

The Reviewing IRB will draft and submit to external parties (e.g., regulatory agencies, other oversight authorities) any reports of unanticipated problems, serious or continuing noncompliance, and suspension or termination of IRB approval that the IRB determines are required in connection with the identified research. Note that the Relying Institution have the right to review/ comment on the draft report(s) and to make/submit their own report(s) in addition to the Reviewing IRB’s report(s).

OPTION 2 – Relying Institution(s) Will Draft and Submit Reports to External Recipients

The Reviewing IRB will request the Relying Institution to draft and submit to external parties (e.g., regulatory agencies, other oversight authorities) any reports of unanticipated problems, serious or continuing noncompliance, and suspension or termination of IRB approval that the IRB determines are required in connection with the identified research. Note that the Reviewing IRB has the right to review/comment on the draft report(s) and to make/submit its own report(s) in addition to the Relying Institution’s report(s).

OPTION 3 – Reviewing IRB and Relying Institution Will Jointly Draft and Submit Reports to External Parties

The Reviewing IRB and the Relying Institution will jointly draft and submit to external parties (e.g., regulatory agencies, other oversight authorities) any reports of unanticipated problems, serious or continuing noncompliance, and suspension or termination of IRB approval that the IRB determines are required in connection with the identified research.

OPTION 4 – Plan for Drafting and Submission of IRB-initiated External Reports Will Be Determined on a Case-By-Case Basis

The Reviewing IRB and the Relying Institution(s) will agree upon a plan for the drafting and submission to external parties (e.g., regulatory agencies, other oversight authorities) of any reports of unanticipated problems, serious or continuing noncompliance, and suspension or termination of IRB approval that the IRB determines are required in connection with the identified research on a case-by-case basis and at the time the matter arises.



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9. Congruence of Federal Grant Applications/ Contract Proposals

Section 5.15

(Note this is applicable when such review is required by federal regulations or oversight agencies)

- (DEFAULT) OPTION 1 – Reviewing IRB Will Review Congruence**
The Reviewing IRB will review the congruence of any federal grant application(s) or contract proposal(s) supporting the identified research with the study protocol(s) submitted to the IRB.

- OPTION 2 – 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 with the study protocol(s) submitted to the IRB to



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Reviewing Institution	
<p>1. Financial agreements (for review costs – indemnification agreements are addressed separately below) Section 2.4</p>	<p><input type="checkbox"/> (DEFAULT) OPTION 1 – 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, if applicable. The Reviewing IRB may charge the sponsor or other third parties for any applicable costs.</p> <p><input type="checkbox"/> OPTION 2 – Reviewing IRB/Institution Will Charge Relying Institution For Review Costs The Reviewing IRB and the Relying Institution will enter a separate agreement or agreements under which the Relying Institution will provide financial support to the Reviewing IRB for the costs of review of the identified research.</p>
<p>2. Quality Assurance / Quality Improvement (“QA/QI”) Function/Program Section 6.11</p>	<p><input type="checkbox"/> (DEFAULT) OPTION 1 – QA/QI Program Access Required Participating Institutions engaged in the identified research 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. If applicable, please provide additional information regarding the alternate means of monitoring that will be used:</p> <p><input type="checkbox"/> OPTION 2 – QA/QI Program Access Not Required Participating Institutions engaged in the identified research are not required to have or have access to a human subjects research QA/QI program or service.</p>



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<p>3. Insurance <i>Section 4.9</i> <i>(Note that state/federal agencies or instrumentalities of state/federal government may provide documentation of self-funded liability coverage or of reliance on applicable law providing immunity from or limiting liability.)</i></p>	<p><input type="checkbox"/> (DEFAULT) OPTION 1 – 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. Participating Institutions may request from one another an insurance certificate or equivalent documentation of the relevant coverage (including any sponsor-provided coverage).</p> <p><input type="checkbox"/> OPTION 2 – Insurance Not Required Participating Institutions are not required to maintain insurance coverage to cover activities with respect to the identified research.</p>
<p>4. Indemnification <i>Section 4.10</i></p>	<p><input type="checkbox"/> (DEFAULT) OPTION 1 – SMART IRB Version 3.0 Indemnification Required If Participating Institutions are members to the optional Version 3.0 SMART IRB Agreement Indemnification addendum, this will apply for this research.</p> <p><input type="checkbox"/> OPTION 2 – Indemnification Agreement Not Required Indemnification agreements or other contractual arrangements for allocation of liability are not required with respect to the identified research.</p> <p><input type="checkbox"/> OPTION 3 – 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.</p>