Purpose: A Reviewing IRB may use this template to identify the key policies that Relying Institutions, Site Investigators, and Lead Study Teams must follow when the single IRB review model is used.

The Reviewing IRB should revise and add language as needed to reflect its policies and processes and to include other policies relevant to external research personnel working with the Reviewing IRB.

This document presumes the Reviewing IRB uses the [SMART IRB Standard Operating Procedures](https://smartirb.org/sites/default/files/SMART_IRB_SOP-090816.pdf) (SOPs) to govern the reliance arrangement, including study team roles. The SMART IRB SOPs require identification of a Lead Study Team that performs specific communication roles, such as submitting the initial review application and local amendments to the Reviewing IRB on behalf of Relying Site Study Teams and disseminating IRB notifications and IRB-approved documents to Relying Site Study Teams on behalf of the Reviewing IRB. If the Lead Study Team model will not be followed, adapt this information to reflect the appropriate roles and responsibilities of the study teams.

Language shaded in gray within brackets [ ] should be modified to reflect the appropriate institution-specific information. We suggest doing a ‘find and replace’ for [NAME OF INSTITUTION]. This can be done by clicking “Edit,” then “Find,” and then “Replace”; paste [NAME OF INSTITUTION] in the top line and then type your institution name below it and click the “Replace all” button.

Model Template for Reviewing IRB to Identify Policies for Relying Institutions, Site Investigators, and Lead Study Teams

This document describes the policies that Lead Study Teams, Relying Institutions, and Site Investigators must follow when [NAME OF INSTITUTION] serves as the Reviewing IRB for ceded research.

Key Definitions

This section defines important terms used in this policy.

* Federalwide Assurance (FWA). The Federalwide Assurance in which a research institution commits to the Department of Health and Human Services that it will comply with the Federal Policy.
* Lead Study Team. Generally, the Lead Study Team is the study team at the Reviewing IRB’s institution. The Lead Study Team is designated by the Overall PI (see below). The Lead Study Team collaborates with the Reviewing IRB to assist with administration of the sites (see below).
* Overall Principal Investigator (PI). The lead multisite principal investigator with ultimate responsibility for the conduct and integrity of Research.
* Relying Institution’s SMART IRB Point of Contact (POC). One or more individuals who will serve as the contact person responsible for communicating on behalf of the Relying Institution with respect to matters concerning research that may be or has been ceded to the Reviewing IRB. See [Reviewing IRB Instructions for Relying Institution Point(s) of Contact](https://smartirb.org/assets/files/Reviewing_IRB_Instructions_to_Relying_Institution_POC.docx).
* Relying Institution. An institution that cedes IRB review to a Reviewing IRB.
* Reviewing IRB. The “IRB of record” to which authority for IRB review and oversight has been ceded by another institution.
* Relying Site Study Team. Relying Site investigators, including any local site personnel designated by the site investigator to carry out the applicable communication, coordination, and administrative procedures related to the ceded research.
* Site Investigator(s) (Site PI). An investigator(s) responsible for the conduct of the research at his/her institution.

1. Requirement to Identify a Lead Study Team

When the [NAME OF INSTITUTION] serves as a Reviewing IRB for other institutions, it requires the Overall PI, who may or may not be [NAME OF INSTITUTION] personnel, to identify a Lead Study Team.

The Lead Study Team is responsible for providing the information or performing the activities described below and outlined in the [SMART IRB Overall PI (and Lead Study Team) Checklist](https://smartirb.org/sites/default/files/PI_checklist.pdf) related to the reliance review process and thereafter once IRB review has been ceded:

* Determine and document specific roles and responsibilities for communicating
and coordinating key information to Relying Institutions’ SMART IRB POCs and the
[NAME OF INSTITUTION] IRB
* Promptly respond to questions or requests for information from Relying Site Study Teams
* Provide the Relying Site Study Teams with this and other [NAME OF INSTITUTION] policies relevant to the ceded research
* Obtain and collate information from Relying Site Study Teams regarding local variations in study conduct (i.e., [Local Considerations: Protocol-specific Document](https://smartirb.org/sites/default/files/Protocol-Specific-20180726.pdf))
* Provide Relying Site Study Teams with the IRB-approved versions of all study documents
* Assist Relying Site Study Teams to ensure consent documents follow the [NAME OF INSTITUTION] IRB’s template form and include applicable site-specific required language
* Notify Site Investigators of all [NAME OF INSTITUTION] IRB determinations
* Follow all requirements of the Relying Institution about ceded review, such as ensuring administrative requirements for documenting ceded review and site approval/acceptance of the reliance arrangement have been met before study activation occurs at a Relying Institution

2. IRB Review of Local Considerations

As part of its review, the [NAME OF INSTITUTION] IRB considers local requirements that can affect oversight of the research. Local requirements that Relying Institution’s SMART IRB POCs should communicate to the [NAME OF INSTITUTION] IRB include any applicable state or local laws, regulations, institutional policies, standards, or other local factors, including local ancillary reviews (this could include review of HIPAA requirements and forms by a separate office), relevant to the ceded research that would affect the conduct or approval of the study at the Relying Institution. The [NAME OF INSTITUTION] IRB may obtain local requirements information through a variety of mechanisms, including requiring the Relying Institutions’ SMART IRB POCs to complete a form or survey to provide key institutional information (i.e., [Local Considerations: Institutional Profile](https://smartirb.org/sites/default/files/Institutional-Profile-20180726.pdf) and [Local Considerations: Protocol-specific Document](https://smartirb.org/sites/default/files/Protocol-Specific-20180726.pdf)).

**Note: The document Local Considerations: Institutional Profile is also available as an online form, which may be completed and/or updated in the** [***SMART IRB Joinder***](https://joinder.smartirb.org/)**; Institutional Profiles may be viewed and downloaded from the** [***Participating Institutions***](https://smartirb.org/participating-institutions/) **page.**

3. Template Consent Forms

After the [NAME OF INSTITUTION] IRB approves applicable template informed consent forms, the Lead Study Team is responsible for disseminating the approved templates to Relying Site Study Teams. The [NAME OF INSTITUTION] IRB will identify which sections of the informed consent documents can be modified. See [SMART IRB Guidance: Inserting “Local Context” Language in Informed Consent Documents](https://smartirb.org/assets/files/Local_Context_Language_Guidelines.pdf)

Additional revisions to the consent documents may be considered if they are required by state or local laws or Relying Institution policies.

The Lead Study Team is responsible for obtaining information from Relying Site Study Teams about local consent form language and ensuring this is communicated to the [NAME OF INSTITUTION] IRB. To ensure the accuracy of the language included in the consent documents, the [NAME OF INSTITUTION] IRB may verify participating site consent form language through Relying Institutions’ SMART IRB POCs.

4. Notification of IRB Determinations

The [NAME OF INSTITUTION] IRB [DESCRIBE PROCESS FOR NOTIFYING STUDY TEAMS OF IRB DETERMINATIONS]

IF USING THE SMART IRB SOPS, APPLICABLE LANGUAGE FOR THE PROCESS WOULD BE “relies on the Lead Study team to inform Relying Site Study Teams of its determinations or review decisions regarding the ceded research at the time of initial review and thereafter. The Lead Study Team must have a mechanism in place to promptly inform Relying Site Study Teams of all IRB determinations.

5. Serious noncompliance, continuing noncompliance, unanticipated problem, suspension or termination determinations

When the [NAME OF INSTITUTION] IRB makes a determination of serious noncompliance, continuing noncompliance, or that an unanticipated problem occurred, or when it suspends or terminates a study, the IRB will inform the Lead Study team. The Lead Study team is responsible for informing relevant participating Relying Site Study Teams of the decisions and any follow up actions required.

The [NAME OF INSTITUTION] IRB will contact the SMART IRB POCs at affected Relying Institutions when it receives information that either a) is likely to result in a determination that serious noncompliance, continuing noncompliance, or an unanticipated problem occurred or b) will or has led to a suspension or termination of a study to provide information about the events and to obtain input, when appropriate, regarding a corrective action plan.

Unless otherwise specified, such as through the [Implementation Checklist for use of the SMART IRB Agreement](https://smartirb.org/sites/default/files/SMART_IRB_Agreement_Implementation_Checklist_FORM.pdf), should the [NAME OF INSTITUTION] IRB take an action that requires reporting to a regulatory agency (e.g., OHRP, FDA), the [NAME OF INSTITUTION] will draft a report to the required agencies and provide a copy of the report to relevant Relying Institutions’ SMART IRB POCs for input. Relying Institutions’ SMART IRB POCs should provide feedback on the draft notifications within 5 business days (or 7 calendar days), when possible. The [NAME OF INSTITUTION] IRB will take the provided feedback into consideration and may revise the report(s) accordingly before sending to the regulatory authority.

Relevant Relying Institutions’ SMART IRB POCs and the Lead Study Team will receive a copy of the final regulatory agency notification from the [NAME OF INSTITUTION] IRB and are responsible for any further distribution at their institutions. If the Relying Institution is the primary awardee for any federal funds or contracts that support the ceded research, the Relying Institution will be responsible for reporting any IRB determinations of serious noncompliance, continuing noncompliance, or unanticipated problems, or any suspension or termination of a study to relevant funding agencies or sponsoring entities.

If the [NAME OF INSTITUTION] IRB receives any communications from the FDA, OHRP, and/or other regulatory agencies regarding unanticipated problems, suspension, or termination of IRB approval, serious and/or continuing noncompliance, or other regulatory compliance concerns regarding the ceded research, the [NAME OF INSTITUTION] IRB (or designee) will promptly notify the Lead Study Team and relevant Relying Institutions’ SMART IRB POCs of such communications.

**Note: The SMART IRB guidance** [**Reportable Events: Recommendations for Investigator-initiated Multisite Studies**](https://smartirb.org/assets/files/Reportable_Events.pdf) **provides harmonized definitions, policies, and procedures for prompt reporting of noncompliance and unanticipated problems.**

6. Study Team Training, Education, and Qualifications

The [NAME OF INSTITUTION] IRB relies on the Relying Institution to ensure their study teams have appropriate credentials and/or qualifications and meet the institution’s standards for eligibility to conduct research for which the [NAME OF INSTITUTION] IRB provides oversight. Study team personnel are required to follow their home institution’s policies regarding required training (e.g., human subjects protection, Good Clinical Practice, HIPAA Privacy Rule). If a Relying Institution does not have a policy for training that researchers must complete, those study teams must follow the [NAME OF INSTITUTION]’s research training policies.

The Lead Study Team is responsible for ensuring that Relying Site Study Team personnel are adequately trained regarding the IRB approved study protocol and procedures and are made aware of any updates to the protocol.

***Note: The SMART IRB guidance*** [***Responsibilities Associated with the Review of Study Personnel***](https://smartirb.org/assets/files/Review_of_Study_Personnel.pdf) ***makes recommendations on how to establish mechanisms for institutions, investigators, and IRBs to work together to ensure study personnel are trained in human subjects protections and are qualified to conduct the research under review.***

7. Conflicts of interest

Unless otherwise specified, such as through the [Implementation Checklist for use of the SMART IRB Agreement](https://smartirb.org/sites/default/files/SMART_IRB_Agreement_Implementation_Checklist_FORM.pdf), Relying Institutions are responsible for maintaining policies regarding the disclosure and management of research personnel conflicts of interest and providing any applicable conflict of interest determinations and associated management plans for the ceded research to the [NAME OF INSTITUTION] IRB. Consequently, Relying Institutions also are responsible for establishing processes to identify and communicate relevant conflict of interest information determinations and management plans to the [NAME OF INSTITUTION] IRB at the time of the reliance arrangement and throughout the life of the ceded research.

During the process of setting up the reliance arrangement, Relying Institution POCs are expected to provide applicable conflict of interest determinations and associated management plans as part of the local considerations information the [NAME OF INSTITUTION] IRB collects, which may be documented in the [Local Considerations: Protocol Specific Document](https://smartirb.org/assets/files/Protocol-Specific-20180726.pdf)). After the [NAME OF INSTITUTION] IRB approves the Relying Institution as a participating site, the Relying Site Study Team is responsible for communicating to the [NAME OF INSTITUTION] IRB any new or updated conflict of interest determinations and associated management plans for the ceded research. The [NAME OF INSTITUTION] IRB may impose additional prohibitions or conflict management requirements more stringent or restrictive than those proposed by a Relying Institution if necessary to approve the research and will reach out to relevant Relying Institutions’ POCs if the IRB wishes to modify or change any management plan or mandated disclosure to subjects required by the Relying Institution.

***Note: The SMART IRB guidance*** [***Conflict of Interest (COI) Review Processes for Single IRB Review***](https://smartirb.org/assets/files/HSC-COI-FINAL-ua.pdf) ***provides a framework for both Relying Institutions and Reviewing IRBs and their institutions to handle this important component of human subjects protections.***

8. Continuing Review

***Note: The SMART IRB guidance*** [***Single IRB Continuing Review Process: Recommendations for Harmonization***](https://smartirb.org/assets/files/Continuing-Review-Recommendations-Final.pdf) ***considers the processes and expectations for continuing review and identifies the relative roles and responsibilities of the Reviewing IRB, Relying Institutions, and study teams.***

Provision of information to the [NAME OF INSTITUTION] IRB.

***Note: The SMART IRB guidance*** [***Continuing Review Content Recommendations for Single IRB Review***](https://smartirb.org/assets/files/CR-ContentRec-HSC-TableExtract.pdf) ***outlines recommendations for the information Reviewing IRBs should collect for continuing review and includes recommendations about who should provide the information to the Reviewing IRB***

The Lead Study Team is responsible for submitting continuing review progress reports to the [NAME OF INSTITUTION] IRB. Continuing review reports must be submitted [IDENTIFY TIMEFRAME] days before study expiration through [DESCRIBE MECHANISM FOR SUBMISSION].

The Lead Study Team is responsible for providing details regarding overall study progress as well as progress at each Relying Institution so that the [NAME OF INSTITUTION] IRB can assess a comprehensive report regarding study progress, new information, and problems that have occurred.

If a Relying Site Study Team does not provide the Lead Study Team with required information before the continuing review application is submitted to the [NAME OF INSTITUTION] IRB, the Lead Study Team must report the absence of this information as part of the continuing review submission.

Further guidance related to the submission of continuing review progress reports to the [NAME OF INSTITUTION] IRB can be found at [PROVIDE LINKS TO RELEVANT INFORMATION].

**Expiration of IRB Approval**. The Lead Study Team is responsible for informing Relying Site Study Teams if study-wide or the site-specific IRB approval lapses. If IRB approval lapses for some or all participating sites, all activities at those sites must cease unless they must continue to ensure the safety of study participants. If any study activities must continue to ensure participant safety, the Lead Study Team is responsible for working with the [NAME OF INSTITUTION] IRB to develop a plan to promptly obtain IRB approval to continue the study and implement any applicable corrective action plans.

9. Amendments

The Lead Study Team is responsible for submitting amendments (study-wide or site-specific) to the [NAME OF INSTITUTION] IRB for review and approval.

When an amendment is planned, it should be submitted to the IRB for review as soon as possible.

Changes in approved research initiated without prior IRB review and approval to eliminate apparent hazards to a participant must be reported to the IRB within [\_\_] days of implementation.

Further guidance related to the submission of amendments to the [NAME OF INSTITUTION] IRB can be found at [PROVIDE LINKS TO RELEVANT INFORMATION].

10. Personnel Changes

Changes in the Overall PI or Site PI must be promptly reported to the [NAME OF INSTITUTION] IRB. [DESCRIBE SUBMISSION REQUIREMENTS FOR PI CHANGES.]

The Lead Study Team will be responsible for ensuring study team members for all sites have the training and qualifications to conduct the research and for disclosing COIs relevant to the research to the [NAME OF INSTITUTION] IRB. Updates to personnel must be provided to the [NAME OF INSITUTION] IRB (or their designee, such as a post-approval monitoring team) upon request.

Further guidance related to the submission of personnel updates to the [NAME OF INSTITUTION] IRB can be found at [PROVIDE LINKS TO RELEVANT INFORMATION].

***Note: The SMART IRB guidance*** [***Responsibilities Associated with the Review of Study Personnel***](https://smartirb.org/assets/files/Review_of_Study_Personnel.pdf) ***makes recommendations on how to establish mechanisms for institutions, investigators, and IRBs to work together to ensure study personnel are trained in human subjects protections and are qualified to conduct the research under review.***

11. Reportable Events

**Reportable Event Policy**. Relying Site Study Teams must promptly notify the Lead Study Team (or their designee) of any unanticipated problems that occurred at the Relying Institution that may involve risks to human subjects or others or events that may constitute serious or continuing noncompliance with applicable human subjects protection regulations or with the requirements or determinations of the [NAME OF INSTITUTION] IRB. The Lead Study Team is responsible for promptly reporting these events to the [NAME OF INSTITUTION] IRB within [IDENTIFY NUMBER OF DAYS; note that the [**Reportable Event Working Group of the SMART IRB Harmonization Steering Committee**](https://smartirb.org/sites/default/files/Reportable_Events.pdf) recommends 7 calendar days] calendar days.

**Subject Injuries and Complaints**. Relying Institutions are required to have mechanisms in place by which complaints about the ceded research can be made by local research participants or others to a local contact. In addition, Relying Site Study Teams must promptly notify the Lead Study Team of any subject injuries related to research participation, or any significant subject complaints that occurred at the Relying Institution for reporting to the [NAME OF INSTITUTION] IRB. The [NAME OF INSTITUTION] IRB will promptly notify the Overall PI via the Lead Study Team and relevant Relying Institution SMART IRB POCs of any subject injuries that occur related to research participation or significant subject complaints (e.g., those that could affect the conduct of the research study) that occurred at a Relying Institution.

**Other Events**. If the [NAME OF INSTITUTION] IRB determines that a reportable event raises issues apart from or in addition to noncompliance with human subjects protection requirements (e.g., a potential allegation of research misconduct), it will refer those issues to the Relying Institutions’ SMART IRB POC for review.

Further guidance related to the submission of reportable events to the [NAME OF INSTITUTION] IRB can be found at [PROVIDE LINKS TO RELEVANT INFORMATION].

12. Study Compliance and Auditing

Relying Institutions are required to ensure their study teams comply with the determinations and requirements of the [NAME OF INSTITUTION] IRB, applicable federal regulations, and all applicable state and local laws and local institutional requirements relating to the research. Unless otherwise specified, such as through the [Implementation Checklist for use of the SMART IRB Agreement](https://smartirb.org/sites/default/files/SMART_IRB_Agreement_Implementation_Checklist_FORM.pdf), the Relying Institution is expected to have a mechanism to conduct for-cause audits of research studies at the request of, and promptly report the results to, the [NAME OF INSTITUTION] IRB.

The [NAME OF INSTITUTION] IRB may request any Relying Institution to conduct its own audit or investigation relevant to the ceded research and report its findings of fact back to the IRB. As necessary, the [NAME OF INSTITUTION] IRB will work with the Relying Institution (or its designee) to provide relevant records and related information, meet with representatives from the Relying Institution, and help to implement corrective actions, as applicable.

13. Study Closure

The [NAME OF INSTITUTION] IRB requires the submission of a study closure report. [DESCRIBE WHEN A STUDY MAY BE CLOSED AND HOW LONG RECORDS MUST BE RETAINED.] If a study must be re-opened, the Lead Study Team should contact the [NAME OF INSTITUTION] IRB to determine the process for reactivating the study with the IRB.

14. HIPAA Privacy Rule Requirements

**Performing Privacy Board Functions**. The [NAME OF INSTITUTION] IRB generally acts as the Privacy Board on behalf of Relying Institutions for studies that fall under the HIPAA Privacy Rule and involve protected health information unless otherwise agreed upon and documented with the Relying Institution, such as through the [Implementation Checklist for use of the SMART IRB Agreement](https://smartirb.org/sites/default/files/SMART_IRB_Agreement_Implementation_Checklist_FORM.pdf).

As part of this responsibility, the [NAME OF INSTITUTION] IRB may grant waiver or alteration of authorization for the use of protected health information (PHI) if it finds that the conditions of the waiver or alteration have been met. Relying Institutions are responsible for ensuring that the waivers or alterations are compatible with their privacy practices, implementation of HIPAA, or obligations under state law.

If the [NAME OF INSTITUTION] IRB allows a Relying Institution to retain responsibility for reviewing and approving waivers of or alterations of authorization for ceded research, this arrangement will be documented, such as through the [Implementation Checklist for use of the SMART IRB Agreement](https://smartirb.org/sites/default/files/SMART_IRB_Agreement_Implementation_Checklist_FORM.pdf).

**Preparatory to Research**. Institutions vary regarding whether they interpret the Preparatory to Research provision of the HIPAA Privacy Rule to allow researchers to access PHI for purposes of determining eligibility and to contact potential subjects for purposes of recruitment. Therefore, the Relying Institution’s SMART IRB POC must communicate to the Reviewing IRB whether the Relying Institution permits the use of the Preparatory to Research provision under the HIPAA Privacy Rule for research recruitment. Notification may be made using the [Local Considerations: Protocol-specific Document](https://smartirb.org/sites/default/files/Protocol-Specific-20180726.pdf). If the Relying Institution communicates to the Reviewing IRB that it does not allow access to PHI for eligibility and recruitment activities under the Preparatory to Research provision or that the Participating Site’s recruitment efforts are outside the scope of what is permitted under Preparatory to Research by the Relying Institution, the Reviewing IRB may grant a partial waiver of authorization for the use of records containing PHI to determine whether a participant is eligible for a study and to approach individuals about potential study participation.

**Review of Authorizations**. When a standalone HIPAA authorization is used for a study overseen by the [NAME OF INSTITUTION] IRB, the Relying Institution is responsible for ensuring the accuracy of the information within the form, the compliance of the form with the HIPAA Privacy Rule, and that the form permits PHI to be used by and disclosed to the [NAME OF INSTITUTION] IRB, [NAME OF INSTITUTION], and all Relying Institutions as necessary for conducting, reviewing and overseeing the Research (including investigation and evaluation of events).

In the case of a combined consent and authorization form, the [NAME OF INSTITUTION] IRB will work with the Relying Institutions’ SMART IRB POCs to include any language specific to the Relying Institution, when appropriate and necessary. Specifics may be documented on the [Local Considerations: Institutional Profile](https://smartirb.org/sites/default/files/Institutional-Profile-20180726.pdf). The [NAME OF INSTITUTION] IRB does not permit an exhaustive listing of specific institutions as recipients of PHI but rather identifies the types of groups that may have access (e.g., oversight agencies, collaborating researchers).

**Restrictions on Use and Disclosure of PHI**. Relying Institutions are responsible for notifying the [NAME OF INSTITUTION] IRB of any specific local requirements and restrictions on use and disclosure of PHI that could prevent the IRB from approving a request for waiver of HIPAA authorization with respect to that Relying Institution. Restrictions may be documented on the [Local Considerations: Institutional Profile](https://smartirb.org/sites/default/files/Institutional-Profile-20180726.pdf).

Note that the Reviewing IRB does not take on responsibility for any other HIPAA requirements applicable to the Relying Institution (such as compliance with or implementation of accounting of disclosures of PHI made by the Relying Institution pursuant to a waiver of authorization).

15. Required Relying Institution Notifications to the Reviewing
 IRB/Institution

The Relying Institution is required to notify the [NAME OF INSTITUTION] IRB or other officials at the [NAME OF INSTITUTION] of the following types of information:

* If it is required or receives a request to provide information pursuant to law or to legal process (e.g., a subpoena or a public records request) in connection with the ceded research, or if it becomes aware of a threatened or actual claim, suit, or action arising from the ceded research
* Any suspension, restriction, termination, or expiration of its FWA
* Any loss of or change to its human research protection program (HRPP) accreditation status or other quality assessment standard
* Any suspension or restriction by the Relying Institution or any third parties of any of its research personnel’s authority to conduct the ceded research.
* A copy of any additional report to a regulatory agency, if the Relying Institution elects to make its own (e.g., in the case of serious or continuing noncompliance, unanticipated problem, suspension or termination of IRB approval)
* Any communications received by the Relying Institution or between the Relying Institution and FDA, OHRP, and/or other regulatory agencies, regarding unanticipated problems, noncompliance, or other compliance concerns regarding the ceded research

16. Which IRB Policies Apply to the Ceded Human Subjects Research

As described above, Relying Site Study Teams are expected to follow the [NAME OF INSTITUTION] IRB’s policies and procedures regarding:

a) the information provided to the IRB and how it is submitted, such as reportable events and conflicts of interest plans; and

b) submission requirements for initial review, continuing review, amendments, personnel changes, and closure reports.

Either the [NAME OF INSTITUTION] IRB’s or the Relying Institution’s policies and procedures may be followed for other processes. In some situations, the [NAME OF INSTITUTION] IRB expects Relying Site Study Teams to follow their local policies and procedures.

The table below outlines which policies and procedures apply when the [NAME OF INSTITUTION] IRB serves as a Reviewing IRB.

|  |  |  |  |
| --- | --- | --- | --- |
| **POLICY & PROCEDURE** | **REVIEWING IRB** | **RELYING INSTITUTION** | **NOTES** |
| **INFORMED CONSENT** |  |  |  |
| Informed consent template used | X |  | Relying Institution will be able to provide limited language |
| Whether informed consent documents are stamped | X |  |  |
| Qualifications of translators for consent forms and other study documents |  | X |  |
| Definition of legally authorized representative and order of priority |  | X |  |
| If an informed consent document is included in a participant’s medical record |  | X |  |
| **ASSENT** |  |  |  |
| When assent is required for a study | X |  |  |
| Whether written assent is required for a study | X |  |  |
| Ages of children from whom assent is obtained |  | X |  |
| When the IRB approves multiple assent forms (e.g., for younger and older children), which form is presented to the child |  | X |  |
| **SUBJECT PAYMENT** |  |  |  |
| Form of payment |  | X | The IRB would be responsible for determining whether and the amount of compensation subjects may receive for participation. However, institutions may have rules that specify acceptable forms of payment (e.g., cash vs. gift). |
| **MEDICAL RECORDS** |  |  |  |
| Who can access medical records for research purposes |  | X | The IRB may approve a subject identification and recruitment plan that involves accessing medical records, but who can access the medical records will be determined by the Relying Institution’s policies |
| **RELEASING RESULTS OF RESEARCH TESTS TO PARTICIPANTS** |  |  |  |
| What research test results can be disclosed to participants | X |  |  |
| How incidental (adventitious) findings, such as the discovery of suicidality or severe depression, will be addressed | X |  |  |
| Disclosure of pregnancy testing results for minors | X |  |  |
| Mandatory reporter requirements |  | X |  |
| **DATA STORAGE & SHARING** |  |  |  |
| Data security requirements |  | X | The IRB is responsible for approving the plan to protect study data, but local security requirements for data storage and transmission also must be met |
| **MANAGEMENT OF TEST ARTICLES** |  |  |  |
| Control of investigational drugs or devices |  | X |  |

Summary of Relying Site Study Team Responsibilities

Relying Institutions, Site Investigators, and Lead Study Teams must be aware of their responsibilities when a study is under the oversight of an IRB external to their institutionas outlined in the [SMART IRB Relying Site Investigator (Site PI) Checklist](https://smartirb.org/sites/default/files/Relying_institution_checklist.pdf).

***Other Possible* [NAME OF INSTITUTION] IRB *Policies or Guidance to Reference for Relying Institutions, Site PIs or Relying Site Study Teams, or Lead Study Teams***

[INCLUDE DETAILS TO OTHER GUIDANCE OR INSTRUCTIONS THAT MAY BE HELPFUL TO THE RELYING INSTITUTIONS OR STUDY TEAMS, SUCH AS

* Guidance on completing the IRB application
* Instructions for any electronic system the IRB uses
* Submission deadlines
* Guidance regarding protocol exceptions and deviations]