Relying on External IRBs and Utilizing SMART IRB - Process and Procedures

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Objectives

- Recognize relevant reliance agreement terms and requirements when establishing an agreement between two or more institutions
- Identify the roles and responsibilities of institutions engaging in reliance agreements
- Understand processes and procedures for reliance agreements
An NIH-funded study being conducted at more than one U.S. sites (domestic) involving non-exempt human.

NIH-funded or -supported studies conducting multi-site or cooperative research may need to have a single IRB (sIRB), if any of the following apply:

- Submitted for an NIH grant application on or after January 25, 2018
- Submitted for an NIH Research & Development (R&D) contract solicitation issued on or after January 25, 2018
- Submitted for an NIH intramural research study with initial review on or after January 25, 2018
- Received initial IRB approval on or after January 20, 2020*
- Transitioned the study at one or more sites to the 2018 Requirements

*Requires that all federally funded research that involves multiple institutions must have only one IRB provide review.

* Applies to all federally funded Cooperative Research.

This is different because cooperative research does not need to be a clinical trial; the research only needs to involve more than one institution.
Reliance Agreement

BASICS
What is a Reliance Agreement?

Also known as Institutional Authorization Agreement (IAA) or Cede Review Agreement (CRA)

It is a written agreement between two or more institutions to describe the delegation of IRB review responsibilities

May be for the review of:

- One or multiple protocols listed by names in the agreement
- Research protocols within a certain set of parameters
What is a Reliance Agreement?

Reliance agreements entered into on a case-by-case basis for one study

Reliance agreements entered into can include multiple studies

Master agreements

SMART IRB
What is a Reliance Agreement?

Master agreements
* NCI
* National Marrow Donor Program (NMDP)
* Maryland Proton Treatment Center (MPTC)
* Public Health Institute (CA)
* NEALS
* Advarra
* WCG
* VA CIRB
* Others in process
What is a Reliance Agreement?

Having a fully executed master agreement is not a “rubber stamp”

A reliance decision is made on a study-by-study basis.

UMB reserves the right to decline to rely/participate on a study-by-study basis.
Effective upon full execution by the parties for as long as IRB review is required.

Reasons for Termination
- IRB Review no longer required
- Mutual agreement, or either party opts, to terminate
- Reviewing IRB terminates IRB approval for the research
- FWA is suspended, restricted, terminated, or expired
- Reviewing IRB fails to remain registered with OHRP
SMART IRB is a platform designed to ease common challenges associated with initiating multisite research and to provide a roadmap for institutions to implement the NIH Single IRB Review policy.

Freely available for institutions and investigators, SMART IRB is an integrated, comprehensive platform that allows flexibility in the size and scope of collaboration to enable IRB reliance for multisite studies across the nation, regardless of funding status.

1,192 Participating Institutions, including all CTSA Hubs

https://smartirb.org/
Documentation Required

- Institutional Authorization Agreement
- Communication Plan
- Local Context Questionnaire checklist

Exceptions
Reliance Agreements executed through the SMARTIRB platform or through an existing master agreement do not require the submission of a separate IAA. The Communication Plan and LCQ Checklist may still be required by the reviewing IRB.

Templates Location
Accessible at the UMB Human Research Protection Office website under the For Researchers/Study Conduct page: https://www.umaryland.edu/hrp/for-researchers/study-conduct/
Local Context

- Information describing site-specific requirements, preferences and variables relevant for the conduct of research at the relying institution
Components of the local context include, but is not limited to:

- Languages spoken by targeted population
- Socio-economic Issues
- Age of Majority
- Community Culture
- Relevant local laws, including reporting of domestic and child abuse
- Site-specific language for the consent document, including subject injury and compensation
- Ancillary review requirements at the study site
- Site-specific contact information
Roles and Responsibilities
Communication Plan

- Identify key communication roles for a study
- Briefly describe how the communication will be handled between the relying institution and the reviewing IRB
ROLES

**Reviewing IRB (IRB) Institution**
- Also known as the IRB of record
- Provide oversight and perform IRB reviews on behalf of one or more institutions

**Relying Institution (Institution)**
- Agrees to rely upon the reviewing IRB
- The Institution, their employees and agents must comply with Agreement

**Signatory Officials**
- The institutional official or designee authorized to approve the Agreement
### Authority of the Reviewing IRB

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<tr>
<th>Action</th>
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<tr>
<td>Approve</td>
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<td>Request Changes</td>
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<td>Disapprove</td>
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<td>Suspend</td>
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<td>Terminate</td>
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- Observe, or request that a 3rd party observe, the informed consent process
Type of Transactions Reviewed

- Initial Protocol Review
- Continuing Reviews
- Protocol Amendments
- Unanticipated Problems That May Involve Risks To Subjects Or Others (UPIRTSOs)
- Instances of Non-Compliance
- Local Context Information Provided By Relying Institution (Institution)
- Review of other documents, requests, or information related to the approval and continuing oversight of the research, as applicable.
## Responsibilities: Applicable Laws

### Reviewing IRB (IRB)
- Ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice
- Considers during the review the state or local laws that would have implications for the research conducted at the relying institution(s)

### Relying Institution (Institution)
- Notify the IRB of applicable state, local, and institutional requirement related to the conduct of research and protection of human subjects
- Maintain compliance with state, local, and institutional requirements
# Responsibilities: Local Context

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<thead>
<tr>
<th>Reviewing IRB (IRB)</th>
<th>Relying Institution (Institution)</th>
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<tr>
<td>• Must have access to information on local context</td>
<td>• Provide the IRB with any local context information applicable to the research and updates as appropriate</td>
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<tr>
<td>• Ensure that the review of the research adequately considers local context issues and concerns</td>
<td>• Submit site-specifics modifications to the consent document for IRB review and approval before use</td>
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<tr>
<td>• Review and approve customized site-specific sections of the consent document as per the local context information provided</td>
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Responsibilities:
Review and Conduct of Research

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<tr>
<th>Reviewing IRB (IRB)</th>
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<tr>
<td>• Review and monitor human research activities</td>
<td>• Safeguard the rights and welfare of each research participant</td>
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<tr>
<td>• Notify the Institution in writing of its findings and actions</td>
<td>• Obtain IRB approval for new protocol or protocol revisions before implementation, except where necessary to eliminate apparent immediate hazards to the participants</td>
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<td>• Provide the institution any relevant IRB meetings minutes and other relevant documentation, upon request</td>
<td>• Obtain, document, and maintain records of consent and HIPAA authorization, as applicable</td>
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<tr>
<td>• Provide the Institution with a copy of their Human Research Protection Program (HRPP) Standard Operating Procedures, upon request</td>
<td>• Ensure that the PI will properly oversee the conduct of the study</td>
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<td>• Comply with the IRB’s HRPP SOPs and research review determinations</td>
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Responsibilities: Monitoring and Auditing

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<tr>
<td>• Monitor research activities to ensure its compliance with requirements of the</td>
<td>• Monitoring protocol compliance</td>
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<tr>
<td>Relying Institution’s FWA(s)</td>
<td>• Assist and cooperate with the reviewing IRB in conducting directed</td>
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<tr>
<td>• Assess compliance with applicable local and federal regulations and ethical</td>
<td>audits</td>
</tr>
<tr>
<td>principles</td>
<td>• Notify the IRB immediately if there is a suspension or restriction</td>
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<tr>
<td>• Conduct post-approval monitoring and for-cause audits</td>
<td>of the Relying Institution’s PI in the conduct of the research</td>
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## Responsibilities: Complaints From Participants

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<tr>
<td>• Review complaints about the research by local research participants or others</td>
<td>• Notify the Reviewing IRB of participants complaints received directly</td>
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<tr>
<td>• Notify institution of participants complaints received directly</td>
<td>• Assist and cooperate with the IRB towards the complaint's resolution</td>
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Responsibilities:
Investigator Qualifications and Education

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<td>• Verify that the study staff education, training, and qualifications are adequate to perform the research activities</td>
<td>• Ensure that the study staff have adequate qualifications and have undergone required training to perform the research activities and safeguard the rights and welfare of research subjects.</td>
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<td>• This includes, but is not limited to</td>
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<td>• having any institutionally required professional staff appointments,</td>
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<td></td>
<td>• credentialing,</td>
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<td>• insurance, or other liability coverage, and</td>
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<td>• training in human subjects' protections</td>
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<td>• Provide, as requested by the IRB, information regarding its study staff education, training, and qualifications</td>
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## Responsibilities:

### Reporting Responsibilities

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<td>• Report the following events and IRB determination to the organizational officials and applicable regulatory agency, as required under applicable rules or regulations:</td>
<td>• Promptly report new safety information that may represent an UPIRTSO or a Serious or Continuing Noncompliance event</td>
</tr>
<tr>
<td>• Serious or Continuing Non-Compliance</td>
<td>• Assist and cooperate with IRB in the preparation of any report to notify OHRP, FDA, or any other applicable agency of determinations of reportable events.</td>
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<tr>
<td>• UPIRTSOs</td>
<td></td>
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<tr>
<td>• Suspension or Termination of IRB Approval</td>
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<tr>
<td>• Notify the Institution of determination to allow them to review and comment before sending report to the applicable regulatory agency</td>
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Responsibilities: Conflict of Interest (COI) Management

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<td>• Verify COI review took place at the Relying Institution</td>
<td>• Obtain, review, manage and report disclosures of COI or FCOI determinations of research study staff</td>
</tr>
<tr>
<td>• Obtain and review COI management plan, as appropriate</td>
<td>• Provide IRB with an assurance documenting training, review, and determinations for conflicted research study staff</td>
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<tr>
<td>• Determine if COI management plan is appropriate for the research under review</td>
<td>• Provide details of any associated management plan specific to the research study</td>
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<tr>
<td>• Convey to, and resolve with, the Relying Institution any concerns regarding the management plan</td>
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Starting the Reliance Process
Starting the Reliance Process:

Contact HRPO at UMB

- Researchers should contact the HRPO prior to submitting any paperwork or electronic applications.
  - Scott Evans – sevans@umaryland.edu
- HRPO will ensure the study in question qualifies for a reliance agreement.
- HRPO can assist with determining the appropriate method for executing the reliance agreement (IAA, SMART IRB, IREx, etc).
Starting the Reliance Process:
Submit the Application via CICERO

• The study MUST be submitted via CICERO when relying on an External IRB of Record.

• Reliance agreements without a corresponding CICERO submission will not be processed.

• Upload all available supporting documentation, including:
  • Reliance agreement documentation
  • Local context forms
  • Site-specific consent forms, protocol, investigator brochure etc
  • IRB of Record approval letter(s)

• Once all required submissions have been received, the CICERO application and reliance request will be administratively reviewed by the HRPO for completeness
Starting the Reliance Process:
Submit the Application via CICERO

- CICERO – Department or Entity Feasibility Review of Research
- CICERO - CCT/Legal review, as applicable
- CICERO - Radiation Safety
- CICERO - Institutional Biosafety
- CICERO - General Clinical Research Center
- CICERO – Conflict of interest
Starting the Reliance Process:
Submit the Application via CICERO

* Reminders:

◦ Contact HRPO in advance to have a discussion
  ◦ Phone call
  ◦ Virtual meeting with the team so HRPO can learn more of the specifics about the study
  ◦ Contact HRPO before submitting to the External IRB.
The Reliance Process

• CICERO application and all ancillary reviews must be complete before the reliance process is finalized.
• Research activities are being conducted at UMB although the IRB of record is another entity.
• UMB and the local PI have roles and responsibilities to fulfill related to any study in which UMB agrees to rely on another IRB.
• The UMB Institutional Official, Dr. Susan Buskirk, is the only individual with the authority to sign reliance agreements on behalf of UMB.
Thank you!

Resources:
- HRPO Website
  www.umaryland.edu
- UMB Reliance Agreement Documentation Templates
  https://www.umaryland.edu/hrp/for-researchers/study-conduct/
- SmartIRB
  https://smartirb.org/
Questions?

Human Research Protections Office
Office of Academic Affairs, Research Compliance
620 W. Lexington Street, 2nd Floor
410-706-5037
hrpo@umaryland.edu
www.umaryland.edu/hrp