UNIVERSITY of MARYLAND BALTIMORE

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

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ASSISTANT VICE PRESIDENT – RESEARCH COMPLIANCE

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

Single IRB for Multi-Site

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

Single IRB for Cooperative Research

* Single IRB Requirement for All Federally Funded Studies in effect January 20, 2020.

*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.

Duration

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

Local Context (cont)

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

Approve

Request Changes

Disapprove

Suspend

Terminate

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)	Relying Institution (Institution)
• 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)	• 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

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

Responsibilities:

Review and Conduct of Research

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

Responsibilities:

Monitoring and Auditing

Reviewing IRB (IRB)	Relying Institution (Institution)
• Monitor research activities to ensure its compliance with requirements of the Relying Institution (Institution)'s FWA(s) • Assess compliance with applicable local and federal regulations and ethical principles • Conduct post-approval monitoring and for-cause audits	• Monitoring protocol compliance • Assist and cooperate with the reviewing IRB in conducting directed audits • Notify the IRB immediately if there is a suspension or restriction of the Relying Institution's PI in the conduct of the research

Responsibilities:
Complaints From Participants

Reviewing IRB (IRB)	Relying Institution (Institution)
• Review complaints about the research by local research participants or others • Notify institution of participants complaints received directly	• Notify the Reviewing IRB of participants complaints received directly • Assist and cooperate with the IRB towards the complaint's resolution

Responsibilities:
Investigator Qualifications and Education

Reviewing IRB (IRB)	Relying Institution (Institution)

• Verify that the study staff education, training, and qualifications are adequate to perform the research activities	• 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.
	• This includes, but is not limited to
	  • having any institutionally required professional staff appointments,
	  • credentialing,
	  • insurance, or other liability coverage, and
	  • training in human subjects' protections
	• Provide, as requested by the IRB, information regarding its study staff education, training, and qualifications

Responsibilities:

Reporting Responsibilities

Reviewing IRB (IRB)	Relying Institution (Institution)

• Report the following events and IRB determination to the organizational officials and applicable regulatory agency, as required under applicable rules or regulations:
  • Serious or Continuing Non-Compliance
  • UPIRTSOs
  • Suspension or Termination of IRB Approval
• Notify the Institution of determination to allow them to review and comment before sending report to the applicable regulatory agency
	• Promptly report new safety information that may represent an UPIRTSO or a Serious or Continuing Noncompliance event
	• 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.

Responsibilities:
Conflict of Interest (COI) Management

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

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.

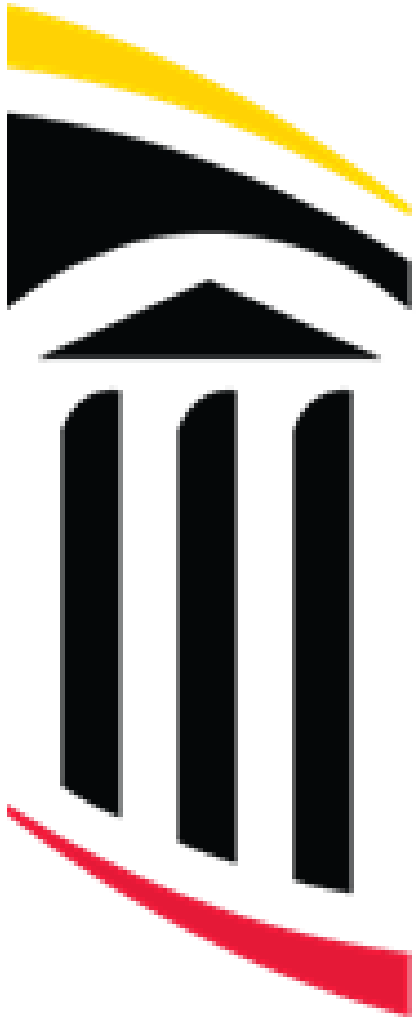
The Reliance Process

- 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