UNIVERSITY of MARYLAND BALTIMORE

When Relying on an External IRB: What Needs to be Reported to UMB

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Objectives

Recognize relevant reliance agreement terms and requirements

Identify the roles and responsibilities of UMB Investigators engaging in reliance agreements

Understand processes UMB reporting processes when relying on an external IRB

Reliance Agreements

A **reliance agreement** is a written agreement that must be established when an institution engaged in research delegates institutional review board (**IRB**) review.

When one institution agrees to rely on another's IRB.

Reliance agreements

May be for the review of:

- One or multiple protocols listed by names in the agreement
- Research protocols within a certain set of parameters
- Case-by-case basis

Master Reliance agreements

* UMCP
* NCI
* National Marrow Donor Program (NMDP)
* Maryland Proton Treatment Center (MPTC)
* Public Health Institute (CA)
* NEALS
* Advarra
* WCG
* VA CIRB
* Others in process

Reliance agreement terms

Ensure that the Principal Investigator ("PI") at the Relying Institution (UMB) will properly oversee the conduct of the study at its institution.

This includes but is not limited to:

Monitoring protocol compliance.

Maintaining compliance with state, local, and institutional requirements related to the protection of human subjects;

Maintain compliance with any additional state, local, or institutional requirements related to the protection of human subjects.

Reliance agreement terms (cont.).

Promptly notify the Reviewing Institution/IRB of new safety information that may represent:

Unanticipated Problems Involving Risk to Subjects or Others

New information in accordance with the Reviewing IRB's HRPP Standard Operating Procedures.

Reliance agreements

IRBs also have an obligation to notify federal oversight agencies (e.g.; FDA/OHRP/VA as applicable) of certain reportable determinations.

Why Report to Relying Institution (UMB)?

UMB must review some types of events promptly, in case steps to be taken to protect participants locally.

These events may impact subject safety, confidentiality, or conduct of the study.

Reportable New Information

UMB HRPP Toolkit

* HRP 105 RNI Bulletin

Workflow

UMB Investigator reports new information as required to the external IRB of record.

The external IRB of record reviews the information and can make a variety of decisions.

IRB of Record Decisions

*Management plan or corrective action plan appropriate?

*Continuing non-compliance
*Serious non-compliance
*Serious & continuing non-compliance
- Unanticipated problem involving risk to research subject(s) or others

*Suspension of IRB approval at UMB
*Termination of IRB approval at UMB

IRB of Record

Issues letter of determination to the principal investigator.

Documents whether the management plan/corrective action plan is appropriate.

Documents level of compliance.

Next steps…….

UMB Principal Investigator must fulfill their human subjects research responsibilities and report the external IRB's determination(s) to UMB as outlined on the UMB RNI Bulletin.

UMB RNI Bulletin

14) Determination from IRB of Record

*Continuing non-compliance
*Serious non- compliance
*Serious & continuing non-compliance
*Unanticipated problem involving risk to research subject(s) or others
*Suspension of IRB approval at UMB
*Termination of IRB approval at UMB

Next Steps……

- Create a Reportable New Information submission in the acknowledged application in CICERO.
- Attach the determination letter from the IRB of record.
- Include an update (as applicable) on the status of any affected research participants.

CICERO Process

Select activity button "Create New Information Report"

Categorization

1. What are you reporting to the IRB?

   - Check the appropriate category (or more than one as appropriate)

CICERO Process - 2

Description

1. Describe the problem/information being reported to the IRB
   - type or nature of the problem/information
   - as appropriate, date problem occurred
   - as appropriate, a full description of the activities leading to the problem
   - as appropriate, interventions/actions taken in response
   - as appropriate, temporal relationship to study activities
   - as appropriate, current status of participant or person affected by the problem

CICERO Process - 3

Description, cont.

2. Date the PI or study staff became aware of this information

3. Participant signed a VA consent?

4. Attach any pertinent documents

CICERO Process - 4

Investigator Analysis

1. Does information indicate new or increased risk?

2. Does protocol require revision?

   If yes, describe and submit a modification

3. Does the consent require revision?

   If yes, describe and submit a modification

Next Steps…..

- Reportable New Information submission is reviewed by the UMB Research Subject Advocate and Safety Specialist
- Additional request for clarification and/or queries related to the submission
- UMB can take additional steps for the safety, rights and welfare of research participants

Next Steps……

The UMB Institutional Official can take additional actions for the rights, safety and welfare of UMB research participants.

REACH OUT!

Contact HRPO for questions as needed.

Recordings of RNI Grand Rounds on HRPO website.

HRPO
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Questions??

THANK YOU!!!