UNIVERSITY of MARYLAND BALTIMORE

After IRB approval--What Needs to be Reported to the UMB IRB?

(Review of Reportable New Information Submission requirements)

Dr. Julie Doherty, DM, MSN, RN, CIP, CCEP
Assistant Vice President
University of Maryland Baltimore
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Why Report?

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

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

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

- Serious/Continuing Noncompliance
- Unanticipated Problems

Reportable New Information

Any information that has not previously been known about the research study or was not previously reviewed by the IRB

UMB HRP Toolkit
* SOP HRP 024 Reportable New Information
* HRP 105 RNI Bulletin

Reportable New Information

New information that falls into one of the reportable categories must be submitted to the IRB within 5 business days of Principal Investigator/Study team becoming aware

*Information may fall into more than one category

Reportable New Information 1

Information that indicates a new or increased risk

a. New information (e.g., an interim analysis, safety monitoring report, publication in the literature, sponsor report, or investigator finding) indicates an increase in the frequency or magnitude of a previously known risk, or uncovers a new risk.

b. An investigator brochure, package insert, or device labeling is revised to indicate an increase in the frequency or magnitude of a previously known risk, or describes a new risk.

Reportable New Information

- Added New Risk:

  Likely*:* Edema face; Other (generalized edema); Localized edema; Periorbital edema
  Risk previously described in the ICF but is occurring at an increased frequency, severity or duration

- Increase in Risk Attribution:
  Changed to Likely from Less Likely: Neutrophil count decreased

Reportable New Information 1

c. Withdrawal, restriction, or modification of a marketed approval of a drug, device, or biologic used in a research protocol.

d. Protocol violation that harmed subjects or others or that indicates subjects or others might be at increased risk of harm.

Reportable New Information 1

e. Complaint of a subject that indicates subjects or others might be at increased risk of harm or at risk of a new harm.

f. Any changes significantly affecting the conduct of the research.

Reportable New Information 2

Any harm experienced by a participant or other individual which in the opinion of the local investigator is

- unexpected

AND

- at least probably related to the research

Reportable New Information 2

A harm is “unexpected” when its specificity or severity are inconsistent with risk information previously reviewed and approved by the IRB in terms of nature, severity, frequency, and characteristics of the study population.

A harm is “a least probably related to the Human Research procedures” if in the opinion of the local investigator, the research procedures more likely than not caused the harm (greater than 50% probability).

Reportable New Information 3

Non-compliance with the federal regulations or with the requirements or determinations of the IRB

* Protocol expiration
    * Research activities occurred in interim?
    * CAP to prevent in future---submit 6 weeks in advance
* Non-adherence with the IRB approved protocol
* Over-enrollment

Reportable New Information 4

Failure to follow the protocol due to the action or inaction of the investigator or research staff

*Non-adherence with the IRB approved protocol

Reportable New Information 5

Breach of confidentiality

Database related to this study sent by email to study group with identifying data that was not encrypted.

Stolen laptops/tablets not encrypted

Reportable New Information 6

Change to the protocol taken without prior IRB review to eliminate an apparent immediate hazard to a subject

- Dosing change not in IRB approved protocol
- Additional study procedures

Reportable New Information 7

Incarceration of a subject in a study not approved by the IRB to involve prisoners

- Enrolled participant shows up for study visit with ankle monitor on
- PI learns participant on study drug is in jail

Reportable New Information 8

Complaint of a subject that cannot be resolved by the research team

*Communication and documentation

Reportable New Information 9

Suspension or premature termination of the research by the sponsor or the investigator

* Locally
* Globally

Reportable New Information 10

Unanticipated adverse device effect

Any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects).

Reportable New Information 11

Audit, inspection, or inquiry by a federal Agency

*FDA
*DoD
*OHRP
*VA ORO

Reportable New Information 12

Written reports of study monitors

Reportable New Information 13

For **Veterans Administration (VA)** research only:

- any **local SAE** that is serious, unanticipated and related to the research
- any **serious problem** that is both unanticipated and related to the research
- any **apparent serious or continuing noncompliance** with IRB or other human research protection requirements

Reportable New Information 13

Serious problem is a problem in human research or **research information security** that may reasonably be regarded as:

(1) **Presenting a genuine risk of substantive harm,** to the safety, rights, or welfare of human research subjects, research personnel, or others, including their rights to privacy and confidentiality of identifiable private information; or

(2) **Substantively compromising a facility's** HRPP [Human Research Protection Program] or **research information security program.**

Reportable New Information 14

Determination from external IRB of Record of:

*noncompliance

*continuing non-compliance

*serious non-compliance

*unanticipated problem involving risk to research subjects or others

*suspension or termination of research at UMB

Reportable New Information 15

RNI submission for OAC, HRPO & VA R&D Use only

- Audit reports
- Paper agenda items

Reportable New Information Processes

Submit documentation within 5 days of receipt from external IRB. Include corrective action plan.

HRPO will review and query PI as needed for clarity.

Reportable New Information Processes

All other information that does not fall under any of the previous categories is not required to be reported to the IRB

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

PI Reporting Requirements

- New information that falls into one or more reportable category must be reported to the IRB within 5 business days of the PI/study team becoming aware
- Applies to any type of study regardless of funding (pharmaceutical sponsor for drug or device study; or investigator initiated)

PI Responsibilities

- Monitor research activities for events that may indicate new information
- Determine if new information falls into a reportable category
- Make a determination about new or increased risk
- Make a determination about protocol and/or consent revisions (modifications)

PI Responsibilities

* External IRB determination----submit to UMB through RNI pathway in CICERO

* Institution in consultation with IRB can take action based on report

IRB Action

- If submission indicates that the information does not increase risk to participants, IRB will acknowledge information

- If submission indicates that the information **does** increase risk to participants, the IRB will review and determine if additional action is required

IRB Action

- Full board review
- Protect rights, safety and welfare of participants and others involved in research
- Management plan appropriate (including re-consent; affect participants willingness to continue participation)
- Corrective action plan appropriate

IRB Action

Unanticipated Problem Involving Risks to Subjects or Others

Any information that is (1) unanticipated and (2)related to the research , and (3) indicates that subjects or others are at increased risk of harm.

IRB ACTION

- Non-Compliance: Failure to follow the regulations, or the requirements or determinations of the IRB.
- Serious Non-Compliance: Non-Compliance that adversely affects the rights or welfare of subjects.
- Continuing Non-Compliance: A pattern of Non-Compliance that indicates a deficiency likely to result in further Non-Compliance or a circumstance in which an investigator fails to cooperate with investigating or correcting Non-Compliance.

IRB ACTION

Communication with PI on rights, safety and welfare of research participants

IRB Determination of RNI

Follow-up with PI and team on CAP or management plan as needed

Reporting to oversight agencies as required

REACH OUT!

Contact HRPO for questions as needed.

Recordings of RNI Grand Rounds on HRPO website.

HRPO
Contact Information

Dr. Julie Doherty
Assistant Vice President, Research Compliance
jdoherty@umaryland.edu

Mary MacFadden - Director
Research Subject Advocate & Safety Specialist
mmacfadden@umaryland.edu

Human Research Protections Office
410-706-5037 (phone)
620 West Lexington Street, 2nd Floor Baltimore, MD 21201
Website: www.hrpo.umaryland.edu
Email: hrpo@umaryland.edu

UNIVERSITY of MARYLAND
BALTIMORE

Questions??

THANK YOU!!!