University of Maryland Baltimore

Human Research Protections Program

Reportable New Information

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New Information

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

    - 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.

New Information - 2

New information that falls into one of the reportable categories must be submitted to the IRB within 5 business days

- *Information may fall into more than one category

Definitions

- 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.

Reportable Categories

1. Information that indicates a <u>new</u> or <u>increased</u> risk
   - see attached

- <u>Added New Risk:</u>

  Likely*:* Edema face; Other (generalized edema); Localized edema; Periorbital edema
- <u>Increase in Risk Attribution</u>:

  Changed to Likely from Less Likely: Neutrophil count decreased

Reportable Categories - 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 Categories - 3

3. Non-compliance with the federal regulations or with the requirements or determinations of the IRB
   * Protocol expiration
   * Non-adherence with the IRB approved protocol
   * Over-enrollment

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 Categories - 4

5. Breach of confidentiality

Database related to this study sent by email to study group with identifying data that was not encrypted. This data and email was immediately deleted by all study members as per PI request and data was de-identified. PI went over importance and rules governing distribution of research data and password protect data and instructed team not to send data of an sort by group emails for this study or any other. PI also distributed a protocol in our research meeting regarding how to distribute data in the future.

Please find the attached drafted letters for review. One version is for the patients that are still alive and the other for the next of kin of those that have passed. Upon IRB approval, these letters will be signed and mailed to each individual patient/next of kin.

Reportable Categories - 5

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

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

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

Reportable Categories - 6

9. Premature suspension or termination of the research by the sponsor or the investigator

10. Unanticipated adverse device effect

11. Audit, inspection, or inquiry by a federal agency

Reportable Categories - 7

12. Written reports of study monitors

Reportable Categories - 8

13. For **Veterans Administration (VA)** research only:
    - any **local SAE** that is both 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

- 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
- 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)

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

- Unanticipated problem involving risk to research subjects or others
- Serious and/or continuing non-compliance
- Allegation of serious or continuing non-compliance

IRB Action

- 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

HRPO
Contact Information

- Questions ??

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