Mandatory Reporting

Purpose

The purpose is to outline the policies and procedures for mandatory reporting to the Institutional Review Board (IRB) or Exempt Review Committee (ERC) concerning human research.

Definitions

An ***adverse event (AE)*** is any untoward or unfavorable occurrence in a human subject, including any abnormal sign (e.g., abnormal physical exam or lab finding), symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research. While it occurs mostly in the context of biomedical research, it can occur in the context of social and behavioral research. Adverse events that occur during clinical trials or multi-site studies can be either internal or external.

- ***Internal AE*** means that the event involved a participant enrolled by the investigator at Marywood University or at a site conducted by an investigator affiliated with Marywood University (within MU-IRB's purview).
- ***External AE*** means that the event involved a participant enrolled by an investigator at another institution participating in a multi-study or trial (i.e., clinical trials that have arms in other countries – not within the IRB's purview, but may affect local participants).

An ***annual check-in report*** is a required report for research projects which are still open one year from approval but which do not require official continuing review.

Continuing review (CR) is an official review which is conducted at a designated interval after a project has received initial review and approval by the Institutional Review Board (IRB) or Exempt Review Committee (ERC).

A ***protocol deviation*** is any divergence or departure from approved research, which is under the investigator's control and which takes place without prospective IRB or ERC approval. Approved research encompasses all approved materials and documents such as the application/protocol, informed consent or assent form, recruitment materials, questionnaires/data collection forms or any other information relating to the study.

- A ***major deviation*** is one that impacts (1) the research risks and benefits, (2) subject well-being or safety, (3) the integrity or validity of study data, or (4) a subject's willingness to participate in the research. Examples include enrolling an ineligible subject, failure to obtain informed consent prior to any study-specific tests/procedures, incorrect dosage, etc.
- A ***minor deviation*** is one that does not impact (1) the research risks and benefits, (2) subject safety, (3) the integrity of study data, or (4) a subject's willingness to participate in the research. Examples include failure to collect specific measures (e.g., questionnaire, baseline weight, etc.), unapproved advertisements used for recruitment, collecting signatures for an exempted study, etc.

A ***safety report*** (for an investigational new drug) is a type of adverse event report used in clinical trial studies which are subject to Food & Drug Administration (FDA) oversight. FDA requires that they be sent to the FDA and all investigators by the trial sponsor or investigator (if study is self-initiated) for any serious and unexpected adverse event taking place during the trial, regardless of the location of the event.

An ***unanticipated problem*** is any incident, experience, or outcome that meets *all* of the following criteria:

- unexpected (in terms of nature, severity, or frequency) given the research procedures that were described in project documents and the characteristics of the subject population;
- related or possibly related to participation in the research; and

- suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

Policies and Procedures

NOTICE - Elimination of Six-Month Status Reports

Six-month status reports have been eliminated as a result of the Revised Common Rule, effective January 21, 2019. Unless a study closes during its approval year, one of the following is required annually, depending on the original review category, the nature of remaining activities, and whether or not changes will be made to any aspect of the research:

- official continuing review (annual renewal)
- annual check-in

ANNUAL CHECK-IN REPORTS

According to Federal regulations at 45 CFR 46 (The Common Rule), the Institutional Review Board shall conduct continuing review of research requiring review by the convened IRB, also known as full review, at intervals appropriate to the degree of risk, but not less than once per year. Effective January 21, 2019, the Revised Common Rule has eliminated certain types of continuing review (see Continuing Review Policy for full details). However, when a research project remains open, but does not require regulatory continuing review, the IRB still maintains oversight, as does the Exempt Review Committee for all exempted studies.

Therefore, annual check-in reports are required for all open studies for which official, regulatory continuing review is not required. Check-in reports are due upon a study's approval anniversary date.

Annual Check-In Report Procedure

1. *The Principal Investigator submits an annual check-in report form to the IRB or ERC via IRBNet at www.irbnet.org.*
2. *An IRB/ERC staff member administratively reviews the report form.*
3. *An IRB/ERC staff member acknowledges it in IRBNet unless further action is required, at which time the PI is contacted.*

DEVIATION REPORTS

Federal regulations and IRB policies require that changes to approved research be reviewed and approved by the IRB or ERC before being implemented, except where necessary to eliminate immediate hazards to human subjects. Any change to a research protocol that is carried out without IRB or ERC approval is considered a protocol deviation.

An investigator is responsible for reporting to the IRB or ERC any instance of non-compliance with policies and procedures or the requirements or determinations of the IRB or ERC. If inadvertently or intentionally, an approved research protocol is not followed exactly as proposed and approved, the investigator must submit a Deviation report as soon as possible to the IRB or ERC, but no later than **five business days for a major deviation** or **ten business days for a minor deviation**. A report form may be found on the IRB Forms or ERC Forms pages.

Deviation reports are acknowledged by the IRB or ERC office within three to five business days of receipt.

Deviation Report Procedure

1. *The Principal Investigator (PI) submits a deviation report to the IRB or ERC via IRBNet at www.irbnet.org.*
2. *The Director of Human Participants Protection and Research Compliance reviews the report.*

    1. *If major, the Director reports it to the IRB Chair and Assistant Provost.*
    2. *If major and also if necessary, the IRB reviews it at a convened meeting.*
    3. *If major and also if necessary, the research is suspended.*
3. *The IRB or ERC notifies the PI of required actions. If no action is required, the IRB or ERC administratively acknowledges it in IRBNet.*
4. *For Federally funded research, the Director promptly reports any serious or continuing non-compliance with human research policies and procedures, or the requirements or determinations of the IRB to the appropriate Federal regulators (e.g., Office of Human Research Protections, appropriate Federal agency, etc.).*

<u>Failure to Report a Deviation</u>

If the Director of Human Participants Protection and Research Compliance discovers an unreported deviation, s/he will attempt contact with the PI via e-mail or telephone. The PI will have **five working days** to respond. Failure to respond may result in suspension of research activities.

UNANTICIPATED PROBLEMS AND ADVERSE EVENT REPORTS

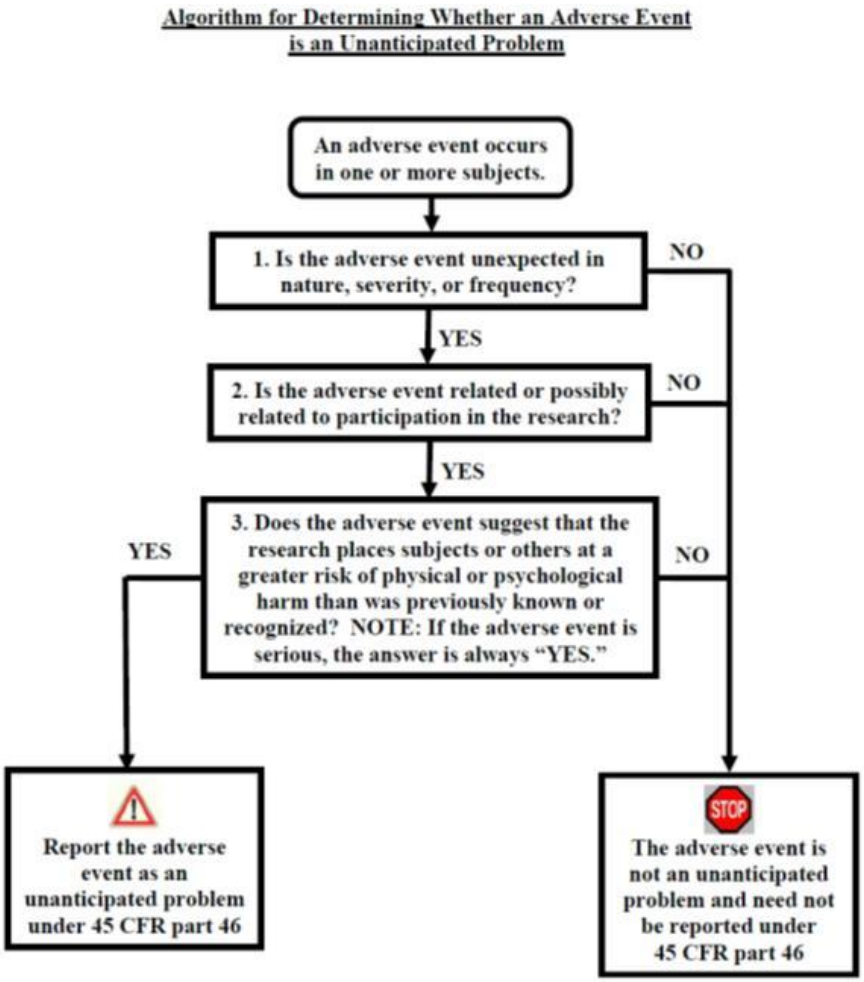
According to the US Office of Human Research Protections, an event or incident that meets the unanticipated problem criteria as defined above will most likely warrant substantive changes to the research protocol, or informed consent document or process, in order to ensure protection of the rights and safety of research subjects. Examples of corrective actions that may be required are:

- changes to research protocol initiated by the PI prior to obtaining IRB approval, only to eliminate immediate hazards to subjects;
- modification of inclusion/exclusion criteria to mitigate newly identified risks;
- implementation of additional procedures for monitoring subjects;
- suspension of enrollment of new subjects;
- suspension of research procedures in currently enrolled subjects;
- modification of informed consent documents to include a description of newly recognized risks; and
- provision of additional information about newly recognized risks to previously enrolled subjects.

Assessment of whether an adverse event is an unanticipated problem includes questions such as:

1. *Is the adverse event unexpected?*
2. *Is the adverse event related, or possibly related, to participation in the research?*
3. *Does the adverse event suggest that research placed subjects or others at a greater risk of harm than was previously known or recognized?*

If the answers to all three questions are YES, then the adverse event is an unanticipated problem and MUST be reported to the IRB/ERC.



An investigator is required to report to the IRB or ERC:

- Any unanticipated problems
- Any serious adverse events, even if they are not unanticipated problems

Research investigators must report all serious events, for example the death or serious injury of a research participant, regardless of relatedness or expectedness to study drug or interventions, immediately **within twenty-four hours** of the event to the Institutional Review Board (IRB) or ERC. Unanticipated Problems must be reported **within five business days** of the event.

Unanticipated problem and adverse event reports are acknowledged by the IRB or ERC within three to five business days of receipt.

IND Safety Reports (Clinical Research)

An IND safety report does not always describe an event which meets the definition of an unanticipated problem. Often, however, clinical research sponsors send IND safety reports to investigators and instruct the investigators to submit them to the IRB. If a research investigator conducting a clinical trial receives a safety report from a clinical research sponsor, and the report qualifies as an unanticipated problem, the investigator must submit the safety report **within five business days** to the IRB. IND safety reports are acknowledged by the IRB within 3-5 business days.

Unanticipated Problem and Serious Adverse Event Procedure

1. *The Principal Investigator (PI) submits an unanticipated problem or serious adverse event report to the IRB or ERC via IRBNet at www.irbnet.org.*
2. *The Director of Human Participants Protection and Research Compliance reviews the report.*
    1. *The Director reports it to the IRB Chair and Assistant Provost.*
    2. *If necessary, the IRB reviews it at a convened meeting.*
    3. *If necessary, the research is suspended.*
3. *The IRB or ERC notifies the PI of required actions. If no action is required, the IRB or ERC administratively acknowledges it in IRBNet.*
4. *For Federally funded research, the Director promptly reports any unanticipated problems involving risks to subjects or others to the appropriate Federal regulators (e.g., Office of Human Research Protections, appropriate Federal agency, etc.).*

Related Policies

Approval of Research

Continuing Review

Closure or Withdrawal

Revisions to Approved Research

Suspension or Termination

History

07/19/2013 - Updated

10/24/2014 - Updated (Identifiable data clarification)

05/30/2019 - Updated as a result of the Revised Common Rule