

I. Purpose

The purpose of the Reportable Events Policy (“the Policy”) is to describe the process and requirements Investigators must follow when reporting events that meet reporting criteria to Mercy University’s Institutional Review Board (the MCIRB).

The Policy defines the processes for reviewing and reporting:

- (a) [Unanticipated Problems Involving Risks to Subjects or Others](#);
- (b) [Unexpected Adverse Events Related to the Research](#);
- (c) [Continuing Noncompliance](#) and [Serious Noncompliance](#); and
- (d) [Suspensions](#) or [Terminations](#) to the Institutional Official and / or department or agency heads.

II. Scope

This Policy applies to all ongoing and future human research studies (i) conducted at Mercy University, where the research activity is supported by Mercy University or under the purview of the Mercy University Institutional Review Board (the “[IRB](#)”), or (ii) where Mercy University is considered to be engaged in the research.

III. Definitions

- *Adverse Event (“[AE](#)”).* Adverse events encompass both physical and psychological harms. AEs occur most commonly in the context of biomedical research, although they also occur in the context of social and behavioral research. An AE includes any untoward or unfavorable medical occurrence in a participant, including any abnormal sign (e.g., abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject’s participation in research, whether or not considered related to the subject’s participation in the research.
- *Allegation of Noncompliance (or “[Allegation](#)”).* An assertion of Noncompliance made against an individual engaged in the research that has yet to be proven.
- *Continuing Noncompliance.* A pattern of Noncompliance that suggests a likelihood that an instance of Noncompliance is not an isolated occurrence, and / or instances of Noncompliance will continue to occur without intervention.
- *Institutional Official.* The individual identified on Mercy University’s Federalwide Assurance with the Office for Human Research Protections (“[OHRP](#)”) as the authorized leader of the MCIRB. At Mercy University, this is the Associate Provost for Research.
- *Investigator.* Any individual, regardless of title or position, who is the primary person responsible for the design, conduct, or reporting of a research study that is subject to this Policy.
- *Noncompliance.* Noncompliance is defined broadly to include (i) a violation of any federal, state, or local regulation that governs human research; or (ii) a violation of any Mercy University policy on

human research; or (iii) any unapproved deviation from an IRB-approved protocol or stipulations imposed by the IRB as a condition of approval, *unless* such deviation is necessary to preserve the life or health of a subject *and* the IRB is notified following such deviation as soon as possible after the deviation occurs.

- *Related or Possibly Related to Participation in Research.* A reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research.
- *Research Personnel.* Investigators and other individuals assisting in the performance or review of a research study.
- *Serious Noncompliance.* A Noncompliance that (i) increases risks, or decreases potential benefits, to subjects; (ii) adversely affects the rights, welfare and safety of subjects; (iii) adversely affects the scientific integrity of a study; or (iv) is the result of a willful violation of any federal, state, or local regulation that governs human research, or (v) is a willful violation of any Mercy University policy on human research.
- *Suspension.* An action taken by the IRB or the IRB Chair to temporarily stop some or all previously approved research activities. Suspended protocols remain open and require continuing review.
- *Termination.* An action taken by the IRB or the IRB Chair to permanently stop all research activities in a previously approved research protocol. Terminated protocols are considered closed and no longer require continuing review.
- *Unanticipated Problems Involving Risk to Subjects or Others (“UP”).* Any incident, experience, or outcome in the course of human research that is (i) unexpected (in terms of nature, severity, or frequency), (ii) Related or Possibly Related to Participation in Research, and (iii) suggests that the research places subjects or others at greater risk of harm (including physical, psychological, economic, or social harm).
- *Unexpected AE.* An AE occurring in one or more subjects participating in a research study, the nature, severity, or frequency of which is not considered consistent with either the known or foreseeable risk of adverse events associated with the procedures involved in the research that are described in the protocol, investigator brochure, informed consent form, or other relevant sources of information regarding the research, such as product or device labeling and package inserts. Anticipated AEs, defined as those that are described in the aforementioned study documents and resources, are not “Reportable Events.”

IV. Reportable Events

A. Investigator Responsibilities

Requirement to Report “Reportable Events”

Investigators must report to the MCIRB the following “Reportable Events,” defined below:

1. Any adverse event (AE) that (i) is an Unexpected AE, **and** (ii) is Related or Possibly Related to Participation in Research.
2. Any Unanticipated Problem (UP).

3. Any breach of privacy or confidentiality, including lost or stolen confidential information.
4. Any medical, procedural, or laboratory error (e.g., errors in drug administration or dosing, surgical or other procedures, testing of samples, or test results).
5. Any interim analysis, safety monitoring report, publication in a peer-reviewed journal, or other finding indicating that there are new or increased risks to subjects or others, or that subjects are less likely to receive any direct benefits from the research study than as initially presented to the IRB.
6. Any complaint by or on behalf of a subject indicating that the rights, welfare, or safety of the subject have been adversely affected.
7. Any change in the Food and Drug Administration (“FDA”) labeling; any change in the status of an Investigational New Drug or Investigational Device Exemption; any withdrawal from market; any manufacturer alert from the sponsor of the research study; or any recall of an FDA-approved drug, device, or biologic under investigation in the research study.
8. Any event that requires prompt reporting to the sponsor of the research study, if applicable.
9. A suspension or termination of a research study or of a study’s enrollment by the FDA, the sponsor of the research study, or others, based on information indicating that the research study places subjects at an increased risk of harm than was previously known or recognized.
10. Any other event that is unanticipated and indicates that the research study places subjects or others (e.g., other investigators, research assistants, students, the public, family members or partners of subjects, etc.) at an increased risk of harm or otherwise adversely affects the rights, welfare or safety of subjects or others.

Protocol deviations

Minor protocol deviations are considered by the Mercy IRB to be distinct from Reportable Events and instead meet the definition of Noncompliance. Minor protocol deviations are defined as deviations from IRB-approved procedures that (i) do not cause harm and have no potential to cause harm to the research subject or others, and (ii) do not impact the integrity of research data. They must be tracked by the research team and reported at the time of continuing review. Multiple protocol deviations may be determined by the Mercy IRB to constitute Continuing Noncompliance; if so, the Investigator may be instructed to submit the Continuing Noncompliance as a Reportable Event.

Minor deviations include: over-enrollment of participants in a minimal risk study; follow-up visits occurring outside the protocol required timeframe because of the participant’s schedule; blood samples obtained at times close to, but not precisely at, the time points specified in the protocol.

B. Reporting Timeframes

Investigators must report Reportable Events to the MCIRB in accordance with the following timeframes:

- a. Reportable Events that are either life-threatening or which have resulted in death **must** be reported to the MCIRB via telephone or email within one (1) business day from the date the Investigator is notified of or discovers the Reportable Event. A Reportable Events Form must be

submitted to the MCIRB within forty-eight (48) hours of the Investigator's initial notification to the MCIRB of the Reportable Event.

- b. Reportable Events that are not life-threatening and have not resulted in death, must be reported to the MCIRB in writing as soon as possible, but not later than seven (7) business days from the date the Investigator is notified of or discovers the Reportable Event.

Minor protocol deviations as defined in IV(A) must be reported to the MCIRB in writing at the time of continuing review.

C. Reportable Events Form

In accordance with the timeframes outlined above, Investigators must submit to the MCIRB a written Reportable Events Form, which includes the following information:

- a. Identifying information for the research protocol, such as the title, the Investigator's name, and the IRB project number;
- b. A detailed description of the Reportable Event, including relevant dates and times;
- c. A detailed description of any corrective action or change to the protocol, planned or already taken, to ensure that the Reportable Event is corrected and will not occur again;
- d. An assessment of whether any subjects or others were placed at risk as a result of the Reportable Event, or suffered any physical, social, or psychological harm and any plan to address these consequences; and
- e. Any other relevant information.

For multisite research studies, if the Investigator engaged in the research independently proposes changes to the protocol or the informed consent document in response to a Reportable Event, the Investigator should consult with the sponsor of the research study or the coordinating center regarding the proposed changes.

D. Review of Reportable Events

1. Once the MCIRB receives a completed Reportable Events Form, it will be reviewed by the MCIRB to ensure it meets the defined reporting criteria, then forwarded to the IRB Chair. The MCIRB will notify the Investigator that the Reportable Event Form was received and whether additional information, actions, or reporting is required of the Investigator or other parties.

The IRB Chair has the authority to require, as a condition of continued approval by the IRB, submission of more detailed information by the Investigator, the sponsor of the research study, or others, about any Reportable Event occurring in a research study.

2. Upon review of the Reportable Events Form, the IRB Chair may take one or more of the following actions:
 - a. Acknowledge the Reportable Event. The MCIRB will retain the associated Reportable Events Form as part of the IRB's records without further review.
 - b. Accept the Reportable Events Form and approve the proposed changes, if any, with no further action required.
 - c. Require additional information related to the Reportable Event from the Investigator and / or

- others.
 - d. Require modifications to the protocol and / or consent documents.
 - e. Require that current subjects be provided with information regarding the Reportable Event or other information (e.g., if the information may relate to the subject's willingness to continue participation).
 - f. Require that subjects who previously participated in the research study be informed of the Reportable Event or of other information.
 - g. Require that current subjects be re-consented.
 - h. Require that the Investigator and / or research study personnel complete additional training.
 - i. Request an audit of the research by Mercy University's IRB.
 - j. Suspend the research.
 - k. Terminate the research.
 - l. Refer the Reportable Event for review by the IRB at a convened meeting if (i) the IRB Chair determines that the changes to the research study in response to the Reportable Event are more than minimal, or (ii) at the discretion of the IRB Chair.
 - m. Require any other appropriate actions.
3. If the IRB Chair refers the event for review by the IRB at a convened meeting, the IRB, by majority vote of a quorum of the members present at the convened meeting, may take one or more of the actions enumerated in Section D.2.
 4. The IRB Chair or the IRB will determine whether the Reportable Event constitutes an UP. If the Reportable Event constitutes an UP, further reporting to the Institutional Official and / or department or agency head is required.
 5. For multisite research studies, if the IRB Chair or the IRB propose changes to the protocol or consent documents in addition to those proposed by the sponsor of the research study, the coordinating center, or the Investigator, the IRB Chair or the IRB should request in writing that the Investigator discuss the proposed modifications with the sponsor of the research study or the coordinating center and submit a response or necessary modifications for review by the IRB Chair or the IRB.
 6. The IRB Chair will notify the Investigator in writing of the findings related to the Reportable Event and will send copies of the findings to the Chair of the Investigator's department and / or research unit. Such notice to the Investigator will inform the Investigator that he or she has ten (10) business days from receipt of the notice to request reconsideration of the IRB's decision by sending the IRB a written request for reconsideration that includes the basis for the Investigator's request. If an Investigator requests reconsideration, the request will be considered by the IRB Chair or by the IRB at the next convened IRB meeting, as appropriate, and a determination will be made whether to uphold, reverse or modify its decision. The IRB Chair will notify the Investigator of the outcome.

V. Serious Noncompliance by Research Personnel

A. Responsibility to Report Allegations of Serious Noncompliance

Research Personnel have the responsibility to report incidences of willful Serious Noncompliance

B. Documenting an Allegation of Serious Noncompliance.

1. Reports of an Allegation of Serious Noncompliance conducted willfully by Research Personnel must be made in writing to the IRB Chair or the Associate Provost for Research. The reporting individual's name will remain confidential.

2. The Allegation of Serious Noncompliance must be raised in good faith, in writing, and should include a complete description of the Serious Noncompliance, the observed circumstances, and the names of the individuals involved. The report must contain sufficient details to allow an assessment of the Serious Noncompliance. An Allegation of Serious Noncompliance should be reported as soon as possible after it is observed or discovered.
3. Only under extenuating circumstances may an Allegation of Serious Noncompliance be made verbally to any of the parties listed in Section V(B)(1). When a report is received orally, the individual receiving the Allegation of Serious Noncompliance is responsible for creating a written account of the report. The complainant must then affirm in writing that the Allegations of Noncompliance are accurate and complete as transcribed.
4. The identity of the individual making an Allegation of Serious Noncompliance will be protected, to the extent possible and upon request, when the complainant makes a report in good faith. This protection will hold even if the Allegation of Serious Noncompliance is found, upon investigation, to be without merit.

C. Preliminary Assessment of Allegation of Serious Noncompliance

1. The individual who receives an Allegation of Serious Noncompliance along with one or more of the parties listed in Section V(B)(1) will conduct a preliminary review of the Allegation of Serious Noncompliance and any other documents relevant to the study and / or the potential Serious Noncompliance. If necessary to better ascertain the nature and scope of the Allegation of Serious Noncompliance, the individuals reviewing the Allegation of Serious Noncompliance may request an audit of the research study, interview the Investigator or other Research Personnel, as appropriate, or take whatever other actions deemed necessary to assess the Allegation of Serious Noncompliance.
2. Following the preliminary review by the parties listed in Section V(B)(1), referrals may be made by the Mercy University IRB chair to other parties, Boards and Committees for assessment if some or all the Allegation(s) fall under the purview of another University policy (e.g., Research Misconduct, Conflicts of Interest in Research, Fiscal Misconduct, etc.)
3. The individuals reviewing the Allegation of Serious Noncompliance will determine if there is support for a finding of Serious Noncompliance.
 - a. If the facts do not support a finding of willful, Serious Noncompliance, as determined by the individuals reviewing the Allegation as part of the preliminary assessment, the Allegations of Serious Noncompliance may be dismissed and no further action is required to be taken.
 - b. If the facts support a finding of willful, Serious Noncompliance, as determined by the individuals reviewing the Allegation, the matter will be referred for further review by the IRB at a convened meeting.
4. A written report of the preliminary assessment and the determination made by the individuals reviewing the Allegation will be filed as part of the IRB's records.
5. If, in the judgment of the individuals reviewing the Allegation, an Allegation (at any point in the preliminary assessment phase) warrants the Suspension or Termination of the research to ensure protection of the rights and welfare of the subjects, the individuals reviewing the Allegation may invoke appropriate procedures to suspend or terminate the research.

D. Considerations by the IRB.

The IRB will review the Allegation and any other documents relevant to the study and / or the potential Serious Noncompliance. The IRB may, at its discretion, consider new or additional information. The IRB may also appoint a subcommittee to further investigate the Allegation and to make recommendations to the IRB with respect to the appropriate corrective actions.

1. Actions with Respect to the Research

The IRB may take one or more of the following actions with respect to the research:

- a. Approve the research to continue with no further action required;
- b. Defer action pending additional information;
- c. Require modifications to the protocol and / or consent documents;
- d. Require that current subjects be provided with information regarding the Noncompliance or other relevant information;
- e. Require that current subjects be re-consented or notified in writing of the Noncompliance or of other relevant information;
- f. Require that subjects who previously participated in the research study be informed of the Noncompliance or of other relevant information;
- g. Modify the study's continuing review schedule;
- h. Suspend, in whole or in part, the research;
- i. Terminate the research;
- j. Require periodic audits of the study; and / or
- k. Any other action the IRB deems appropriate in relation to the Noncompliance.

2. Actions with Respect to the Investigator / Research Personnel Involved in the Serious Noncompliance

The IRB may take one or more of the following actions with respect to the Investigator / research personnel involved in the Serious Noncompliance:

- a. Require remedial education;
- b. Require oversight by a senior Investigator;
- c. Restrict the conduct of research;
- d. Restrict human subject research privileges; and / or
- e. Other disciplinary actions.

3. Reporting to Institutional Officials and Regulatory Agencies

If the IRB determines that the Allegation constitutes Serious Noncompliance or Continuing Noncompliance, further reporting to the Institutional Official and / or department or agency head is required in accordance with Section VI.

4. Communication to Research Personnel Involved in the Serious Noncompliance and the Complainant

The outcome of the IRB review may be communicated in writing to the complainant. The IRB Chair will notify the individual involved in the Noncompliance and will send copies of the findings to the Chair of the individual's research unit. Such notice to the individual will inform the individual that he / she has ten (10) business days from receipt of the notice to request reconsideration of the IRB's decision by sending the IRB a written request for reconsideration, including the basis for the individual's request. If an individual requests reconsideration, the request will be considered by the IRB Chair or by the IRB at the next convened IRB meeting, as appropriate. A determination will be made whether to uphold, reverse or modify the decision. The IRB Chair will notify the individual of the

outcome.

VI. Reporting to the Institutional Official and Regulatory Agencies

A. Reporting to the Institutional Official.

1. Depending on the event and the type of review, the IRB Chair (or his/her designee) will report in writing the following events to the Institutional Official:
 - a. UPs;
 - b. Noncompliance determined to constitute Serious or Continuing Noncompliance;
 - c. Suspensions; and
 - d. Terminations.
2. The contents of the report for the Institutional Official must include:
 - a. The title and protocol number of the research study
 - b. The name of the Investigator
 - c. A detailed description of the event
 - d. The related findings
 - e. Actions taken to address the issue
 - f. The basis for the reviewing individual / reviewing committee actions
 - g. The research study's IND number (if applicable)
 - h. Any further investigation or action recommended to be taken (if applicable)

B. Institutional Official Reporting Responsibilities.

1. Within fifteen (15) days, the Institutional Official (or his/her designee) will submit a formal report regarding the events identified to the following:
 - a. External Recipients (as appropriate):
 - i. OHRP, if the research study is subject to U.S. Department of Health and Human Services regulations
 - ii. Other federal agencies, if the research study is subject to those agencies and the agency requires reporting separate from that to OHRP
 - iii. FDA, if the research study is FDA-regulated
 - iv. The Sponsor of the research study, if appropriate
 - v. Funding source of the research study, if appropriate
 - b. Internal Recipients:
 - i. The IRB, if appropriate
 - ii. The Associate Provost for Research
 - iii. The Office of Sponsored Programs, if appropriate
 - iv. The Office of the General Counsel, if appropriate