11 Reporting to Institutional Officials, Regulatory Agencies, and AAHRPP

11.1 Reporting Triggers

Federal regulations require prompt reporting to appropriate institutional officials and, if the research is funded by an agency of the federal government, to the department or agency head of (a) any unanticipated problems involving risks to subjects or others or any serious or continuing noncompliance with this policy or the requirements or determinations of the IRB; and (b) any suspension or termination of IRB approval. The CMU HRPP will comply with this requirement, and the following procedures describe how these reports are handled.

Reporting procedures are initiated as soon as the IRB takes any of the following actions:

1. Determines that an event may be considered an unanticipated problem involving risks to participants or others.
2. Determines that non-compliance was serious or continuing.
3. Suspends or terminates approval of research.

11.2 Preparation of Report

The DRC or designee is responsible for preparing reports or letters which include the following information:

1. The nature of the event (e.g., unanticipated problem involving risks to participants or others, serious or continuing non-compliance, suspension or termination of approval of research).
2. Name of the institution(s) conducting the research.
3. Title of the research project and/or grant proposal in which the problem occurred.
4. Name of the PI on the protocol.
5. Number of the research project assigned by the IRB and the number of any applicable federal award(s) (e.g., grant, contract, or cooperative agreement).
6. A detailed description of the problem including the findings of CMU and the reasons for the IRB's decision.
7. Actions the institution is taking or plans to address the problem (e.g., revise the protocol, suspend subject enrollment, terminate the research, revise the informed consent document, inform enrolled subjects, increase monitoring of subjects, etc.).
8. Plans, if any, to send a follow-up or final report by the earlier of
    i. a specific date, or
    ii. when an investigation has been completed or a corrective action plan has been implemented.
9. The IRB Chair and the IO review the letter and modify the letter/report as needed.
10. The IO signs all correspondence from the facility.

11.3 Recipients of Report

The DRC or designee sends a copy of the report to the following:

1. The IRB, by including the letter in the next agenda packet as an information item.
2. The IO.
3. The following federal agencies:
   i. OHRP, if the study is subject to DHHS regulations or subject to a DHHS Federalwide Assurance.
   ii. FDA, if the study is subject to FDA regulations.
   iii. If the study is conducted or funded by any federal agency other than DHHS that is subject to "The Common Rule," the report is sent to OHRP or the head of the agency as required by the agency.

   Note: Reporting to a regulatory agency is not required if the event occurred at a site that was not subject to the direct oversight of Central Michigan University, and the agency has been notified of the event by the investigator, sponsor, another organization, or other mechanisms.
4. The PI.
5. The Sponsor, if the study is sponsored.
6. Contract research organization, if the study is overseen by a contract research organization.
7. Chairman or supervisor of the PI.
8. The Privacy Officer of a covered entity, if the event involved unauthorized use, loss, or disclosure of individually-identifiable patient information from that covered entity
9. The Information Security Officer of an organization if the event involved violations of information security requirements of that organization.
10. J. Office of Risk Management (if appropriate).
11. Others as deemed appropriate by the IO.

The DRC ensures that all steps of this policy are completed within ten (10) working days of the determination. For more serious actions, the DRC will expedite reporting.

11.4 Reporting to AAHRPP

CMU will report to AAHRPP will report:

1. Any negative actions by a government oversight office, including, but not limited to, OHRP Determination Letters, FDA Warning Letters, FDA 483 Inspection Reports with official action indicated, FDA Restrictions Placed on IRBs or Investigators, and corresponding compliance actions taken under non-US authorities related to human research protections.
2. Any litigation, arbitration, or settlements initiated related to human research protections, *subject to approval be university counsel.*
3 Any press coverage (including but not limited to radio, TV, newspaper, online publications) of a negative nature regarding the Organization's HRPP.

The report will be developed by the DRC and signed by the IO as soon as possible but generally with 48 hours after the organization becomes aware of any of the triggering events listed above.