“Assurances applicable to federally supported or conducted research shall at a minimum include [In order to fulfill the requirements of these regulations, each IRB shall]:

“[Follow] [w]ritten procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and the Department or Agency head [Food and Drug Administration] of (i) [1] any unanticipated problems involving risks to subjects or others [2] or any [instance of] serious or continuing noncompliance with this policy [these regulations] or the requirements or determinations of the IRB; and (ii) [or 3] any suspension or termination of IRB approval.” 45 CFR 46.103(b)(5), 21 CFR 56.108(b) [FDA]

Compliance with the federal regulations and institutional requirements applicable to reporting concerning human subject research is required of all individuals under the jurisdiction of the Michigan State University (MSU) Human Research Protection Program (HRPP). See HRPP Manual 4-1 “Applicability.”

Investigators are required to report activities, events, and/or information to the Institutional Review Board (IRB) for continuing review, for review of unanticipated events, revisions to the research, determination of exemption for emergency use of investigational drugs or devices, for closure of the research, and for any other circumstance that affects the rights and/or welfare of research subjects.

The IRB is required to promptly report to appropriate officials and entities if the IRB:

- Determines that there has been an unanticipated problem involving risks to subjects or others, or
- Determines that there has been serious or continuing noncompliance with this policy or the requirements or determinations of the IRB, or
- Suspends or terminates IRB approval.

**Investigator Reporting**

If reporting is required, the investigator notifies the IRB as detailed in the specific policy of the HRPP Manual:

- 4-6 Responsibilities of Investigators
- 7-3 Emergency Use of Investigational Drugs or Devices
- 8-1 Exemptions
IRB Reporting
When reporting is required, the report will provide adequate information and promptly be sent to appropriate individuals. The report could be a preliminary report, an interim report, or a final report. A preliminary report should be sent if further investigation or review is needed. The preliminary report will summarize the incident; provide a description of actions or steps to follow, and a time frame for investigation or review. The time frame may indicate that an interim report or final report will follow by the earlier of a specific date or when an investigation has been completed or a corrective action plan implemented. An interim report is sent if the investigation or review is still ongoing to provide updates as appropriate. The interim report will include a detailed description of the incident, preliminary findings, actions or steps, reasons for actions or steps, and a time frame for the investigation or review. A final report is sent at the conclusion of the investigation or review. The final report will include a detailed description of the incident, actions and steps taken, and any corrective actions taken. Updates or follow-up reports may be sent to appropriate officials as needed or requested. The report must be sent within 15 working days of the IRB's determination. For serious incidents, reporting may be required prior to 15 working days and may initially be reported verbally.

Each report, at a minimum, should include:
- Name of institution conducting the research
- Title of research study in which problem occurred
- Title of grant proposal in which problem occurred (when funded)
- Name of principal investigator on the research study
- Number of the research study assigned by the IRB
- Number of any applicable federal award(s) (grant, contract, or cooperative agreement (when funded)
- Detailed description of the unanticipated problem involving risks to subjects or others, the serious or continuing noncompliance, or the suspension or termination
- Actions the institution is taking, plans to take, or has taken to address the unanticipated problem involving risks to subjects or others, the serious or continuing noncompliance, or the suspension or termination (e.g. corrective or protecting actions) for the particular incident and institution-wide, when appropriate

The IRB chair, in consultation with others (i.e. IRB administration, IRB manager), will draft the report and provide the draft report to the HRPP director. The HRPP director will provide the draft report to the Institutional Official to finalize. The Institutional Official or
designee will send the report to appropriate individuals within 15 working days of the IRB’s determination.

The report will be sent to:

1. Assistant vice president for the Office of Regulatory Affairs
2. Other appropriate university administrators (e.g., vice presidents, deans, chairs)
3. U.S. Office for Human Research Protection (when research is covered by U.S. Department of Health and Human Services (DHHS) regulations)
4. U.S. Food and Drug Administration (FDA) (for all regulated FDA research)
5. University research integrity officer (in situations of possible misconduct)
6. Other IRBs which have approved the study or rely on an MSU IRB (if applicable)
7. Administrators at other sites where the research is being performed (if applicable)
8. Funding agency or sponsor (if applicable)
9. Other federal agencies when the research is overseen by those agencies, and they require reporting separate from to OHRP (if applicable) (e.g., Department of Defense)
10. Appropriate MSU IRB chair
11. Other affected individuals as determined appropriate by the IRB chair and/or HRPP director