Reporting to the Institutional Official and Regulatory Agencies

Content Applies To

Mayo Clinic Human Research Protection Program

Purpose

This document describes the IRB's requirements for reporting problems or events to the Institutional Official and/or to appropriate regulatory agencies and the allotted timeframe of fulfilling the reporting requirements.

Policy

Federal Regulations require the IRB to promptly report the following determinations to applicable regulatory agencies, i.e. Office of Human Research Protections (OHRP), Food and Drug Administration (FDA), Department of Defense (DoD), and the Mayo Clinic Institutional Official:

- Unanticipated problems involving risk to subjects or others
- Serious or continuing non-compliance with Federal regulations, IRB polices, or with determinations of the IRB
- Suspensions or terminations of IRB approval

The IRB Medical Director or IRB Administrator will notify the Institutional Official and applicable regulatory agencies, in writing, **within 30 days of the IRB's determination**.

Procedure

IRB Medical Director or IRB Administrator (or their designees) responsibilities include:

1. Drafting the notification letter, that includes a description of the problem or event, determination(s) of the IRB, action(s) taken by the IRB, corrective action plan(s) or modifications to the research, the name of the institution conducting the research, and the name of the Principal Investigator named on the research project. See the IRB document on *Preparing and Sending Notification Letters.*
2. Sending a copy of the notification letter to the following, as applicable:
    - Principal Investigator
    - Institutional Official
    - Office of Human Research Protection (OHRP) when the human research is supported by the Department of Health and Human Services (DHHS)
    - Food and Drug Administration (FDA) when the clinical investigation is subject to FDA regulations
    - Department of Defense (DoD) Human Research Protection Officer
    - Appropriate officials at external sites where the research is conducted for whom Mayo Clinic IRB serves as the IRB of Record
    - At the discretion of the IRB Medical Director or pursuant to a determination of the IRB, to other appropriate Mayo department

chairperson(s) or others, **including other institutions and/or regulatory agencies**

- For determinations of serious and/or continuing non-compliance, a copy of the notification letter should be sent to the following Mayo Clinic officials:
    1. Department Chair of the PI
    2. Research Compliance Officer, Rochester, MN
    3. Chair of Personnel Committee at the respective location
    4. Dean of Research at the respective location
    5. Administrator(s), Office for Human Research Protection Office

3. Documentation of notification letters are uploaded in the IRB electronic study file and are also maintained in the IRB Administrative Office files.
4. Department of Defense (DoD) Supported Research:
    - Determinations of serious or continuing non-compliance, unanticipated problems involving risk to subjects or others, or suspension or termination of DoD supported research must be reported within 30 days to the DoD Human Research Protection Officer.

Related Documents

Preparing and Sending Notification Letters

Suspension or Termination of IRB Approval of Research

Reporting an Unanticipated Problem Involving Risks to Subjects or Others (UPIRTSO) to the IRB

References

Association for the Accreditation of Human Research Protection Programs (AAHRPP) version 1/2012

45 CFR Part 46 - Protection of Human Subjects

21 CFR 50 - Protection of Human Subjects