Reporting to the Institutional Official and Regulatory Agencies

Content Applies To
Mayo Clinic Human Research Protection Program
Research for which Mayo Clinic IRB is the IRB of Record

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) and the corresponding Department of Health and Human Services (DHHS) agency when the human research is supported by the 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
- Submitting a Reportable Event to the IRB
- Submitting a Reportable Event when Mayo Clinic IRB is not the IRB of Record

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

Effective Date
- September 27, 2016

Revision History

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<th>Date</th>
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<td>September 27, 2016</td>
<td>Scheduled review. No changes.</td>
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