Reporting to the Institutional Official and Regulatory Agencies Procedure

Scope

Applies to personnel within the Mayo Clinic Human Research Protection Program (HRPP) when reporting problems and events to the Institutional Official and regulatory agencies about research for which Mayo Clinic Institutional Review Board (IRB) is the IRB of Record.

Purpose

To describe 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.

Equipment/Supplies

N/A

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, actions 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. Refer Preparing and Sending Notification Letters Procedure.
2. Sending a copy of the notification letter to the following, as applicable:
    a. Principal Investigator (PI)
    b. Institutional Official
    c. OHRP and the corresponding Department of Health and Human Services (DHHS) agency when the human research is supported by the DHHS
    d. Food and Drug Administration (FDA) when the clinical investigation is subject to FDA regulations
    e. Department of Defense (DoD) Human Research Protection Officer
    f. Appropriate officials at external sites where the research is conducted when Mayo Clinic IRB is the IRB of Record
    g. 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**
    h. For determinations of serious and/or continuing non-compliance, a copy of the notification letter should be sent to the following Mayo Clinic officials:
        i. Department Chair of the PI

ii. Research Compliance Officer, Rochester, MN
iii. Chair of Personnel Committee at the respective location
iv. Dean of Research at the respective location
v. 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:
    a. 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.

Troubleshooting

N/A

Procedural Notes

- Federal Regulations require the IRB to promptly report the following determinations to applicable regulatory agencies, including 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 (UPIRTSO)
    - 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**.

Related Documents

Preparing and Sending Notification Letters Procedure

Submitting a Reportable Event to the Institutional Review Board (IRB) Policy

Submitting a Reportable Event When Mayo Clinic Institutional Review Board (IRB) is not the IRB of Record Policy

Suspension or Termination of IRB Approval of Research Policy

Definitions

N/A

References

21 CFR 50 Protection of Human Subjects

45 CFR Part 46 Protection of Human Subjects

Association for the Accreditation of Human Research Protection Programs (AAHRPP)

Owner

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Revision History

Date	Synopsis of Change
01/25/2024	Scheduled review. Updated Owner and Contact,
04/28/2021	Scheduled review. Transferred to the standardized template. Updated Owner and Contact, and minor edits.
09/27/ 2016	Scheduled review. No changes.
03/03/2016	Under Related Documents: Fixed broken link for Preparing and Sending Notification Letters.
	Approval for need to establish document: Unknown

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Applicable Sites

Arizona Sites:
Arizona

Florida Sites:
Florida

Rochester Sites:
Duluth, Kasson, Litchfield, Little Falls, Minneapolis, Northfield, Rochester, St. Cloud, Superior

NW WI Region:
Barron, Bloomer, Chetek, Chippewa Falls, Eau Claire, Glenwood City, Menomonie, Mondovi, Osseo, Rice Lake

SE MN Region:
Adams, Albert Lea, Austin, Cannon Falls, Ellsworth, Faribault, Lake City, Lake Mills, New Richland, Owatonna, Plainview, Red Wing, Wells, Zumbrota

SW MN Region:
Belle Plaine, Fairmont, Janesville, Le Sueur, Mankato, Montgomery, New Prague, St. James, St. Peter, Waseca, Waterville

SW WI Region:
Arcadia, Caledonia, Holmen, La Crosse, Onalaska, Prairie du Chien, Sparta, Tomah

Reviewer(s):

Approver(s):

Michelle K. Daiss