Marshfield Clinic

Suspension and Termination of Research

1. SCOPE

1.1. System Wide

2. DEFINITIONS & EXPLANATIONS OF TERMS

2.1. Institutional Official

- The individual named on the Federal Wide Assurance as Institutional Official.

2.2. Non-compliance

- Continuing non-compliance
  - ◊ When the same investigator, research staff member, IRB, IRB member, or ORIP staff member makes multiple departures from established human subject protection requirements, IRB policies or procedures, and/or rulings of the IRB, after an initial instance of non-compliance has been addressed.
- Serious non-compliance
  - ◊ Any of the following that occurs in a research study, or by MCRF IRB or its staff:
    - Intentional departure from established human subject protection requirements, IRB policies or procedures, and/or rulings of the IRB specific to a research activity;
    - Unintentional departure from established human subject protection requirements, IRB policies or procedures, and/or rulings of the IRB specific to a research activity that seriously jeopardized the rights and/or welfare of the research subjects;
    - Greater than minimal risk human subjects research conducted without IRB review and approval;
    - Greater than minimal risk human subjects research conducted without legally effective informed consent. This does not include circumstances where the subject or their legally authorized representative signs on the wrong line of the consent document (i.e., signing assent line in error); or
    - Substantive modifications to IRB-approved research, which are changes that have the potential of materially affecting the risk/benefit assessment of the study, without prior IRB approval.

2.3. Suspension

- An official action by the IRB to suspend or temporarily close the conduct of a specific aspect of a study or an entire study. Suspension does not include protocol-planned suspension (e.g., for interim data analysis).

2.4. Termination

- The permanent closure of a study and its IRB oversight. Termination may be initiated "for cause" by the IRB or voluntarily by the principal investigator.

3. PROCEDURE BODY

The Marshfield Clinic Research Foundation Institutional Review Board (MCRF IRB) has the authority to suspend or terminate approval of human subjects research when it is not being conducted in accordance with human subjects protection requirements, IRB policies or procedures, rulings of the IRB, or when it has been associated with unexpected serious harm to subjects or others. This policy describes the IRB's authority to suspend or terminate research, discusses considerations prior to and upon suspending or terminating a study, and in conjunction with the document, "Reporting to IRB, Institutional Officials, and Regulatory Bodies," outlines the requirements imposed by federal regulations at 45 CFR 46.113 and 21 CFR 56.113 to report such suspensions or terminations.

3.1. Authority to Suspend Research

a. The MCRF IRB Chairperson, or in the Chairperson's absence, a designee (the Vice-Chair, Assistant Director of the Office of Research Integrity & Protections (ORIP), or a MCRF IRB member who is a physician or PhD) may act to suspend previously approved human research, or an investigator's or key personnel's privilege to conduct human subject research. The Chairperson or designee can do so when there is alleged serious or continuing noncompliance with human subject protection requirements, IRB policies or procedures, rulings of the IRB, or when an incident that has been associated with unexpected serious harm to subjects appears to pose imminent threat to subject safety. The designee will contact the Chairperson as soon as possible to confirm the decision.

b. ORIP staff will place the suspensions imposed by the IRB Chairperson or designee on the next convened IRB meeting agenda. The convened board will confirm or reverse the decision to suspend or terminate the previously approved research.

3.2. Suspension and Termination Considerations

a. Before MCRF IRB, or the IRB Chairperson or designee, considers imposing a suspension or termination of approval of research, it should consider the effect that the suspension or termination may have on the rights and welfare of current research subjects. It should also consider whether any additional actions should be taken to protect research subjects' interests, including:

   - Requiring the Principal Investigator (PI) or research staff to follow up with research subjects;
   - Transferring responsibility for the research study to a different PI;
   - Referring subjects for follow-up with a health care provider; and
   - Referring subjects to stay on the study if it is conducted at another institution.

b. If a termination or suspension of research approval involves the disenrollment of current research subjects, the PI and research staff must:

- Notify subjects that their enrollment has been suspended or terminated, providing the reasons as those recognized by the IRB. The notice to subjects may be verbal or in writing, as determined appropriate by the IRB;
- Inform subjects of any actions the PI and research staff will take to ensure the subjects' rights and welfare are protected; and
- When follow-up of subjects is necessary, informed the subjects of that fact, and indicate any adverse events or unanticipated problems involving risks to participants or others will be reported to the appropriate regulatory bodies. See the document, "Reporting to IRB, Institutional Officials, and Regulatory Bodies."

c. The MCRF IRB will inform the Institutional Official and investigators of all suspensions and terminations as they occur, per the document, "Reporting IRB Actions and Findings to the Investigator and Institution."

d. The MCRF IRB can take require additional actions when suspensions or terminations occur, including responding to any alleged non-compliance in accordance with the document, "Non-Compliance in Human Subjects Research," educating investigators , key personnel, or all research staff, or require monitoring of an investigator or project.

3.3. Reporting Suspensions and Terminations Externally

a. Suspensions or Terminations of approved research will to be reported as required by the policy, "Reporting to IRB, Institutional Officials, and Regulatory Bodies." Investigators should be familiar with their reporting responsibilities, and ORIP will perform its reporting duties, each as outlined in that document.

b. For multi-site studies, if the IRB believes a problem leading to suspension or termination is a factor at other sites, it will report the concern as part of the suspension or termination notification to external bodies.

4. ADDITIONAL RESOURCES

4.1. References:

- Reporting IRB Actions and Findings to the Investigator and Institution
- Reporting to IRB, Institutional Officials, and Regulatory Bodies

4.2. Supporting documents available:

- None.

5. DOCUMENT HISTORY

Version No.	Revision Description
1.0	New Document in Document Control transferred from Policy & Handbook Library - #4444.1 Revised definition of termination.

2.0	
3.0	

6. DOCUMENT PROPERTIES

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