Marshfield Clinic

Enhancing Understanding and Responding to Human Research Questions, Concern & Input

1. SCOPE

1.1. System-Wide

2. DEFINITIONS & EXPLANATIONS OF TERMS

2.1. None

3. PROCEDURE BODY

This document sets forth the process that Marshfield Clinic Research Foundation's (MCRF) Office of Research Integrity and Protections (ORIP) will use to enhance the understanding of participants, prospective participants and communities as well as processes for responding to questions, concerns or input regarding the human research process that are received from research participants or others.

3.1. Enhancing Understanding of Human Participant Research

a. Marshfield Clinic Research Foundation (MCRF) websites will include information on ongoing research, the clinical trial process, human participant protection requirements and processes, and other information to enhance participant, prospective participant and community understanding.

b. Pamphlets and brochures on clinical research and research participant responsibilities and rights may be available in patient waiting areas.

c. MCRF will periodically publish and distribute information on research being conducted at Marshfield Clinic (MC).

d. An annual questionnaire will evaluate participant, prospective participant and community understanding of human participant research. Results will be used to respond to the concerns and questions of research participants.

3.2. Accepting Questions/Concerns/Input

a. The individual receiving the initial communication from research participants or others will document the general nature of the issue, the parties involved and the date the communication was received, and will then refer the issue to one of the following individuals::

- Institutional Review Board (IRB) Chairperson
- Institutional Review Board (IRB) Administrator

b. Depending on the nature of issue, it may be subsequently re-directed to or the above-named individuals may consult with:

- Marshfield Clinic Risk Management Nurse Manager (patient care issues)
- Marshfield Clinic Privacy Officer (privacy issues)
- Marshfield Clinic Legal Services Department

- An appropriate Manager within the Clinic or Foundation

3.3. Process for Responding

a. Regardless of the party handling the issue, every attempt will be made to consider, and if necessary, investigate and resolve within 30 working days of receipt of the initial communication. If this is not possible, the party handling the issue will provide an update to the research participant or other individual who raised the issue, if the party raising the issue is expecting a response.

b. Final resolution will be appropriately communicated, as deemed necessary by the party handling the issue.

c. When determined to be non-compliance, the issue will be handled as dictated by policy, "Non-Compliance with Federal Regulations, Institutional Policies and IRB Approved Applications and Protocols." If it is determined that the non-compliance requires tracking or reporting per other IRB policies, necessary steps will be taken.

d. Any issue that is determined to involve privacy concerns will be handled as dictated by institutional policy "Review and Resolution of Privacy Complaints." Any issue involving facts that may meet the definition of research misconduct will be handled in accordance with policy, "Responding to Allegations of Research Misconduct."

4. ADDITIONAL RESOURCES

4.1. References:

- Non-Compliance with Federal Regulations, Institutional Policies and IRB Approved Applications and Protocols
- Responding to Allegations of Research Misconduct
- Review and Resolution of Privacy Complaints

4.2. Supporting documents available:

- None.

5. DOCUMENT HISTORY

Version No.	Revision Description
1.0	New Document in Document Control System transferred from Policy & Handbook Library - #1531.3. Remove reference to Director of ORIP; Updated title of non-compliance procedure. Changed 3.1.d statement to address AAHRPP standard of the annual questionnaire.
2.0	Add hyperlink to other applicable policies in this document

3.0	

6. DOCUMENT PROPERTIES

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