Marshfield Clinic

Human Subject Protection Training

1. SCOPE

1.1. System Wide

2. DEFINITIONS & EXPLANATIONS OF TERMS

2.1. Engaged in Research:

- The Institution's employees or agents intervene or interact with human subjects for purposes of research; or
- The Institution's employees or agents obtain individually identifiable private information about human subjects for purposes of research;

3. PROCEDURE BODY

3.1. Background

- Marshfield Clinic and the Marshfield Clinic Research Foundation acknowledge the need for and importance of providing its researchers with both initial and continuing education on the protection of human subjects who choose to participate in medical research. The Federal Office of Human Research Protections (OHRP) and the National Institutes of Health (NIH) also recognize this need.
- OHRP strongly recommends that institutions and their IRBs establish a mechanism to ensure that research investigators, IRB members and staff, and other appropriate personnel maintain continuing knowledge of, and comply with relevant ethical principles and federal regulations, institutional policies and IRB procedures for the protection of human subjects, OHRP and other applicable guidance, and state and local laws. Furthermore, OHRP recommends that IRB members and staff complete relevant educational training before reviewing human subjects research, and that research investigators complete appropriate institutional educational training before conducting human subjects research.
- The National Institutes of Health requires investigators to provide a description of education completed in the protection of human subjects for all "key personnel" involved in NIH funded research. This policy applies to investigators applying to NIH for new grants and contracts involving human subjects research, as well as to investigators who receive competitive or non-competitive continuation awards. "Key personnel" is defined in the NIH policy as all individuals responsible for the design and conduct of the study.
- Effective October 1, 2006, MCRF has required human subjects protection training through the Collaborative IRB Training Initiative (CITI). CITI is a web-based training program that began as a collaborative undertaking between the University of Miami and Fred Hutchinson Cancer Center. CITI content was developed (and is regularly updated) by a national consortium of experts in human subjects research protections. Over 600 institutions subscribe to CITI, which is maintained on a secure server at the University of Miami (https:// www.citiprogram.org).

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3.2. MCRF requires human subjects protection training be completed via the CITI program. www.citiprogram.org. Those not completing CITI training will not be allowed to serve as IRB staff, or be engaged in or conduct review of human subject research. The IRB may, at any time, require additional training for a specific individual or those personnel involved on a specific project.

3.3. To supplement the required computer-based training program, MCRF Office of Research Integrity & Protections (ORIP) will offer other optional educational opportunities including presentations by internal staff, presentations by external speakers, webinars, and conference opportunities.

3.4. Principal Investigators (PIs) who wish to submit a research protocol for IRB review must first complete the required initial CITI training modules. Co-investigators (Co-Is) will be approved for work on new studies only after the individual has completed the required initial CITI training. Co-investigators who do not have CITI training completed at the time of new study submissions are not allowed to participate in research activities until the training requirements are met and confirmed. Thereafter, investigators and co-investigators must be "current" with their CITI training prior to opening a new study or serving as a co-investigator on a new study. "Current" is defined as having completed initial or "refresher" CITI training within the past two years.

3.5. All others who are required by this policy to complete CITI training must do so prior to engagement in, review of, or administration of human subject research, and then every two years. The CITI program issues a notice to complete refresher training to anyone who has completed the initial training. This notice is issued 30 days prior to expiration.

3.6. IRB staff will verify that training requirements are met for PIs and Co-Is before issuing the study approval notice.

3.7. Ongoing compliance with training requirements for others is the responsibility of the PI and may be confirmed by ORIP through random monitoring. Those found to be non-compliant upon monitoring must stop their involvement in human subject research until training requirements are met.

3.8. Human Use Device (HUD) protocols and projects deemed to be IRB Exempt, reviewed by the IRB are not considered research and therefore training requirements referenced in this policy do not apply.

4. ADDITIONAL RESOURCES

4.1. References:
- None

4.2. Supporting documents available:
- None

PROCEDURE

5. DOCUMENT HISTORY

Version No.	Revision Description
1.0	New Document in Document Control System transferred from Policy & Handbook Library - #2016.5. (no changes made)
2.0	
3.0	

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6. DOCUMENT PROPERTIES

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