University of Maryland School of Nursing Human Subjects Research Required Education and Oversight

Responsible Administrator: Associate Dean of Research
Sponsoring Unit: Office of Research and Scholarship
Effective Date: 01/03/2017
Last Reviewed: 09/21/17
Next Scheduled: 06/2020

POLICY STATEMENT

This policy establishes requirements for education, training, and oversight for University of Maryland School of Nursing (UMSON) employees and affiliates engaged in human subjects research.

RATIONALE

To provide systematic and ongoing education, training, and oversight and additional protections for human subjects, UMSON has implemented requirements for individuals engaged in human subjects research. This policy supplements human subjects protections training required by the University of Maryland, Baltimore Human Research Protections Program (UMB HRPP).

SCOPE

This policy applies to all UMSON employees and affiliates engaging in human subjects research at UMSON.

RELATED POLICIES, PROCEDURES, STATUTES, AND REGULATIONS

- University of Maryland Human Research Protections Office protection of human subjects training requirements[1]

CONTACTS

Office of Research and Scholarship

RESPONSIBILITIES

Principal Investigator (PI)
Responsible for all activities associated with the conduct of the research study and for ensuring compliance with all applicable policies and regulations

[1] https://www.umaryland.edu/hrp/for-researchers/required-training/

Office of Research and Scholarship (ORS)
Responsible for providing support to UMSON employees and affiliates conducting human subjects research

Associate Dean of the PhD Program
Responsible for reviewing annual research reports submitted by PhD students

UMSON Employees and Affiliates
Responsible for maintaining and documenting required human subjects research training

Faculty Advisor
Responsible for overseeing and supervising students conducting research and for ensuring adherence to applicable policies and regulations governing human subjects research; responsible for providing relevant research training and ongoing education

PROCEDURES

1. All UMSON employees and affiliates engaged in human subjects research are required to complete **ONE** of the following courses:
    - National Drug Abuse Treatment Clinical Trials Network Good Clinical Practice (GCP) course (https://gcp.nihtraining.com/)
    - GCP for Social and Behavioral Research course offered through The Society of Behavioral Medicine (http://www.sbm.org/training/good-clinical-practice-for-social-and-behavioral-research-elearning-course) or through the CITI program as GCP-Social and Behavioral Research Best Practices for Clinical Research (www.citiprogram.org).

    Certificates of completion must be emailed to ORS at NRS-research@umaryland.edu. GCP training should be completed initially and then every three years, consistent with the course refresher requirements for the Collaborative Institutional Training Imitative (CITI) protection of human subjects training course. All PhD students are required to retake the GCP and CITI protection of human subjects refreshers prior to their dissertation proposal defenses. The UMB HRPP and/or sponsors may require additional training.

2. To assist new UMSON employees and affiliates engaged in human subjects research, ORS must review regulatory files and case report forms prior to study initiation. Reviews will occur for any investigators conducting their first studies as UMSON investigators or for students (and their faculty advisor) conducting their first studies at UMSON. As part of new research staff training, ORS will be available to review the regulatory file with new staff for applicable studies at the request of the investigator. New investigators will be required to complete an Investigator Quality Assurance Assessment within the first six months of enrolling the first study participant. ORS will be available to help investigators complete ongoing monitoring, to review findings, and to create corrective action plans if necessary.

3. Annual quality assurance monitoring for Greater than Minimal Risk studies is required. To support investigators, ORS will assist researchers in conducting annual monitoring within the four months preceding the continuing review of all active and enrolling studies classified as Greater than Minimal Risk. ORS also will provide study monitoring for any study upon request of the PI or at the discretion of the associate dean of research.

4. All PhD students conducting human subjects research projects under the supervision of a faculty advisor are required to submit an annual study status report to their faculty advisor and to the associate dean of the PhD program. To support faculty advisors, ORS will be available to review the reports and offer recommendations at the request of the student, the faculty advisor, or the associate dean of the PhD program. This annual report will include the following information:
    - projected IRB approved enrollment number
    - total number of participants enrolled to date
    - summary of modifications to the protocol over the last year
    - summary of any reportable new information submitted to date
    - summary of any adverse events occurring to date
    - summary of study findings to date
    - plans for the upcoming year
    - projected completion date.

5. To support faculty advisors and students conducting human subjects research, PhD students and their advisors must complete annual self-monitoring. ORS will be available to assist with monitoring, to review findings, and to create corrective action plans if necessary.

6. ORS will work with the PhD and DNP faculty to offer additional human subjects research education content to students, aimed at improving research processes and raising awareness of applicable regulations, policies, and guidance.

7. ORS will provide human subjects research training and educational opportunities for those involved in human subjects research and will continue to be a resource for human subjects-related issues and concerns. ORS will recommend and make available additional trainings, such as the NIH Human Subjects Protections online training (https://phrp.nihtraining.com/users/login.php) or the Office of Research Integrity Research Clinic simulation exercise (https://ori.hhs.gov/the-research-clinic).

8. These requirements will be added to the PhD program guidelines.

SPECIAL INSTRUCTIONS FOR INITIAL IMPLEMENTATION

Research team members must keep CITI protection of human subjects training, Health Insurance Portability and Accountability Act (HIPAA), and GCP training documentation on file. These records should be placed in appropriate study binders, if applicable. Students involved in human subjects research are required to submit documentation of completion to the PI of the study and to the associate dean of their degree program.

UMSON employees and affiliates engaged in human subjects research are required to submit initial documentation of GCP training to ORS within three months of policy implementation. UMSON employees and affiliates are responsible for providing training documentation to the University of Maryland, Baltimore Human Research Protections Office (HRPO) as applicable.

DATE AND SIGNATURE

Date: September 21, 2017

Approved by the Dean: