



UNIVERSITY of MARYLAND SCHOOL OF NURSING

Human Subjects Research Required Education and Oversight

Responsible Administrator: Associate Dean for Research

Sponsoring Unit: Office of Research and Scholarship

Effective Date: 01/03/2017

Last Reviewed: 06/02/2020

Next Scheduled: 03/2024

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 for 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 Good Clinical Practice (GCP) courses:
 - National Drug Abuse Treatment Clinical Trials Network GCP course (<https://gcp.nidatrain.org/>)
 - GCP eCourse offered through The Society of Behavioral Medicine (www.sbm.org/training/good-clinical-practice-for-social-and-behavioral-research-elearning-course)
 - Collaborative Institutional Training Initiative (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 NRSresearch@umaryland.edu. GCP training should be completed initially and then every three years, consistent with the course refresher requirements for the CITI protection of human subjects training course. All PhD students are required to retake the GCP and CITI protection of human subjects refreshers within the six months 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 for 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 for 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 for the PhD program. This annual report will include the following information:
 - projected Institutional Review Board 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 Doctor of Nursing Practice 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 [Protecting Human Research Participants online training](https://phrptraining.com/)² or the U.S. Department of Health and Human Services [Office of Research Integrity Research Clinic simulation exercise](https://ori.hhs.gov/the-research-clinic)³.
8. These requirements are included in the PhD program guidelines.

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: June 8, 2020

Approved by the Dean:



² <https://phrptraining.com/>

³ <https://ori.hhs.gov/the-research-clinic>