Human Subjects Scientific, Ethical, and Feasibility Review

Responsible Administrator: Associate Dean for Research
Sponsoring Unit: Office of Research and Scholarship
Effective Date: 12/05/2016
Last Reviewed: 04/06/2021
Next Scheduled Review: 01/2025

POLICY STATEMENT

The University of Maryland, Baltimore (UMB) Human Research Protections Plan (HRPP) requires all human subjects research protocols submitted to the UMB Institutional Review Board (IRB) to undergo department or entity scientific, ethical, and feasibility review by a UMB school designee, hereinafter referred to as the signatory.

RATIONALE

The purpose of this policy is to meet the UMB HRPP requirement and ensure that all human subjects research conducted by University of Maryland School of Nursing (UMSON) investigators meets ethical and regulatory requirements and is scientifically meritorious.

SCOPE

This policy applies to all investigators conducting human subjects research at UMSON.

RELATED POLICIES, PROCEDURES, STATUTES, AND REGULATIONS

- UMB Human Research Protection Program Plan[1]
- UMSON Human Subjects Research Required Education and Oversight[2]
- UMSON Protected Health and Private Information Research Data Use and Storage[3]

CONTACTS

Questions regarding this policy should be directed to the Responsible Administrator.

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[1] http://www.umaryland.edu/media/umb/oaa/hrp/documents/HRP-101---HRPP-Plan.pdf
[2] https://www.nursing.umaryland.edu/intranet/media/son/intranet/policies-procedures/Policy-Human-Subjects-Research-Required-Education-Oversight.pdf
[3] https://www.nursing.umaryland.edu/intranet/media/son/intranet/policies-procedures/Protected-Health-Information-Research-Data-Use-Storage.PDF

DEFINITIONS

UMSON Principal Investigator (PI) – a full-time (> 51%) faculty investigator holding the rank of assistant professor or higher at UMSON

Other individuals (i.e., staff or students) may be involved in the conduct of a research study; however, only full-time faculty members holding the rank of assistant professor, associate professor, or professor may qualify as the PI unless otherwise granted approval. When the PI for clinical studies involving medical/clinical interventions or investigational agents does not have an MD, a sub-investigator who is a qualified MD with appropriate expertise must be on the study. The PI requirements noted above can be found in the UMB Human Research Protections Investigator Manual[4].

RESPONSIBILITIES

UMSON Office of Research and Scholarship

UMSON's associate dean for research (ADR) is responsible for appointing a signatory and ensuring the implementation of this policy. The ADR, research quality manager, or designee will be available for consultation on issues related to the conduct of human subjects research at UMSON and will ensure that appropriate levels of review are conducted.

UMSON Signatory

The UMSON signatory is responsible for conducting the scientific review for all UMSON human subjects research protocols. The signatory makes a determination of approved, modifications required, or disapproved based on findings from the review. An alternate signatory will be selected by the ADR in the event the primary signatory is unavailable or unable to conduct the review.

Research Quality Manager

The research quality manager for UMSON is responsible for conducting ethical and feasibility review for all UMSON human subjects research protocols jointly with the UMSON Signatory.

UMSON PI

The UMSON PI submits all human subjects research protocols for review using the electronic submission system, CICERO. The PI also is responsible for ensuring that the CICERO submission is complete and that all requests for modifications, clarifications, or concerns raised by the signatory are addressed.

UMSON Scientific Review Designee/Committee

At the discretion of the UMSON signatory or ADR, an individual or committee of individuals can be assigned to provide additional scientific review of UMSON protocols.

PROCEDURES

All initial human subjects research protocols are submitted by the PI to the signatory for review in CICERO. An investigator may request a pre-review of the submission from the research quality manager and/or signatory prior to submission. The signatory will review the protocol and

[4] https://www.umaryland.edu/hrp/for-researchers/investigator-manual/

assess the scientific merit. The research quality manager will review the protocol to assess available resources (i.e., qualified staff, adequate facilities, and availability of medical or psychological resources that human subjects may need as a consequence of the research), potential conflicts of interest (COI), and study feasibility. The signatory and research quality manager may also identify other issues related to the scientific merit or the protection of human subjects and query as appropriate.

Additional consultation during the review may be sought, or the review may be assigned to a secondary reviewer or committee. This consultation may include a single individual with appropriate expertise or a committee of individuals. All protocols submitted as Greater Than Minimal Risk, conducting clinical interventions with a vulnerable population, or at the signatory's discretion will be assigned to a secondary review by an individual or committee. Protocols already receiving a secondary or specialty review (i.e., review by the Veterans Affairs Maryland Health Care System, Greenebaum Comprehensive Cancer Center, or pediatric reviewer) or having been approved by an external IRB will be exempt from an additional secondary review at UMSON. If the signatory has a conflict of interest, whether real or perceived, he/she will assign the review to another designated individual with the expertise and knowledge to complete the review.

The signatory or committee will review the protocol and answer the following questions in CICERO as required by the UMB IRB:

1. Is the research question meritorious?
2. Is the study design sound/valid?
3. Is the study design able to answer the proposed questions, and is it likely to result in significant new information for the field?
4. Is the sample size adequate to answer the major scientific questions in the project?
5. Have all potential risks been identified?
6. Does the protocol incorporate all possible mechanisms for reducing risks?
7. Are there adequate resources (i.e., adequate number of qualified staff, adequate facilities, availability of medical or psychological resources that participants may need as a consequence of the research, and adequate access to patients/participants) to carry out the study and to ensure the safety and welfare of all participants?
8. Are all investigators aware of their responsibilities with respect to the study?
9. Does the PI have adequate time and expertise to supervise the study appropriately?
10. Have the financial implications of the research been considered and deemed acceptable to the department?
11. Have ethical principles and conflict of interest issues been appropriately addressed?

The signatory will document his/her review by answering the questions in CICERO and make a determination of:

- Approval
  If approved with no modifications requested, the signatory will enter a brief description of his/her findings and submit to the IRB for review.

- Modifications Required
  If modifications are required, the signatory will return the CICERO application to the PI to address queries. The PI will address the required modifications and return to the

research quality manager and signatory via email prior to resubmission in CICERO for review. The research quality manager and signatory will review the protocol to ensure all requested modifications were addressed. If all modifications were satisfactorily addressed, the PI will be asked to return the protocol in CICERO for UMSON signatory approval and subsequent specialty or IRB review. The signatory may return the submission to the PI for additional revisions, if needed.

- Disapproval
  The signatory may only disapprove a protocol after consultation with a scientific review committee and the ADR. All efforts will be made to assist the PI with revising the protocol to meet standards for approval.

FORMS AND TOOLS

UMB HRPP Investigator Manual and Resources

The UMB HRPP Investigator Manual[5] guides investigators through policies, procedures, and relevant regulations. In addition, the UMB HRPP provides resources to assist investigators in the responsible conduct of research and with adhering to applicable policies, procedures, and relevant regulations. Investigators are encouraged to become familiar with the Investigator Manual and utilize UMB HRPP resources.

- UMB HRPP Investigator Manual[6]
- UMB HRPP Investigator Manual Referenced Materials[7]
- UMB HRPP Investigator Resources[8]
- UMSON Researcher Toolkit[9]

DATE AND SIGNATURE

Date: April 6, 2021

Dean's Signature: 

[5] https://www.umaryland.edu/hrp/for-researchers/investigator-manual/
[6] https://www.umaryland.edu/hrp/for-researchers/investigator-manual/
[7] https://www.umaryland.edu/hrp/for-researchers/investigator-manual/referenced-materials/
[8] https://www.umaryland.edu/hrp/for-researchers/
[9] https://www.nursing.umaryland.edu/research/resources/regulatory-affairs/researcher-toolkit/