



# UNIVERSITY of MARYLAND SCHOOL OF NURSING

## Procedures for Submission of Human Subjects Research Protocols to the University of Maryland, Baltimore Institutional Review Board

**Responsible Administrator:** Associate Dean for Research

**Sponsoring Unit:** Office of Research and Scholarship

**Effective Date:** 01/18/2022

**Last Reviewed:** 01/18/2022

**Next Scheduled Review:** 10/2023

### PROCEDURE STATEMENT

This procedural document is intended to support the UMSON [Policy on Human Subjects Scientific, Ethical, and Feasibility Review](#)<sup>1</sup>. All new human subjects research proposed by University of Maryland School of Nursing (UMSON) investigators must be reviewed and approved by the UMSON research quality manager and the University of Maryland, Baltimore (UMB) Institutional Review Board (IRB) signatory (departmental reviewers) prior to being submitted for Human Research Protections Office (HRPO) and IRB review. Prior to submission of your protocol for departmental review, you must:

1. Ensure that the current Good Clinical Practice training for all study team members listed in the CICERO (IRB) application have been sent to [NRSresearch@umaryland.edu](mailto:NRSresearch@umaryland.edu).
2. Ensure that any consent forms, if included, are written at an 8th-grade reading level to the best extent possible, avoiding multisyllabic words and “manuscript speak.” The concise summary on the consent form should be written conversationally and simplified. (Hint! It should read as though it were being relayed to someone in a grocery store line).

### PROCEDURES (For a stepwise table, please see next page.)

1. Submit the CICERO application for UMSON departmental review. The UMSON research quality manager will conduct the primary ethical review. The UMSON IRB signatory will further evaluate the scientific merit and feasibility of the protocol and screen for any other issues related to the protection of human subjects, potential conflicts of interest, and/or availability of resources.
2. The research quality manager will contact the principal investigator (PI) by email when the initial review has been completed, sending a Word document that lists any queries to be addressed. The CICERO application will then be returned to the PI by the IRB signatory so that required modifications can be made.
  - a. In addition to making the requested modifications in CICERO, the study team should record their responses to each of the departmental queries listed in the Word document. When the

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<sup>1</sup> <https://www.nursing.umaryland.edu/intranet/media/son/intranet/policies-procedures/Policy-Human-Subjects-Scientific-Ethical-Feasibility-Review.PDF>

queries have been addressed, the updated Word document should be returned to the departmental reviewers by email for further review.

- b. The protocol should not be resubmitted in CICERO until the departmental reviewers have evaluated the study team’s responses to the initial inquiries and have determined that all concerns have been sufficiently addressed. At that point, the UMSON research quality manager will notify the PI to resubmit the protocol in CICERO.

3. After the protocol has been resubmitted, the IRB signatory makes a determination of “approved,” and the application will automatically move forward to the administrative reviewer in the HRPO/IRB.

Steps	Instructions
<p><b>Step 1:</b> PI prepares CICERO application</p> <p style="text-align: center;">↓</p>	<p>See notes in Procedure Statement above. Ensure application is complete, clean, free of references outside of the reference section, without grammatical/spelling errors, and contains only answers relevant to the respective question.</p> <p>Research quality manager is available for any questions that arise while the application is being completed, if needed.</p>
<p><b>Step 2:</b> PI submits CICERO application</p> <p style="text-align: center;">↓</p>	<p>Submit via CICERO web portal</p>
<p><b>Step 3:</b> Departmental reviewers review application</p> <p style="text-align: center;">↓</p>	<p>Departmental reviewers are automatically notified via CICERO that the application has been submitted and is ready for review.</p>
<p><b>Step 4:</b> Departmental reviewers send queries to PI via email</p> <p style="text-align: center;">↓</p>	<p>The queries sent by email are outlined in a Word document. Queries should be addressed in the document in addition to being updated in CICERO.</p>
<p><b>Step 5:</b> PI addresses queries and returns the Word document to departmental reviewers for counter-review</p> <p style="text-align: center;">↓</p>	<p>Do not resubmit in CICERO until instructed to do so. Query reviews should occur through email only at this point. Steps 4 and 5 may be repeated until all queries are addressed</p>
<p><b>Step 6:</b> Departmental reviewers conclude their review</p> <p style="text-align: center;">↓</p>	<p>Departmental reviewers will email the PI to resubmit in CICERO.</p>

<p><b>Step 7:</b> PI resubmits CICERO application</p> <p style="text-align: center;">↓</p>	<p>May respond stating “All departmental queries have been addressed.”</p> <p>PI waits for further instruction from the HRPO.</p>
<p><b>Step 8:</b> IRB signatory approves review; application moves to the HRPO/IRB</p>	

**Additional Procedures (where applicable)**

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.

Faculty advisors for students submitting protocols and new investigators at UMSON should review the UMSON [Human Subjects Research Required Education and Oversight Policy](#)<sup>2</sup> and meet with the research quality manager to discuss quality assurance requirements during study conduct.

**RELATED POLICIES, PROCEDURES, STATUTES, AND REGULATIONS**

See the UMSON [Policy on Human Subjects Scientific, Ethical, and Feasibility Review](#)<sup>3</sup> for further details.

**DATE AND SIGNATURE**

Date: January 18, 2022



Approved by the Dean:

<sup>2</sup> <https://www.nursing.umaryland.edu/intranet/media/son/intranet/policies-procedures/Policy-Human-Subjects-Research-Required-Education-Oversight.pdf>

<sup>3</sup> <https://www.nursing.umaryland.edu/intranet/media/son/intranet/policies-procedures/Policy-Human-Subjects-Scientific-Ethical-Feasibility-Review.PDF>