

Memo: Guidelines for Faculty Mentorship of PhD Students Conducting Human Subjects Research

Audience:

- UMSON faculty who are mentoring PhD students in the conduct of human subjects research and related scholarship activities
- PhD students who are working under the mentorship of a UMSON faculty member for the purposes of human subjects research and related scholarship activities

Purpose:

This memo serves to provide guidance on the responsibilities, requirements, and processes involved in PhD student mentorship through the conduct of human subjects research and related scholarship activities. This guidance applies to any human subjects research project and/or project intended to be published, regardless of whether it is supporting dissertation work or not.

Guidelines:

IRB Application

- For PhD student dissertation work, IRB applications must be initiated, fully reviewed for accuracy and regulatory compliance, finalized and submitted by the dissertation chair, who serves as the Principal Investigator (PI).
 - Note- only after their dissertation proposal has been approved by the full committee following a successful proposal defense can an IRB application be submitted.
 - The IRB application must explicitly state the dissertation research purpose in the application.
- For PhD student research work outside of their dissertation (whether related to it or not), IRB applications must be initiated, fully reviewed for accuracy and regulatory compliance, finalized and submitted by the faculty mentor, who serves as the Principal Investigator (PI).
 - The IRB application must explicitly state the student's research learning purpose in the application.
- The dissertation chair (or research mentor) is responsible for supervising the student's compliance with all human subjects-related regulations.
- All students conducting human subjects research at UMSON are required to comply with the UMSON Human Subjects Research Required Education and Oversight Policy.
- Before submitting the IRB application, the dissertation chair/faculty mentor may request guidance from the Office of Research and Scholarship (ORS) Quality Assurance (QA) by contacting Casey Jackson at casey.jackson@umaryland.edu.

Regulatory Binders

- Prior to beginning recruitment, students must:
 - Collaborate with their PI/faculty mentor to finalize the regulatory binder, Manual of Procedures (MOP), and all data collection instruments.
 - Schedule a meeting with the ORS QA to review the finalized and PI/faculty mentor vetted regulatory binder.

- It is the responsibility of the PI (dissertation chair or UMSO research mentor) to schedule the initial regulatory binder review. (Contact: casey.jackson@umaryland.edu).
 - The ORS QA will communicate with the PI if any concerns arise.
- Within the first 6 months of enrollment, the UMSO Human Subjects Research Required Education and Oversight Policy requires:
 - PI/Faculty mentor and student conduct and document internal QA monitoring of the regulatory binder and all participant-related files.
 - PI/Faculty mentor and student submit the regulatory binder, participant files, and QA documentation to the Office of Research and Scholarship for assessment and feedback.
- Although it is not required, the ORS highly recommends that the PI/Faculty mentor and student conduct and document internal QA monitoring of the regulatory binder and all participant-related files on an annual basis until the research is completed.