UNIVERSITY of NORTH CAROLINA WILMINGTON

Research Integrity Office

Institutional Review Board

Questions? Email: IRB@uncw.edu

Frequently Asked Questions for Capstone Projects

What is the IRB?

The Institutional Review Board (IRB) is a federally mandated committee on campus that reviews research projects involving the use of human subjects. The purpose of the IRB is to ensure that the individuals who are recruited to participate in research studies ("human subjects") are protected and fully informed about the research project, and that research is conducted in an ethical manner, consistent with *The Belmont Report,* a statement of basic ethical principles governing research involving human subjects.

Why does this concern me?

UNCW has assured the U.S. Department of Health and Human Services that it will follow all regulations pertaining to human subjects protection. UNCW also has the highest standards for conducting research and protecting the people we ask to participate in our research. Even if you do not conduct research that involves human subjects, it is important for the campus community to be aware of their institution's human subjects protection program.

The IRB is just for medical research, right?

The IRB is not just for medical research. There are non-medical risks that can potentially be associated with other types of studies such as surveys, interviews and focus groups. The IRB helps researchers identify less obvious emotional and social risks, and assures that subjects are fully informed about the purpose of the research, how their information will be used, and how their confidentiality will be protected.

If a study meets the IRB definitions of "research" and "human subjects" it is subject to IRB review. The IRB has several decision charts to explain what is meant by "research" and "human subjects." You can find the decision charts on the IRB website.

If I am conducting a masters-level capstone project, is my study subject to IRB review?

This depends on the type of study you conduct. Capstone projects are often practical applications of one or more of the areas students learn about in the program they are in (policy analysis, program evaluation, etc.), and the purpose of the project is often to solve a local problem or answer a question for a particular organization. That type of project would likely not be considered "research" by the IRB. The IRB defines research as a "systematic investigation designed to develop or contribute to generalizable knowledge." If a student is trying to answer a question for a specific organization, it is likely not going to be designed to be applicable ("generalizable") to other organizations.

Also, although capstone students sometime conduct interviews or surveys to collect data on a topic, this kind of activity is also not always viewed as "human subjects" research. Projects conducted in the Cameron School of Business or the Public and International Affairs Department often collect data from individuals the IRB considers "key informants" rather than "human subjects." Studies conducted in these areas are generally geared toward learning about organizational practices rather than personal beliefs and experiences, so the questions included on surveys or in interviews are typically not about the individuals personally, but about some expertise the individual has due to his or her position in an organization. For example, an MPA capstone student might be interested in interviewing budget officers in rural counties, or directors of publicly-funded youth programs to learn about policies and procedures related to the local government or program, but the student might not really be interested in an individual's personal motivations or beliefs. If questions are included about personal motivations or beliefs ("What made you decide to go into public service?" or "What would you tell a graduate student about serving in a public service role?"), the activity might be considered human subjects research IF the study is designed in a way to allow the findings to be generalized to broader populations.

My advisor and I agree that my capstone does not meet the IRB definition of "human subjects research." What am I required to do?

When a project does not meet the IRB definition of "research" or "human subjects," best practice is to complete a brief "NHSR" (**N**ot **H**uman **S**ubjects **R**esearch) application in IRBIS (the IRB's online application system). Importantly, in order for IRBIS to generate the limited "NHSR" application form, the applicant must respond "No" to either the screening question that asks if the project is "research" and/or the screening questions that ask if the project involves "human subjects." There will be a few more questions to complete, then after submission and confirmation by IRB staff, the applicant receives an email from the IRB confirming that the activity does not constitute human subjects research. If the applicant plans to conduct a survey or interviews, the applicant must upload the planned survey or interview questions in the Attachments section of the application.

My advisor and I agree that my capstone meets the IRB definition of "human subjects research." What am I required to do?

First, any member of the research team who is involved in the design or conduct of the research is required to complete an online training course offered by the Collaborative Institutional Training Initiative (CITI). The link to CITI and instructions on how to properly register for the correct course can be found on the IRB website.

UNCW uses an online IRB submission and management system ("IRBIS"). The principal investigator (PI) completes the online application, uploads any attachments or supporting documentation, and submits it to the IRB. If the PI is a student, a faculty advisor must be listed, and the faculty advisor must review and certify the application before it can be forwarded to the IRB.

The PI should read and follow the instructions within the application carefully. In the Study Design, Methods and Procedures section, the PI should provide a detailed, step-by-step explanation of the study design so that IRB reviewers who are outside of the study discipline can understand all study methods. If the PI needs IRB approval by a certain

date, the PI should submit the application at least ten (10) days prior to the desired start date to allow time for review and approval. Applicants should be mindful that lots of students on campus are anxious to get started on their research projects, and the IRB cannot guarantee a speedy response when submission volumes are high. Also, it is unlikely that a capstone project would require review at the highest level (see below), but if so, the applicant should check to see when the next scheduled IRB meeting is, and what the deadline is for protocol submission. These dates are posted on the IRB website.

What is the difference between exempt, expedited and full IRB review?

There are three levels of IRB review: exempt, expedited and full board review. When a study is considered "exempt," it is because it meets certain regulatory requirements for low-risk human subjects research. IF a capstone project is considered "human subjects research" it is likely to qualify for a determination of exemption. A good example of an exempt study is a completely anonymous written or online survey, but many non-anonymous studies can qualify for exemption as well. Research that the IRB approves by the expedited review process also has to involve no more than minimal risk to subjects, but the activities might involve using children, or the data collected might contain sensitive or confidential data that necessitates a more detailed review. Exempt and expedited applications are reviewed continually throughout the year and are not subject to annual review by the IRB. Research projects that require full board review are projects that utilize a procedure involving more than minimal risk to subjects, or involve subjects who may be particularly susceptible to coercion, such as prisoners or economically disadvantaged people, or subjects who need additional protections, such as mentally or physically disabled people. Full board studies are subject to an annual review. When a study requires full board review, it must be submitted by a submission deadline posted on the IRB website, and it is placed on the agenda for the next scheduled IRB meeting. IRB meetings are held monthly from September to May.

I submitted my protocol. What happens next?

When a protocol is received, IRB staff conduct an initial review. If there are omissions or clarifications needed, IRB staff add stipulations to the application and return it to the PI through IRBIS. When the application is complete, IRB staff forwards it to either the IRB chair or a designated IRB member, or places it on the next agenda for a full board meeting, depending on the level of review. When a protocol requires full IRB review, the PI is notified and required to attend the next scheduled IRB meeting to answer any questions IRB members may have regarding the study.

For more information, check out the IRB Website: http://uncw.edu/sparc/integrity/irb.html

or contact:
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