



## Research Integrity Office

### Institutional Review Board

Questions? Email: [IRB@uncw.edu](mailto:IRB@uncw.edu)

## Frequently Asked Questions

UNCW IRB website: <http://uncw.edu/sparc/integrity/irb.html>

### 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 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 attached decision charts explain what the IRB means by "research" and "human subjects."

The UNCW IRB has approved research protocols from many UNCW departments and offices, including: Psychology, Nursing, Social Work, Health and Applied Human Science, History, Foreign Language and Literature, Randall Library, Chemistry, Political Science and others. There are well over a hundred active human subject projects being conducted by UNCW faculty and students today.

### Do undergraduate student projects need IRB approval?

Sometimes undergraduate student projects do need IRB approval. IRB approval is not necessary if the students are conducting studies on campus and do not plan to publish or externally present their work. Instead, this type of project should be reviewed by the relevant professor or advisor.

## **I am planning a research project that will involve human subjects. 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:

<http://uncw.edu/sparc/integrity/irb.html>

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 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. However, if the PI believes the project will require review by the full IRB at a convened meeting, the PI should check to see when the next scheduled IRB meeting is, and when 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. A good example of an exempt study is a completely anonymous written or online survey, but many non-anonymous studies can qualify for an 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 information that must be kept confidential. Studies approved by expedited or exempt review are not subject to annual review by the IRB. Exempt and expedited applications are reviewed continually throughout the year. 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 the online system. When the application is complete, the IRB chair reviews the application and determines if it can be approved through an expedited review process, or if it requires review by the full IRB committee. When a protocol requires full IRB review, the PI is notified and the application is placed on the agenda for the next scheduled meeting.

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

**Or contact:** [IRB@uncw.edu](mailto:IRB@uncw.edu)