10 Things Directors of Undergraduate Studies at UNC-CH Should Know about the IRB

Directors of Undergraduate Studies, together with IRB Chairs, have put together a short list of IRB FAQs for you and faculty in your department who are teaching undergraduates and mentoring student research.

1. What is the IRB, why is it important, and how is it relevant to undergraduates?
The Institutional Review Board (IRB) is an independent committee established to review and approve research involving human subjects. The primary purpose of the IRB is to protect the rights and welfare of the human subjects. Informed consent is an important component.
UNC undergraduates who are planning to do research involving human subjects need to submit an application to the IRB and receive IRB approval before they can start recruiting subjects or collecting any data, or they may not be able to use those data in their research. Students and their faculty research advisors must also complete the online Human Research Ethics training course. The IRB application helps establish the credibility of the researcher.
To read more information about the IRB process, and to begin an IRB Application submission, see the OHRE website for an overview of the review process.

2. How does a student or faculty research advisor determine if a project is research and if the project will need IRB approval?
According to the IRB, a project is human subjects research if the researcher obtains data through interacting with one or more people or through obtaining identifiable private information. Three other criteria define research: research contributes to generalizable knowledge, research is designed in advance, and research utilizes a systematic approach.

3. What is the IRB review process and how long does it take?
There are three levels of IRB Review: full board review, expedited review, and exempt from continuing IRB review. The level of review is determined by the level of potential risk to human subjects and the vulnerability of the subject population (e.g., children, pregnant women, and prisoners are considered especially vulnerable groups). The full board of the IRB convenes to review any research study that involves greater than a minimal risk. Only research involving no more than minimal risk to subjects may be considered for expedited review, and this review is done by an individual reviewer or several reviewers, and not the full board. Regardless of the level of review, researchers submit the same online application form. After a student submits her or his IRB application, the IRB reviewer may contact her or him to clarify or expand on parts of the application. The amount of time the IRB review process takes depends on the level of review and also on the revisions that a student needs to make to the original application.

4. Are there special IRB requirements for students who plan to do research internationally?
Depending on the nature of the research, researchers may be required to get approval from the in-country IRB before they can begin their research. Students should show in their application that they understand the ethical and cultural context of the locale where they will be doing research and that they are prepared to carry out their research sensitively, responsibly, and credibly. It may also help if the student demonstrates support from local agencies or organizations that are aware of the student's research plans. In general, some kind of on-the-ground supervision of the student is often necessary.

5. Do instructors need IRB approval for class research projects?

If the goal of the class project is to learn about conducting research or how to implement a particular procedure—in other words, if the goal is purely educational (there is no plan to disseminate the research outside the class setting)—IRB approval is not required.

6. If a student's research falls in the realm of journalism, do they need to apply for IRB approval?
Yes—the student, as a student, is working as a member of the UNC-CH community, and not as a professional journalist. Note the contingencies, however, with regards to "class projects needing IRB approval."

7. What is the role of the faculty research advisor in the IRB process for undergraduates?
The faculty research advisor is essential to the student's research and to the IRB application. Not only does the faculty research advisor serve as the student's research mentor, consulting with and advising the student on his or her research plan, but the advisor also must sign ("certify") the undergraduate's IRB application before the online process is complete and the application can be submitted. Faculty research advisors must also complete the required Human Research Ethics Training (CITI) before the student submits the IRB application.

8. How does a Principal Investigator (PI) add an undergraduate researcher to a research project that has already received IRB approval?
Adding an undergraduate student to research personnel requires submitting a Modification of Approved Human Subjects Research form on the IRBIS portal with the student's name, plus documentation of the student having completed the required research ethics training.

9. How can faculty prepare undergraduates in their department for the IRB process?
A good first step is to ask students to take the online Human Research Ethics training called CITI, which will introduce them to the IRB rationale and process. The training is accessible from the OHRE website. Students completing the course receive certification and are listed in the CITI database. They will need this human research ethics course certification before they submit their IRB application. Students often find that if they have a well thought out research plan, they will find the application relatively straightforward. If students have not thought through their research plan in a focused and detailed way, the application process will require that they do.

10. What resources are available to help students with the IRB process? Who can answer questions about the IRB?
Navigating the IRB is a bi-directional, educational process. You and/or students may call the Office of Human Research Ethics (OHRE) and discuss your questions with an IRB consultant (966-3113). OHRE also has an excellent website with many resources, such as sample consent forms. In addition, several times a year, the Office for Undergraduate Research offers workshops on the IRB process for undergraduates.

For more information on the IRB, see the following resources on the Office of Human Research Ethics website:

- *A Guide to the Online Submission Process*
- Online submission FAQs
- *Human Research Ethics Training: online CITI course*
- OHRE SOP 4601: Trainee or Study Projects Involving Human Subjects