Navigating the IRB Process: Steps for Students

UNC-Chapel Hill is committed to upholding the highest standards in research involving human subjects. This requires knowledge of the ethical and regulatory obligations and applies to all faculty, staff, and students who are engaged in the design and conduct of human subjects' research that is conducted under the aegis of UNC-Chapel Hill.

As a student conducting human subjects' research, you are responsible for ensuring that you are conducting research in an appropriate manner and in concordance with federal requirements and UNC-CH policies. You should begin thinking about the IRB process at the same time you are discussing your research plans with a faculty member. Note the following:

1. Begin discussing your research with a faculty member. Ask about the IRB at the start and ask for their guidance on completing the on-line IRB application.
2. Your research cannot be initiated until you have IRB approval. The IRB cannot grant retroactive approval after research has been initiated or completed.
3. You should allow a couple of weeks for review of your IRB application. Refer to the OHRE website for important dates and deadlines if the research will require Full IRB review.
4. Check out the UNC-CH Office of Human Research Ethics (IRB) website for useful information, Frequently Asked Questions, and links to additional resources.
5. Review -OHRE Standard Operating Procedure 4601: Trainee or Study Projects Involving Human Subjects Research.
6. If human subjects' research will take place outside of the United States, there are additional requirements, so the IRB process should be started as soon as possible. It is essential that researchers have sufficient knowledge of the local research context to be able to design and conduct research in a way that protects the rights and welfare of the subjects. To gain a better appreciation for what the IRB has to consider when reviewing human subjects research being conducted outside the US, consider reviewing OHRE Standard Operating Procedure 4701Transnational Research. This will assist you with providing the IRB with all the required information.
7. Ensure you are familiar with the federal guidance from the Office of Human Research Protections (OHRP) on conducting human subjects' research outside the United States.
8. Ensure you are familiar with the UNC-CH policy on Study, Travel, and Research in Countries Under State Department Warnings.
9. All applications are submitted on-line. If you have questions about the application or other general questions, contact the IRB by email or by phone (919) 966-3113. It is better to get questions clarified before the IRB application is submitted. Once the application is submitted, any changes will require a Modification.
10. Ensure that your faculty advisor is aware of the IRB and their responsibilities (Navigating the IRB Process: Steps for Faculty Advisors). Get your advisor's input throughout the IRB application process.
11. A note about Informed Consent. Obtaining informed consent is a PROCESS in which the investigator discloses all relevant information; the potential subject has the opportunity to ask questions; the investigator answers the questions; and if the subject is willing to participate, the subject signs a consent form. The consent form is a permanent record of information conveyed and the subject's willingness to participate. The IRB may waive certain elements of the consent form or the requirement for the investigator to obtain a signed consent form under certain circumstances. As you complete your on-line IRB application, consent forms are "built" by the on-line system depending on your application responses.
12. Complete your on-line CITI human subjects protection (IRB) training and be sure your faculty advisor has completed the training too. If you have questions about training, contact the IRB Training Coordinator by email or by phone:

Charlotte Coley, Training Coordinator / Office of Human Research Ethics
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