Navigating the IRB Process: Steps for Faculty Advisors

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 faculty advisor to a student conducting human subjects' research, you have several responsibilities regarding the IRB. You are accepting full responsibility for the work, both conceptually and ethically. You are responsible for ensuring that the student is conducting human subjects' research in an appropriate manner and in concordance with federal requirements and UNC-CH policies. Note the following:

1. Student human subjects' research cannot be initiated until the student has IRB approval. The IRB cannot grant retroactive approval after research has been initiated or completed.

2. Students should allow a couple of weeks for review of the IRB application. Refer to the OHRE website for important dates and deadlines if the research will require Full IRB review.

3. Be familiar with OHRE Standard Operating Procedure 4601: Trainee or Student Projects Involving Human Subjects Research.

4. 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 Research. This will assist you with providing the IRB with all the required information. Ensure your student is familiar with the federal guidance from the Office of Human Research Protections (OHRP) on conducting human subjects' research outside the United States. Ensure your student is familiar with the UNC-CH policy on Study, Travel, and Research in Countries Under State Department Warnings.

5. All applications are submitted on-line. Refer to the OHRE website for on-line submission training materials.

6. Consider assisting the student with the IRB application and be sure to follow all instructions. If you have questions about the application, the forms, or 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.

7. 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 your student completes their application, consent forms are "built" by the on-line system depending on their application responses.

8. Complete your on-line CITI human subjects protection (IRB) training and be sure your student 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
   Phone: 919-966-1594
   Email: chcoley@email.unc.edu