



Office of Human Research Ethics Training Tips: Essential Facts & Requirements

1. The **Office of Human Research Ethics (OHRE)** is responsible for ethical and regulatory oversight of research at UNC-Chapel Hill that involves human subjects. (<http://research.unc.edu/offices/human-research-ethics/about/>). Please see the Federal Regulatory definitions of “research” and “human subject” below, if your study meets these definitions, then you **MUST** submit to the IRB for a determination:

“**Research** means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.”

“**Human subject** means a living individual about whom an investigator (whether professional or student) conducting research obtains

- (1) Data through intervention or interaction with the individual, **or**
- (2) Identifiable private information.”

2. **Required Ethics Training** is required. Links to the required CITI Human Research Ethics online training course, and UNC’s training data base; UNC’s policy on human research ethics training and certification; and FAQs. [CITI Course Information](#)
3. All applications (i.e., Initial, Modification, Renewal, Closure/ Unanticipated Problem/Adverse Event) are online. Please go to <http://irbis.unc.edu> to complete and submit your application to the IRB.

IRBIS Help Desk: [David Tegnell](#), 919-966-3685

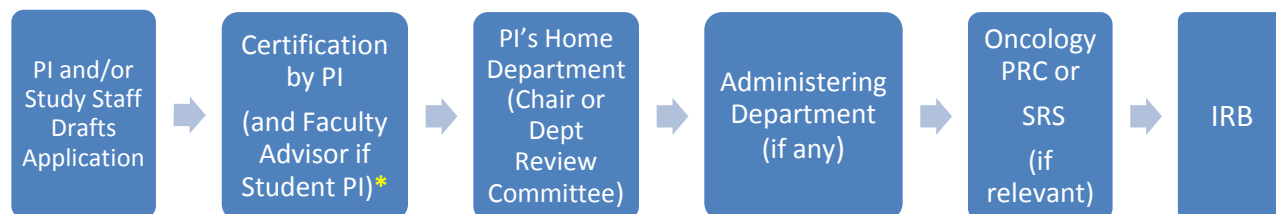
[Online Submission FAQ](#)

[Online Submission Guide](#)

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4. **Standard Operating Procedures (SOP)**— [University of North Carolina at Chapel Hill Human Research Protection Program Standard Operating Procedures \(SOP\)](#) can be found at: <http://research.unc.edu/files/2014/05/2014-04-24-OHRE-Standard-Operating-Procedures-FINAL-CLEAN.pdf>

Routing of IRB Submissions



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