

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. (). 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: a systematic investigation, including development, testing, & evaluation designed to develop or contribute to generalizable knowledge.
- "Human subject: a (living)* individual about whom an investigator (whether professional or student) conducting research:
 - Obtains data through intervention or interaction with the individual,
 - Obtains, uses, studies, analyzes, or generates identifiable private information; or
 - Obtains, uses studies, or analyzes biospecimens.
- 2. <u>Required Ethics Training</u> 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. <u>CITI Course Information</u>
- 3. All applications (i.e., Initial, Modification, Renewal, Closure/ Unanticipated Problem/Adverse Event) are online. Please go to the online system, <u>IRBIS</u>, to complete and submit your application to the IRB.

IRBIS Help Desk: 919-5-966-5113

Online Submission FAQ Online Submission Guide irb guestions@unc.edu

4. **Standard Operating Procedures (SOP)**— University of North Carolina at Chapel Hill Human Research Protection Program Standard Operating Procedures (SOP) can be found at: https://ohresop.web.unc.edu/

Routing of IRB Submissions









