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/](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 database; 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](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
   irb_training@unc.edu


**Routing of IRB Submissions**

- PI and/or Study Staff Drafts Application
- Certification by PI (and Faculty Advisor if Student PI)*
- PI’s Home Department (Chair or Dept Review Committee)
- Administering Department (if any)
- Oncology PRC or SRS (if relevant)
- IRB

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