Office of Human Research Ethics Training Tips

Basic IRB Submission Facts

IRB Mission Statement: *The University of North Carolina at Chapel Hill is committed to expanding and disseminating knowledge for the benefit of the people of North Carolina and the world. An important part of that commitment to knowledge is research of the highest quality on all aspects of the health and behavior of people, and such research is only possible through the participation of humans as research subjects. Human subjects are partners and participants in research and a precious resource to the university. At UNC-Chapel Hill, human subjects research is a privilege, but not a right. Consistent with that philosophy, it is the mission of the UNC-Chapel Hill Human Research Protection Program to ensure that*

1. *the rights and welfare of human subjects are paramount in the research process;*
2. *the highest standards of ethical conduct are employed in all research involving human subjects;*
3. *research investigators are properly trained in the ethical and regulatory aspects of research with human subjects;*
4. *research investigators deal honestly and fairly with human subjects, informing them fully of procedures to be followed, and the risks and benefits of participating in research; and*
5. *research using human subjects at UNC-Chapel Hill conforms with all applicable local, state, and federal laws and regulations and the policies of the university.*

Federal Wide Assurance Name & Number: University of North Carolina, Chapel Hill FWA00004801
Number of IRBs that Meet Monthly: 6
IRB Meeting Day & Time: 4 Biomedical IRBs meet every Monday from 1pm to approximately 4pm
1 Non-Biomedical IRB meets the 2nd. Tuesday of each month from 2pm to approximately 4pm
1 Special Issues IRB meets the 2nd. Thursday of each month from 1pm to approximately 4pm

What is Human Subject Research?

Office of Human Research Protections (OHRP) Definitions

- ***Research*** means a systematic investigation, including development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for the purposes of this policy, whether or not they are supported under a program which is considered research for other purposes. --- **45 CFR46.102(d)**

- ***Human subject*** means a living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information. --- **45 CFR 46.102(f)(1),(2)**

- ***Identifiable private information*** includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). --- **45 CFR 46.102(f)(2)**

- ***Informed consent*** must be sought under circumstances that minimize the possibility of coercion or undue influence and must include the eight basic information elements described in the regulations. Information must be presented in language understandable to the subject or the subject's legally authorized representative. --- **45 CFR 46.116(a),(b)**

- ***Informed consent*** must be documented with a written form approved by the IRB and signed by the subject or the subject's legally authorized representative. --- **45 CFR 46.117**

Food & Drug Administration (FDA) Definitions:

- ***Clinical investigation*** means any experiment that involves a test article and one or more human subjects and that either is subject to requirements for prior submission to the Food and Drug Administration under section 505(i) or 520(g) of the act, or is not subject to requirements for prior submission to the Food and Drug Administration under these sections of the act, but the results of which are intended to be submitted later to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit. The term does not include experiments that are subject to the provisions of part 58 of this chapter, regarding nonclinical laboratory studies. **21 CFR 50.3 (c)**
- ***Test article*** means any drug (including a biological product for human use), medical device for human use, human food additive, color additive, electronic product, or any other article subject to regulation under the act or under sections 351 and 354-360F of the Public Health Service Act (42 U.S.C. 262 and 263b-263n). . **21 CFR 50.3 (j)**
- ***Human subject*** means an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient. . **21 CFR 50.3 (g)**

Submission Process: The UNC-CH IRB uses an electronic submission process (IRBIS) the link to the site is: http://research.unc.edu/offices/human-research-ethics/online-submission/

IRB Home Page http://research.unc.edu/offices/human-research-ethics/

IRB Volume: During the last fiscal year (January 1, 2014 – December 31, 2014). The UNC IRB received the following:

Submissions by Outcome

Report showing the number of initial submissions listed by their outcomes (Full Board, Expedited, Exempt, NHSR, Not approved, pending, withdrawn, Rely's and Terminated)and a percentage breakdown.
All Submissions from 01/01/2014 through 12/31/2014 are 13117.

Category	Count	Percentage
Expedited	9078	69.21%
Full Board	1046	7.97%
Closed	508	3.87%
Exempt	839	6.40%
NHSR	793	6.05%
Not Approved	129	0.98%
Rely on External IRB	359	2.74%
Rely on NCI-CIRB	131	1.00%
Submitted	4	0.03%
Withdrawn	230	1.75%
Total	**13117**	**100.00%**

IRB Levels of Review: Not Human Research, Exempt, Expedited, Full Board Review

Criteria for IRB Approval: ***45 CFR 46.111 & 21 CFR 56.111 , OHRE SOP 24.0***

1. Risks minimized
2. Favorable risk : benefit ratio
3. Equitable selection of subjects
4. Informed consent sought
5. Informed consent documented
6. Monitoring plan for safety
7. Privacy and confidentiality protected
8. Additional safeguards for vulnerable populations

IRB Membership:

1. ≥ 5 members (UNC IRBs have 10-15 members)
2. Not all members of one profession
3. Diversity
4. Expertise appropriate to the research
5. At least one scientist, one non-scientist
6. At least unaffiliated member

IRB Actions:

1. Reviews research to evaluate ethical issues and ensure regulatory compliance
2. Approve, disapprove or modify research involving human subjects
3. Conduct continuing review of research
4. Observe, monitor, audit research
5. Suspend or terminate approval of research