Office of Human Research Ethics Training Tips

Basic IRB Facts

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 Safety Issues IRB meets the 2nd. Thursday of each month from 1pm to approximately 4pm

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: ~ 7100 studies

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. Diverse membership
4. Expertise appropriate to the research
5. At least one scientist, one non-scientist
6. At least 1 unaffiliated member

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

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
6. Recommend suspension or termination of researchers from research for continuing non-compliance
7. Final authority to accept, strength or reject COI Management Plans.
8. Final authority to declare non-compliance as serious non-compliance or serious continuing non-compliance reportable to Federal agency & sponsor.

Reporting Requirements: New or increased risk to subjects or others: 7 calendar days

18 HIPAA Identifiers:

1. Name
2. Address (Street, City, Zip except for first 3 digits)
3. Dates (all elements directly related to individual; all ages >89)
4. Telephone number
5. FAX number
6. E-mail address
7. Social Security Number
8. Medical Record Number
9. Health Plan Beneficiary Numbers
10. Account Numbers

11. Vehicle identifiers (e.g., serial numbers and license plate numbers)
12. device identifiers and serial numbers
13. URL addresses
14. Biometric identifiers (e.g., finger or voice prints)
15. Full face photographs or comparable images
16. Internet Protocol address numbers
17. Any other unique identifiers
18. Certificate or Professional License Numbers

Office of Human Research Protections (OHRP) Current 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)**

Child Findings

- §46.404 Research not involving greater than minimal risk. 1 or 2 parent signature as determined by the IRB
- §46.405 Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects. 1 or 2 parent signature as determined by the IRB
- §46.406 Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition.

  2 parent signature required unless one parent is deceased, unknown, incompetent or not reasonably available or when only one parent has legal responsibility for the care and custody of the child.
- §46.407 Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.

  2 parent signature required unless one parent is deceased, unknown, incompetent or not reasonably available or when only one parent has legal responsibility for the care and custody of the child.