



Office of Human Research Ethics Training Tips

Basic Audit Tips

IRB Mandate: To protect the rights and welfare of human research subjects.

1. Auditors want to learn if we do what we say in the UNC-CH SOPs that we do. Do we follow our own rules/SOPs; Belmont & Federal Regulations.
2. Will ask how you do your job within OHRE & what resources/guides do you use:
 - a. 45 CFR 46 & 45 CFR 164 (HIPAA); 20 CFR 50 (Consent), 56 (IRBs), 312 (IND) & 812 (IDE),
 - b. Belmont Report Principles: Respect for Person, Beneficence & Justice
 - c. IRB SOPs, Institutional Guidelines & State Laws
3. If an IRB Member:
 - a. **Use the 111 Criteria (45CFR46 111) to judge protocols.**
 - b. Review agenda items
 - c. Recuse yourself if you have a conflict of interest
 - d. Be prepared
 - e. IRB Member Responsibilities
 - i. Make an organized presentation to the group
 - ii. Enter your stipulations, if any, in the appropriate section
 - iii. Allow for other perspectives and viewpoints
 - iv. Maintain focus
 - v. Seek consultation, when needed
 - vi. Honor the hair on the back of your neck
 - vii. Don't take yourself too seriously
 - viii. Understand IRB's power – IRB is a partner in the research process and we want to propose solutions when possible!
4. **DO NOT make up an answer**, if you do not know a response to a question. Instead tell an auditor where you would go to get an answer or more information about a question/issue.
5. Always answer their questions.
6. **Do not volunteer information not requested.**