Human Research Ethics Training Tips

How to Prepare an Annual Review as the IRB Primary Reviewer

1. Read the consent form first. You should be able to understand the study purpose, design and risks.

2. Read the protocol summary and compare it to what you read in the consent. Are there discrepancies between the two, for example:

    a. the number of clinic visits,
    b. length of the study,
    c. PI name,
    d. sponsor name
    e. inclusion and exclusion criteria do not match
    f. risk mentioned in protocol summary that is not mentioned in the consent

3. Keep the Federal Regulations criteria for IRB review in mind.

4. Have there been an unusual amount of SAEs (serious adverse events) reports? If so, should the study be stopped or the consent revised?

5. What does subject recruitment show?

    a. Have they recruited the numbers that they initially planned to each year?
    b. Are they within the total number of subjects approved for this study by the IRB? If they have exceeded that limit, a protocol deviation report/UPIRTSO is required. Do they need to request a higher recruitment number?
    c. Is the recruitment ethnic and gender diverse? If not, is there a reason?

6. Has the sponsor changed since the last review? For example, was it originally funded by the department and has now received NIH funding? If so, then there is a good chance that concordance has not been declared for this study and will need to be done at this review. Call the Board Specialist for your meeting and inquire.