Accompanying document:

Office of Human Research Ethics Training Tips

How to Review & Present Protocols as the Presenter

Effective June 1, 2016 Required Use

(free to pilot it sooner)

I. **Pre-Meeting:**

a. Begin early, you could have questions & not be able to get answers your questions soon.
b. Start by reading the consent form, it will give you an overview of the study. If you don't understand it, then subjects won't either. Also, great way to see disconnects between it and the protocol.
c. Call the PI or Coordinator with any questions you have. Include information in your summary, so there is not need to repeat the same question next year.
d. If uncomfortable contacting the study team, the IRB Analyst will be happy to contact the study team with your questions.
e. Only ask for clarification or additional information about a study. **NEVER** direct the study team to make any changes to their study at this point. ***Until the IRB votes on stipulations, there are no changes to be made.***
f. Read the following sections of the study submission or protocol:
    i. Primary & secondary objectives
    ii. Study design
    iii. Recruitment
    iv. Safety Plan
g. Read the Investigational Brochure (IB) for:
    i. FDA information on the Investigational New Drug (IND)
    ii. Study drug pregnancy rating
h. Identify and resolve, if possible, deferrable issues ***PRIOR*** to the meeting. Communicate with the study team or IRB Analyst to reduce the chances of deferral at the meeting
i. **Alert the Chair** of any potentially deferrable or controversial issues PRIOR to the meeting for **ANY** study on the agenda.
j. **Prepare recommended solutions** to controverted issues for presentation at the meeting.
k. **Email your completed checklist by 8am on meeting day to your IRB Analyst who will upload it into IRBIS.**

II. **At the Meeting:**

a. **Be brief**: Do not read through the entire Checklist. Discuss only important issues as outlined below.
b. **Provide a 3-5 minute review of key points in your oral presentation** ***(can be your oral presentation outline & uploaded into the Presenter summary block of IRBIS).***
    i. One sentence description of the study objectives,
    ii. Short summary of the study design,
    iii. Short summary of risks, benefits,
    iv. Identification of subjects **(is a HIPAA waiver needed to ID potential subjects?)**;
    v. how the consent process will occur,
    vi. If applicable:
        1. evaluate the pediatric risk level and/or appropriateness of inclusion of children,

2. inclusion of vulnerable groups in the study -- pregnant women, prisoners, adults incapable of consent
3. IND/IDE status of investigational drugs/devices/biologics, remember to consult the information sheet provided by staff

c. Address any conditions of approval, such as:
   i. Legally Authorized Representative (LAR)
   ii. Declaration of Concordance if NIH funded,
   iii. If children in the study, what is your recommendation for risk level and number of parent signatures
   iv. Recommend Category 9 eligibility at the time of Continuing Review to allow future expedited review of the study. If the study is no greater than minimal risk and does not involve an IDE/IND.
   v. Recommend any stipulations citing specific sections to be modified

d. Make the final motion to:
   i. Approve, including period of approval, approval for LAR or not; child risk level & number of parents to sign the consent
   ii. Based on the risk assessment by the IRB, the approval period can be less than 1-year; can be less, i.e., after enrollment of "X" number of subjects; or 3, 6, or 9-months.
   iii. Approve with stipulations
   iv. Defer/Table (**If it does not meet the 111 Criteria: You MUST defer the study!**)
   v. Disapprove

What is a Deferral?

"OPRR recommends the following guidelines in such cases:

(i) When the convened IRB requests substantive clarifications, protocol modifications, or informed consent document revisions, IRB approval of the proposed research must be deferred, pending subsequent review of responsive materials by the convened IRB.

(ii) Only when the convened IRB stipulates specific revisions requiring simple concurrence by the investigator may the IRB chair or designated reviewer subsequently approve the research on behalf of the IRB."

THE *'-ATION''* LIST

A protocol may be deferred if any of the following are required during review by a convened IRB:

Elabor*ation*	**Explan*ation***
Clarific*ation*	**Justific*ation***
Document*ation*	**Modific*ation***

Adapted from Joseph F. Farmer, MD

NOTE: Using an alternative word (i.e. not using clarify, explain, etc.) does not make the question a stipulation and not a deferrable study!

EXAMPLES:

- What is the rationale for studying nine analytes? **[See 111 Criteria #1]**
- What is your hypothesis for the inflammatory profile? **[See 111 Criteria #1]**
- ***Clarification*** about the choice of study is necessary - why is this a cross-sectional study of 30 participants which is not going to provide ample information. Please list all the specific aims and match the analysis plans to them.

- The list of specific aims in this section is incomplete. Furthermore the stated specific aims are not closely matched with the statistical analysis plans.

- please ***clarify*** reduction in number of participants from 45 to 30 (*goes to risk : benefit analysis)*

- Will it be fasting or non-fasting maternal blood?

- ....since they are not expected to be normally distributed - please revise this sentence. **[MUST provide the exact sentence for the PI to use.]**

- No one from Sport and Exercise Science is listed among the project personnel. As several of your outcome measures will be obtained by graduate students in Sport and Exercise Science, please include a faculty member from that department who will supervise the students***. [This is fine, they are asked to add the name of faculty from Sport & Exercise Science; so the staff & chairs can easily see if that is done. Once faculty name added to the study, then it can be approved. UNLESS there are other changes required by the IRB.]***

- You indicate that subjects will only participate in one session. But here you say you will mail results to subjects (which obviously must be some time after the subjects' single session), and that they will have an "opportunity to discuss results." How and when can they discuss these results with the resident physician? Will they have to come in for a second session? Will there be a follow-up session by phone? **Please clarify. *(Lack information needed to answer 111 Criteria Questions)***

- Please address the process for identifying incidental findings on the radiographic exam. If a new fracture or other issue is identified, explain how (and how soon) the participant will be notified.

- Please provide a plan for ensuring data quality. **[*See 111 Criteria #6*]**