Office of Human Research Ethics Training Tips: Deferral of Studies

"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*

Clarific*ation*

Document*ation*

Explan*ation*

Justific*ation*

Modific*ation*

Adapted from Joseph F. Farmer, MD

- ***To clarify*** - (paragraph 2) - your hypothesis is that…… **[See 111 Criteria #1]**
- Is there any evidence currently that characterizes the relationship between……**See 111 Criteria #1]**
- 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
- Will it be fasting or non-fasting maternal blood?
- What is the interobserver variability in this measures?
- ....since they are not expected to be normally distributed - please revise this sentence. **[MUST provide the exact sentence for the PI to use.]**
- As this study entails x-rays for research purposes only, and the consent form indicates that pregnant women may be "precluded", it is assumed that this means excluded from the study. Assuming this to be true, please revise this answer and the exclusion criteria in A.3.1 to reconcile the responses, and clarify consent language regarding pregnancy, and indicate how you will test for pregnancy in females (urine test, for example).
- 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.**
- 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*** *]*

Criteria for IRB Approval of Research

§46.111 & §56.111

(a) In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied:

(1) Risks to subjects are minimized:

(i) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, **and**

(ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

(2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.

In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research).

The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

(3) Selection of subjects is equitable. In making this assessment the IRB should take research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disable persons, or economically or educationally disadvantaged persons.

(4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by §46.116.

(5) Informed consent will be appropriately documented, in accordance with, and to the extent required by §46.117.

(6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

(7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

(b) When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.