# Supplemental Digital Appendix 1

## Interview Script, From a National Study of Conflict of Interest Management at sIRBs, 2015–2017

**1. Background**:

a. What field did you train in/what is your degree?

b. Do you have any other advanced training/degrees?

c. How did you get into the field?

d. How long have you been a member of this IRB?

e. What do you do, if anything, outside of the IRB?

f. Can you tell me about any additional experiences or training you have received to assist you in your role on the IRB?

**2. Views of central IRBs (C-IRBs[1])**

a. What do you see as the advantages of C-IRBs?

b. What do you see as the disadvantages of C-IRBs?

c. Do you think your IRB functions differently from local IRBs (L-IRBs)? If yes, in what ways?

d. Do you think your IRB functions differently when performing single-site versus C-IRB reviews? If yes, in what ways?

e. What kinds of problems have you observed at C-IRBs? Are these different than those at L-IRB?

[1] For the purposes of our research, the terms "CIRB" and "sIRB" are synonymous. The study queried about "CIRBs" as that term was more common at the time the study was conducted, but in recently "sIRB" has been the preferred language to describe single IRBs reviewing multi-site research.

 

**3. Views of IRB policies**

f. Do you think the current IRB system could be improved in any way regarding C-IRBs? If so, how?

g. Regarding other aspects of federal regulations? If so, how?

h. Some observers argue that use of C-IRBs should be increased for multisite studies. Do you see any challenges involved in that? If so, what?

i. What other challenges do you face when you review as a C-IRB? Do you have any additional thoughts about these issues?

**4. Views of COIs**

j. Do you feel that C-IRBs have any COIs as individuals or an organization, and if so, what are they?

k. Do you feel you have any COIs as an individual or an organization, and if so, how do you view and manage these?

l. In for-profit independent IRBs, do you feel that the fact that funders are paying the C-IRB for the review affects the review in any way?

m. How would you respond to critics' concerns that such COIs may exist?

n. Do you ever take actions to avoid or manage such COIs, and if so, what?

**5. Relationships with local institutions, researchers and funder**

g. How do you think central IRBs handle or can handle local knowledge issues?

h. Do you ever receive feedback from local IRBs concerning C-IRB reviews? If so, of what does it consist?

i. Do you know if L-IRBs accept wholly, modify or reject C-IRB reviews?

If so, what are the responses of L-IRBs?

How often do they change the review and/or insist on local co- review?

When? Concerning what issues?

 

j. What are your relationships with PIs like?

    i. Do PIs ever challenge C-IRB reviews? If so, about what topics?

    ii. Do you ever have conflicts with PIs? If so, when, how, about what topics?

    iii. What are the most difficult issues your C-IRB has had to confront with PIs?

k. What are your relationships with academic institutions like?
    i. Do you ever have conflicts with them? If so, what kinds?

    ii. What are the most difficult issues your C-IRB has had to confront with academic institutions?

l. What are your relationships with funders/sponsors like?
    i. Do your relationships differ between different funders or type of funders? If so, how and why?

    ii. Are some funders easier or more difficult to work with than are others? If so, how?

    iii. Have your relationships with particular funders changed over time? If so, how?

m. Do you ever encounter "IRB shopping" by funders/sponsors or researchers? If so, what and how?

n. Do you ever interact with Data Safety Monitoring Boards? If so, when and how?

o. How do you handle significant and unanticipated adverse events (AEs)?
    i. Is this different than for single-site trials?

p. Do local sites send all adverse events to you for review, and/or does each site review its own?
    i. How do you view the pros and cons of each possible approach?

q. What are your thoughts about the cost benefits of the Central IRB review process? Alternatively, do you have thoughts about the additional or unexpected costs associated with CIRB review, or the need for local IRB review in addition to central review of studies?

 

**6. Content of decisions**

r. Do the issues that arise with multi-site C-IRB reviewed studies vs with single-site studies differ? If so, how
    i. How do you treat a protocol that is multi-site versus single-site?

s. Do you think there are cultural or local differences across sites and if so how do you handle it?

t. Some people say that IRBs were designed to be "local" in order to reflect local community values and local or state laws. What do think about that?

u. Has your CIRB encountered instances of "local community values " or local or state laws affecting protocol reviews, and if so, when and how?

v. Some observers argue that C-IRBs lack "local knowledge" needed to review protocols. What do you think of that?

w. Do you try to obtain "local knowledge" about a protocol? If so, what, when and how?

x. Do you ever try to obtain "local knowledge" about a PI? If so, what, when, and how?

y. Do you obtain information about PIs' COIs? If so, how? What do you do with the knowledge? Do you ever try to obtain "local knowledge" about potential study participants and populations?
    i. If so, what, when and how?

z. How do you use "local" knowledge in your evaluating the protocol?

**7. Organizational issues specific to C-IRB**

m. How often does your panel meet?
n. Do meetings typically take place in person or online?
o. Are there typically discussions among protocol reviewers that take place by email, etc., prior to meetings?
p. On the average, how many protocols do you review per meeting?
q. How much time to do you have to review protocols prior to meetings?
r. How many of these are centralized review?
s. How many members does your panel have?
t. How do you choose members?

 