

From: [OC GCP Questions](#)
To: [REDACTED]
Subject: RE: Question re: IRB Review of research study
Date: Friday, May 17, 2019 2:28:00 PM
Attachments: [REDACTED]

Dear [REDACTED] -

Thank you for your questions. It can be somewhat difficult to respond to questions about a specific scenario without having access to all the necessary information. However, based on the limited information provided, I have responded to each of your questions below with some thoughts for your consideration.

Questions:

1. Institution A's IRB typically only reviews the activities that Institution A is engaged in (in this case the administration of the surveys). Given that the qualitative interviews are part of the trial protocol and are consented to as part of the overall study consent form, can Institution A's IRB just review and approve the interviews administered in the study and not the entire study itself (since it is not conducting the trial in its entirety)?

OGCP RESPONSE: FDA's IRB cooperative review regulations found at [21 CFR 56.114](#) allow institutions involved in multi-institutional studies to use joint review, reliance upon the review of another qualified IRB, or similar arrangements aimed at avoidance of duplication of effort. The IRB at institution A may choose to review and approve/require modifications in to secure approval/disapprove the study activities their institution is involved in, or they may choose to rely on the review of another qualified IRB for those specific activities.

- a. If so, is there anything specific that should be included in the review documentation so that the limited scope of the review is clear?

OGCP RESPONSE: FDA's IRB records regulations at [21 CFR 56.115\(a\)\(2\)](#) require that an institution, or where appropriate an IRB, prepare and maintain minutes of IRB meetings in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution. FDA's guidance titled, "[Minutes of IRB Meetings](#)" says that to be in sufficient detail to show actions taken by the IRB, the minutes must provide sufficient information to identify the research activities being reviewed and voted on by the IRB at that meeting (e.g., initial review of protocol title/protocol number).

2. As an alternative to Institution A's IRB review of survey portion of the study, they could cede/rely on another IRB's review. However, since each performance site IRB is reviewing the study and there is not a central (single) IRB, it seems impractical to execute an IRB authorization agreement (IAA) with each performance site. Are there any options where Institution A could rely on another IRB's review of the study without having to execute an IAA with each of the 100 performance sites?

OGCP RESPONSE: As noted above, the IRB at institution A may choose to rely on the review of another qualified IRB. FDA's guidance titled, "[Using a Centralized IRB Review Process in Multicenter Clinical Trials](#)" recommends that if an institution, its IRB, and a central IRB agree under 21 CFR 56.114 to participate in a centralized IRB review process, they should document that action in an agreement signed by the parties.

FDA does not have a Federal Wide Assurance requirement, so I am unable to address your question about IAAs. I suggest you reach out to OHRP to discuss your question – see <https://www.hhs.gov/ohrp/about-ohrp/contact-us/index.html#go-to-education-outreach-inquiries> for information on how to contact OHRP.

I hope this information is useful. If you need further information and/or have additional questions, please feel free to contact us at the official GCP mailbox, gcp.questions@fda.hhs.gov. You may also find it useful to access the set of redacted GCP e-mails found at <http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/RepliestoInquiriesToFDAonGoodClinicalPractice/default.htm> since we find that many questions and concerns are repeated over time.

Best Regards,

Janet
Janet Donnelly, RAC
Policy Analyst

Office of the Commissioner
Office of Good Clinical Practice
U.S. Food and Drug Administration



This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

From: [REDACTED]
Sent: Tuesday, May 14, 2019 9:42 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: Question re: IRB Review of research study

Hello,

We are currently working with an institution (Institution A) that has an IRB and typically collaborates with other institutions/companies to perform specific activities in research studies. They have a specific situation for which we would be interested in FDA's feedback.

Scenario:

- There is a multi-site Phase 1b-2 trial that is being conducted both internationally and domestically. Each site is responsible for its own IRB oversight domestically. Overseas, it varies by country but many use local review. There will ultimately be over 100 sites. Institution A is not the sponsor of the study.
- As part of the clinical trial, there are optional qualitative participant interviews. Institution A is responsible for developing and administering these surveys to participants and are not conducting any other portion of the clinical trial. The informed consent form for the clinical trial includes a description of these optional qualitative interviews.

Questions:

1. Institution A's IRB typically only reviews the activities that Institution A is engaged in (in this case the administration of the surveys). Given that the qualitative interviews are part of the trial protocol and are consented to as part of the overall study consent form, can Institution A's IRB just review and approve the interviews administered in the study and not the entire study itself (since it is not conducting the trial in its entirety)?
 - a. If so, is there anything specific that should be included in the review documentation so that the limited scope of the review is clear?
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I appreciate your insight.



