

From: OC GCP Questions
To: [REDACTED]
Cc: [OC GCP Questions](#)
Subject: RE: Questions about transfer of IRB oversight
Date: Friday, May 24, 2019 10:51:00 AM
Attachments: [REDACTED]

Good morning,

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 (highlighted in red) with some thoughts for your consideration.

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional questions.

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U.S. Food and Drug Administration**



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From: [REDACTED]
Sent: Thursday, May 16, 2019 8:12 AM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: Questions about transfer of IRB oversight

Hello,

We are working with a client to help set them up a new IRB. Here is the scenario:

- This organization (Org A) was previously part of another organization (Org B) and then legally

separated, which eventually included separation of the research portfolio.

- Initially Org B retained IRB oversight of all research via a Memorandum of Understanding for IRB reliance while the research infrastructure at Org A was being developed and implemented. Org A is now setting up its own IRB and will be transferring the research it is engaged in from Org B's IRB; there will be over 1000 protocols transferred.
- The transfer for the majority of these studies will happen at a single point in time (an identified date).
- Part of the transfer process will include notification to subjects at the time of transfer of the change in the contact information regarding subject rights and/or whom to contact in the event of research-related injury. The plan is to develop an informed consent addendum for new subjects and a letter for enrolled subjects that includes the change in IRB contact information for the transferred studies.
 - The informed consent forms for transferred studies will eventually be revised to change the IRB contact information in the form either at the first modification or continuing review reviewed by Org A's IRB.

Our questions are:

1. Since there will be over 1000 protocols transferred at a single time, there is a need to have the informed consent addendum and letter available to all Investigators for all of these studies on the date of the transfer. It does not seem feasible for the IRB to review and approve modifications individually for each of these 1000 studies for the consent addendum and letter; would it be acceptable for the IRB to review the informed consent addendum and letter (for the change in IRB contact information) one time and then approve it for use for all transferred studies?

Response: FDA regulations require that an IRB review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by the applicable regulations (21 CFR 56.109(a)). The IRB must review and approve the informed consent and any amendments to the informed consent that the subject will receive and view (see 21 CFR 56.109(a)). The IRBs must maintain and retain copies of materials that have been reviewed in accordance with 21 CFR 56.115. Furthermore, FDA's regulation at 21 CFR 56.108(a) requires (among other things) that an IRB shall follow written procedures for ensuring changes in approved research, during a period for which IRB approval has already been given, may not be initiated without IRB review and approval except where necessary to eliminate apparent immediate hazards to the human subjects. The process by which the IRB must review the changes to the consent forms may be dependent on the written procedures of Org A.

- a. If so, in the IRB's electronic system, would the FDA still expect to see the IRB approved informed consent addendum and letter in each of the 1000 individual study records? Or would a record in the system of the single review of the addendum and letter with the list of applicable studies be acceptable?

See above response.

2. FDA's *Guidance for IRBs, Clinical Investigators, and Sponsors Considerations When Transferring Clinical Investigation Oversight to Another IRB (May 2014)* states in Section III.(6), "Therefore, when a change in IRB oversight results in changes in the contact information regarding subject rights and/or whom to contact in the event of research-related injury, the new contact information must be provided. For subjects who are already enrolled (whether or not they are active), this may be accomplished in a number of ways, including sending a letter providing the relevant contact information." For notification to enrolled subjects, what other methods of notification of change in contact information would be acceptable to the FDA besides a letter? Email? Phone call? Posting on a webpage/website?

Response: There may be a variety of approaches to fulfill the requirements for informed consent (21 CFR part 50). You may wish to review the 2016 guidance on the [Use of Electronic Informed Consent - Questions and Answers](#) to address your situation.

a. If there is no contact information available for an enrolled subject, is it acceptable to put a note in the subject's file indicating that they were not provided the notification of change in IRB contact information?

See above response.

b. For subjects who have participated in a registry or repository study that is transferred, what is FDA's expectation regarding notification to those subjects? Do all subjects who have samples/data stored need to be notified of the change in IRB contact information? If so, depending on how long the registry/repository study has been going on, this could include a large number of enrolled subjects; does FDA have an expectation for the timeframe for when subjects should be notified after the transfer occurs (e.g. subjects should be notified within X days after the IRB transfer occurs).

Response: FDA's regulations and guidance do not address this specific question. When the regulations are silent, IRBs are free to develop their own procedures and practices as long as applicable regulatory requirements are met. In some instances registries may not be subject to FDA regulations. You may wish to refer to FDA's guidance [Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices](#) in deciding how best to address your situation.

Thank you in advance for any guidance. If a conversation is helpful, I am happy to schedule a phone call to discuss.

Thanks!

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