

From: [OC GCP Questions](#)
To: [REDACTED]
Subject: RE: IRB Re-Approval Question
Date: Monday, February 4, 2019 2:19:00 PM
Attachments: [REDACTED]

Dear [REDACTED]

FDA's guidance titled "IRB Continuing Review After Clinical Investigation Approval" published in February 2012 addresses the issue of a lapse in IRB approval; see <https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM294558.pdf>. Please note the section called "Lapse in IRB Approval" on pages 19-21 of the guidance.

FDA regulations at 21 CFR part 56 make no provision for any grace period extending the conduct of research beyond the expiration date of IRB approval. When continuing review of the research does not occur prior to the end of the approval period specified by the IRB, IRB approval expires automatically. A lapse in IRB approval of research occurs whenever an investigator has failed to provide continuing review information to the IRB or the IRB has not conducted continuing review and re-approved the research by the expiration date of IRB approval. In such circumstances, all research activities involving human subjects must stop. Enrollment of new subjects cannot occur after the expiration of IRB approval.

Sponsors are responsible for the assurance of proper monitoring of a clinical investigation (21 CFR 312.50 and 21 CFR 812.40). The guidance notes that the lapse of IRB approval due to a failure to complete continuing review and obtain reapproval prior to expiration of the prior approval does not automatically constitute a suspension or termination of IRB approval, for reporting purposes under 21 CFR 56.113. Conducting a study subject to IRB oversight during a period of lapsed approval, however, is a violation of an investigator's duties under FDA regulations. See 21 CFR 312.60 (investigator is responsible for ensuring that an investigation is conducted according to the signed investigator statement, the investigational plan, and applicable regulations); 312.66 (requiring investigators to assure that study is subject to continuing review by an IRB meeting the requirements of part 56); 21 CFR 812.100 (investigators must ensure that study is conducted in accordance with applicable FDA regulations and conditions of IRB approval); 812.110(a) (investigator shall not request the written informed consent of any subject to participate, and shall not allow any subject to participate before obtaining IRB and FDA approval); 21 CFR 56.103(a) (studies that must meet requirements for prior submission in parts 312, 812, and 813 "shall not be initiated unless that investigation has been reviewed and approved by, and remains subject to continuing review by, an IRB meeting the requirements of this part").

You indicated that documentation that explains the six day gap between the IRB and the site was filed in the regulatory binder. You also indicated that no new subjects were enrolled and that there were no study visits during the lapse in IRB approval. You do not state whether already enrolled subjects continued participation in the study, whether the investigator

determined whether it was in the best interests of the already enrolled subjects to continue to participate in the research during the lapse in IRB approval, whether and how the investigator communicated this information to the IRB and whether the IRB agreed with the investigator's determination. It might be a good idea to ensure that this information is included in the documentation of the lapse of IRB approval.

Note that the guidance mentions that the IRB should document why the lapse occurred (e.g., insufficient number of IRB meetings to accommodate all continuing reviews, investigator failure to respond to a reminder notice of the anniversary date of approval, investigator failure to provide information to allow the IRB to conduct continuing review) and identify the steps taken to prevent any future lapses (e.g., modification of written procedures, adding more IRB meetings).

Regards,

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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: Sunday, February 3, 2019 9:29 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: IRB Re-Approval Question

Good day. Can you provide some guidance on how this scenario could/should be handled from a QA perspective:

The sites continuing review was IRB approved on 15 Nov 2018, expiration date 09 Nov 2019. In review of the sites IRB continuing date, the CRA confirmed that there was a six (6) day gap in the

expiration date of the annual IRB expiration date 09 Nov 2018 and the IRB re-approval date of 15 Nov 2018. The IRB required additional information from the site prior to them receiving IRB approval before the expiration date of 09 Nov 2018. Documentation that explains this six (6) day gap between the IRB and the site is filed in the regulatory binder. The CRA confirmed that no subjects were consented during the six (6) day gap nor were there any study visits conducted for any subjects during that six (6) day gap.

Thanks,

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