

**From:** [OC GCP Questions](#)  
**To:** [REDACTED]  
**Subject:** Institutional Effective Date vs. External IRB Effective Date  
**Date:** Thursday, November 07, 2019 11:13:39 AM  
**Attachments:** [REDACTED]

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Good morning –

Thank you for your email. I consulted with a few of my OGCP colleagues.

We believe the question being asked is: Would it be acceptable to develop an SOP supporting that externally IRB-approved documents may not be immediately implemented for use (e.g., re-consenting, enrollment of new subjects) until local ancillary and HSRO administrative reviews are completed? Institutions are free to develop whatever processes they want to implement for the review by an external IRB because the regulations don't address this. If this is a process you want to implement than having an SOP describing it is a good idea, but it will also be important for the individuals within your institution to be familiar with the institutional process and SOP to make sure the SOP is actually followed. It would be ideal for the institution to share the process and SOP with the reviewing IRB/sIRB/external IRB so that all parties are familiar with the process

Additionally, it may not be an issue with delaying implementation of an external IRB-approved protocol being implemented until the local cancer-specific scientific review board and/or institutional biosafety committee (when applicable) review the protocol.

Also, as long as your local Human Subjects Research Office is only conducting an administrative review of the documents, and not approving the protocol as a second IRB of record, we don't see this to be a problem.

Please remember that putting an SOP in place and train all that are involved in the process would assist you in implementing what you would like to do.

Kind regards,

Doreen M. Kezer, MSN  
Senior Health Policy Analyst  
Office of Good Clinical Practice  
Office of the Commissioner, FDA



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**From:** [REDACTED]  
**Sent:** Wednesday, November 06, 2019 1:36 PM  
**To:** OC GCP Questions <[gcpquestions@fda.hhs.gov](mailto:gcpquestions@fda.hhs.gov)>  
**Cc:** [REDACTED]  
**Subject:** Institutional Effective Date vs. External IRB Effective Date

Dear FDA,

The purpose of this correspondence is to request guidance on whether it may be permissible to implement a “local effective date” for the use of study documents that would be subsequent to IRB approval. ***Note that this would apply to studies utilizing an external IRB only.***

The issue we are facing is that while an external IRB may provide its approval of amended study documents, the amendment must also be reviewed locally by our cancer-specific scientific review board and/or our institutional biosafety committee (when applicable), and this review many times would occur *after* approval by the external IRB. Furthermore, our Human Subjects Research Office also conducts an *administrative* review of the documents and so there will inevitably be at least a few days delay.

(This is a non-issue for studies reviewed by our local IRB, as their approval is not released until all ancillary reviews are complete.)

Would it be acceptable to develop an SOP supporting that externally IRB-approved documents may not be immediately implemented for use (e.g., re-consenting, enrollment of new subjects) until local ancillary and HSRO administrative reviews are completed?

I would appreciate your guidance on this, as I would like to address this issue in a manner that is compliant with good clinical practice.

Thanks,

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