

**From:** [OC GCP Questions](#)  
**To:** [REDACTED]  
**Subject:** Question on IRB submission and signatures on initial review submissions  
**Date:** Wednesday, July 17, 2019 12:02:07 PM  
**Attachments:** [REDACTED]

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Good morning –

The scenario you describe is not addressed in FDA regulations or guidance. When the regulations are silent institutions can develop their own policies and procedures to address a particular issue or situation.

Please see the guidance document – Investigator Responsibilities – Protecting the Rights, Safety, and Welfare of Study Subjects <https://www.fda.gov/media/77765/download>  
This document discusses clinical investigator responsibilities and delegation of tasks. FDA would not want to see over-delegation of tasks, as you state the CI is ultimately responsible for overseeing the study.

What does your IRB want to decide? Are they okay with someone other than the PI signing the initial submission to the IRB? This situation should be addressed in your IRB written procedures.

Also, please see for your review, FDA guidance on IRB written procedures and FDA IRB CPGM. (links below)

<https://www.fda.gov/media/99271/download>

<https://www.fda.gov/media/75909/download>

Kind regards,

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



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.

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**From:** [REDACTED]  
**Sent:** Tuesday, July 16, 2019 11:45 AM  
**To:** OC GCP Questions <[gcpquestions@fda.hhs.gov](mailto:gcpquestions@fda.hhs.gov)>  
**Subject:** Question on IRB submission and signatures on initial review submissions

Good morning:

We have been approached by some clients about the possibility of having someone other than the Principal Investigator sign off on the initial submission to the IRB.

They have stated that certain IRBs allow the Investigator to designate a signatory authority to a regulatory team member (or other specified staff) to submit their application to an IRB.

We are inquiring about the FDA's opinion on whether this is an acceptable practice, if there is documentation in place / process / policy to fully document this delegation.

We contacted [REDACTED] and they stated that they had no requirements surrounding this, and to contact FDA for an opinion.

They said we would need to clearly document that the PI is ultimately responsible for all study activities; and if they delegate that they concur with this and will ensure that all FDA regulations and guidances are followed. A conflict of interest statement is also included in the agreement.

Please can you let us know if you have an opinion on whether this would be an unacceptable practice as per your policies/practices.

Thank you in advance,

[REDACTED]