**From:** OC GCP Questions
**To:** [redacted]
**Subject:** Informed Consent process
**Date:** Wednesday, May 20, 2015 10:55:02 AM

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Dear [redacted] –

In general, yes I would say that the PI could delegate the task of consenting and reconsenting. However, since the IRB specifically states that the PI and/or attending physicians should consent, I would ask the reviewing IRB for clarification and document their answer to you.

Kind regards,

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



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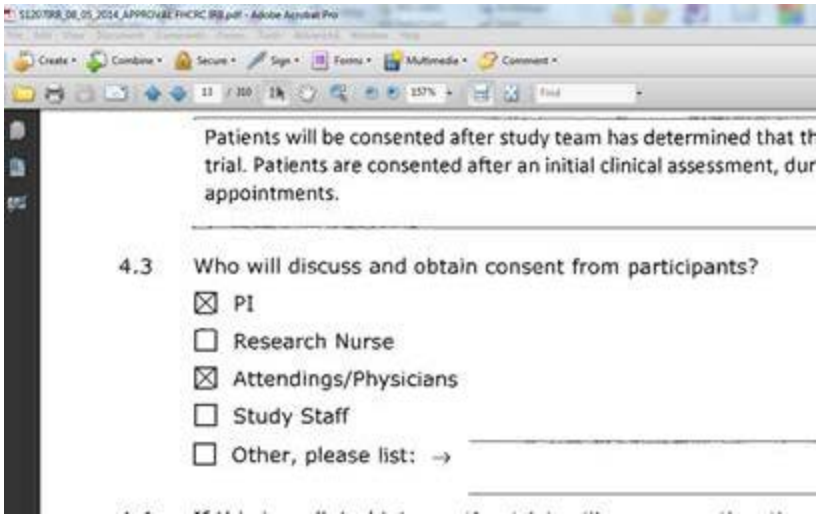
**From:** [redacted]
**Sent:** Tuesday, May 19, 2015 1:16 PM
**To:** OC GCP Questions
**Subject:** RE: Informed Consent process

Hi Doreen,

Thank you for this information. One more question… If the IRB application was marked as only the Physician/Attending Physician who will discuss and obtain consent from the participants, could the PI still delegate any part of the consent process (such as reconsenting) to the research coordinator?


Patients will be consented after study team has determined that th
trial. Patients are consented after an initial clinical assessment, dur
appointments.

4.3 Who will discuss and obtain consent from participants?

- ☒ PI
- ☐ Research Nurse
- ☒ Attendings/Physicians
- ☐ Study Staff
- ☐ Other, please list: →

Thank you,
[redacted]