From: OC GCP Questions
To: [redacted]
Subject: RE: Question Regarding Non-FDA IRB
Date: Friday, May 08, 2015 5:40:00 PM

Dear [redacted] -

Thank you for your question. The question you ask about whether or not your IRB should continue to be involved in decisions related to outsourcing IRB review of FDA-regulated studies to external IRBs is an institutional process question that you will need to discuss with the appropriate institutional officials at your institution.

As you know, the regulations found in 21 CFR 56.114 address cooperative research but don't address your specific scenario. FDA does have a guidance document titled, "*Guidance for Industry – Using a Centralized IRB Review Process in Multicenter Clinical Trials*" that can be found at http://www.fda.gov/downloads/RegulatoryInformation/Guidances/ucm127013.pdf. While this guidance does not address your specific scenario, it does recommend that IRBs have procedures for implementing a centralized review process. So once decided, you may want to consider addressing the process of how your institution handles oversight of FDA-regulated studies at your institution in your written procedures.

You may also wish to discuss your question with the external IRB(s) you are working with for oversight of FDA-regulated studies.

I'm sorry I can't be more helpful to you, but the answer to your question depends on a lot of details that are specific to your institution (e.g., institutional policies, procedures, and written agreements/contracts your institution may have with external IRBs).

If you need further information and/or have additional questions, please feel free to contact us once again at the official GCP mailbox, gcp.questions@fda.hhs.gov. You may also find it useful to access the set of redacted GCP e-mails found at http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/RepliestoInquiriestoFDAonGoodClinicalPractice/default.htm since we find that many questions and concerns are repeated over time.

Best Regards,

Janet

Janet Donnelly, RAC, CIP
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Office of the Commissioner, Food and Drug Administration

From: [redacted]
Sent: Wednesday, May 06, 2015 3:48 PM
To: OC GCP Questions
Subject: Question Regarding Non-FDA IRB

Dear Janet,

[redacted]

Just to let you know that on [redacted] IRB officially transitioned to an IRB that does not approve or oversee any FDA-regulated studies. Our IRB is still registered with OHRP, but we have relinquished our registration with the FDA.

Currently, we are only overseeing [redacted] and research studies that do not involve FDA-regulated drugs or devices.

Currently, we have members of our Medical Staff that conduct clinical research trials with oversight through Central IRBs. In the past

when our IRB was registered with the FDA, our IRB would review and waive oversight to these clinical trials, completing waiver forms to send to the Principal Investigators and the Central IRBs.

My question is this: Now since our IRB not registered with the FDA, is our IRB allowed to be involved in any future waiver process of clinical trials? In other words, since our IRB cannot oversee any clinical trial that involves FDA-regulated drugs or devices, do Principal Investigators still need to submit their studies to our IRB for waiver?

I would appreciate any feedback or resources that I could bring to my IRB members to address this issue.

Thank you very much.

[redacted]