From: OC GCP Questions
To: [redacted]
Subject: RE: IRB Study Transition
Date: Tuesday, February 16, 2016 11:14:00 AM

Dear [redacted] -

Thank you for your question. The FDA regulations do not specifically address the transfer of IRB oversight. When the regulations are silent, IRBs, institutions, sponsors, investigators are free to develop their own procedures and practices as long as applicable regulatory requirements are met.

FDA has guidance titled, "*Guidance for IRBs, Clinical Investigators, and Sponsors - Considerations When Transferring Clinical Investigation Oversight to Another IRB*" that you can find at http://www.fda.gov/downloads/regulatoryinformation/guidances/ucm307779.pdf. This guidance discusses the regulatory responsibilities of IRBs, clinical investigators, and sponsors when oversight of a previously approved, ongoing clinical investigation under FDA's jurisdiction is transferred from one IRB to another IRB. This guidance also addresses questions that have been previously raised concerning procedures and processes that are required and/or recommended by FDA when such oversight is transferred.

I hope this information is useful. If you need further information and/or have additional questions, please feel free to contact us 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
Policy Analyst, Office of Good Clinical Practice
Office of Special Medical Programs, Food and Drug Administration

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From: [redacted]
Sent: Monday, February 15, 2016 4:15 PM
To: OC GCP Questions
Subject: IRB Study Transition

A new medical school is now up and running within our community. Previously, both community hospitals had clinical research departments and each had their own IRB. Now, both of these research departments have transitioned under the medical school and the plan is to dissolve each hospital's IRB and provide oversight for all studies under the medical school's newly formed IRB. We are looking for guidance on this transition process specifically addressing the need to review studies prior to transferring them to the new IRB. In this scenario, would you agree the best option would be to have an independent reviewer evaluate each study to determine the overall risk and any potential problems prior to the new IRB assuming this responsibility?

Also, would you agree that each sponsor should be given the option of transitioning to the newly formed IRB under the medical school or choosing a central IRB of their choice? If there are any specific rules & regulations that we could refer to for guidance, would you please reference them.

[redacted]