From: OC GCP Questions
To: [redacted]
Cc: **[redacted]**
Subject: RE: [Redacted] IRB question - [Redacted]
Date: Monday, November 17, 2014 2:40:00 PM
Attachments: [redacted]

Dear [Redacted]-

Thank you for your question, which was forwarded to my office by Sharon Matson who is busy working on a project. Sharon asked if my office could respond to you. I am glad that Sharon forwarded your message so that I can share with you our OGCP public mailbox resource for future reference. FDA has a public mailbox for GCP questions and you can feel free to send your GCP questions to gcp.questions@fda.hhs.gov. Information about my office and the public mailbox can be found at http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ucm134476.htm. Simply for your reference, FDA also posts "Replies to Inquiries to FDA on Good Clinical Practice" which is a compilation of previous GCP questions from the public and our responses. The questions are redacted and are followed by the OGCP office response. Questions and responses are categorized by topic and filed in folders by year (years 2002 to 2013). You can see the redacted questions and responses at http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/RepliestoInquiriestoFDAonGoodClinicalPractice/default.htm .

If I understand your question correctly, your PI is requesting IRB close out of a study (Plan A) because at this time, he/she has completed the study and does not need IRB continuing review and oversight. You are asking whether, if at some time in the future the PI decides to do new/additional analyses on the Plan A data, he/she has to submit this plan (Plan B) to the IRB for review and approval as an initial review. Based on the limited information provided, it appears that yes, the plan for new/additional analyses (Plan B) would need to be submitted to your IRB for an initial review since this is a new study and the Plan A study is closed out.

As you found when you looked, the regulations do not address your specific scenario. The regulations at 21 CFR 56.108(a)(1) requires:

> *Sec. 56.108 IRB functions and operations.*
>
> *In order to fulfill the requirements of these regulations, each IRB shall:*
>
> *(a) Follow written procedures: (1) For conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and the institution;*

The regulations do not address IRB close out of a study. When the regulations are silent, IRBs and institutions are free to develop their own procedures and practices as long as applicable regulatory requirements are met. In addition to the required written procedures noted above, many IRBs have written procedures to address close out of IRB oversight when a study is completed.

If in the future the PI submits a new plan/study to your IRB for an initial review, you may wish to treat any future submission as a new study rather than reopening the old study because it may be easier to track for record retention purposes. This may be an opportune time for you to discuss how you might best handle this scenario in the future with the appropriate institutional officials at your institution. It is most important that your IRB follow its written procedures for conducting initial and continuing review and any institutional policies and procedures regarding study close out.

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. As I mentioned above, 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, November 10, 2014 10:57 AM
To: Matson, Sharon L
Subject: [Redacted] IRB question - [Redacted]

Hi Sharon,

[Redacted]

I have an IRB question, I hope you will be able to answer:
A very brief Abstract: An PI will be closing an IRB approved study (approved 1/2013) this month. His study (name it Plan A) already has gone through one continuing review approval. I sent him a continuing review notification (second time around) in which he replied that he will close the study (Plan A). He also stated, if he finds he will need to do some more analysis (in the future) he will request the IRB to review the study.

Question: Let's say the PI received an official approval that he study is closed (final) and within 6 months he decides to do more analysis (Plan B Study) on the same study. He will need to re-submit his study as an initial review- right? Could his "new" (Plan B) analysis be added to the "old" analysis (Plan A)?

I hope this makes sense. I cannot find in the fda regs if a PI can re-submit the same study (Plan A), when Plan A Study received a final closure review from the IRB.

Sharon, thank you for your time and I appreciate your expertise in the matter. [Redacted]