From: OC GCP Questions
To: [redacted]
Cc: Blatt, Hal (OS)
Subject: RE: Process for IRB Transitioning to Non-FDA IRB
Date: Friday, February 13, 2015 2:12:00 PM

Dear [redacted] -

Thank you for your question. If I understand your question correctly, your institution and IRB has decided to no longer oversee FDA-regulated research and you would like to know how to update your IRB registration to reflect this change.

As you know, FDA's IRB registration regulations can be found at 21 CFR 56.106 (see http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=56.106). The regulations at 56.106(e) specifically state:

> Sec. 56.106 Registration.
>
> (e) *How does an IRB revise its registration information ?* If an IRB's contact or chair person information changes, the IRB must revise its registration information by submitting any changes in that information within 90 days of the change. **An IRB's decision to review new types of FDA-regulated products (such as a decision to review studies pertaining to food additives whereas the IRB previously reviewed studies pertaining to drug products), or to discontinue reviewing clinical investigations regulated by FDA is a change that must be reported within 30 days of the change.**[emphasis added] An IRB's decision to disband is a change that must be reported within 30 days of permanent cessation of the IRB's review of research. All other information changes may be reported when the IRB renews its registration. The revised information must be sent to FDA either electronically or in writing in accordance with paragraph (d) of this section.

FDA also has Guidance for Institutional Review Boards (IRBs) titled, "Frequently Asked Questions – IRB Registration" that can be found at http://www.fda.gov/downloads/regulatoryinformation/guidances/ucm171256.pdf.

Given that your institution and IRB has decided to discontinue reviewing clinical investigations regulated by FDA you must update your IRB registration within 30 days of the change. As you are likely aware, IRB registration information is entered into an Internet-based registration system maintained by the Department of Health and Human Services (HHS). This system is a modification of the one used by the Office for Human Research Protections (OHRP) for registration of IRBs that are designated by institutions under Federalwide Assurances (FWAs). To update your IRB registration to reflect this change, you can go to the OHRP web page at http://www.hhs.gov/ohrp/assurances/irb/index.html and follow the instructions on the left hand side of the page to Update/Renew a Registration. You should make the necessary change to your IRB registration to reflect the decision to no longer oversee FDA-regulated research. Should you need assistance with updating your IRB registration, you can contact Dr. Hal Blatt, OHRP Assurances/IRB Registrations at hal.blatt@hhs.gov. Dr. Blatt can also be reached by telephone at 240-453-8232 if you have any difficulty accessing the IRB registration database, and I have copied him on this response. Dr. Blatt can also answer any questions you may have about your OHRP registration status.

You also mentioned that you have a few FDA-regulated studies that you have advised your investigators to either close out or transfer to a central IRB. I wanted to mention that FDA has Guidance for IRBs, Clinical Investigators, and Sponsors titled, "Considerations When Transferring Clinical Investigation Oversight to Another IRB" that can be found at http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM307779.pdf that may be helpful in the transfer process as 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.

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
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Office of Special Medical Programs, Food and Drug Administration

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.

From [redacted]
Sent: Tuesday, February 10, 2015 7:37 PM
To: OC GCP Questions
Subject: Process for IRB Transitioning to Non-FDA IRB

To Whom It May Concern,

My name is [redacted] and I am the [redacted]. We currently have a hospital IRB in place and recently had an FDA site visit [redacted].

[redacted]

Due to the fact that our IRB has approved only two clinical studies (FDA-regulated) in the last 24 months, our IRB and hospital administration have decided to transition to an IRB that will not review, approve or oversee any FDA-regulated studies. We have contacted and requested the Principal Investigators of the few studies that we do oversee to either close the studies or transfer them to a central IRB. This process should be completed by [redacted].

I would like to ask what process does our IRB have to undergo through the FDA to either decertify or reclassify our IRB as a non-FDA regulated study institutional review board?
Our plan is for our IRB to continue to review and approve [redacted] studies that do not involve FDA-regulated drugs, devices or trials.

Our IRB is registered with both the FDA and OHRP. I already know the OHRP procedures to deactivate our IRB, but wanted to go through the FDA process first.

I would appreciate your assistance as to the process we need to take to implement this transition.

Please feel free to contact me should you have any questions.

Thank you very much for your help in this matter.

[redacted]