From: OC GCP Questions
To: [redacted]
Subject: RE: IRB Record Retention after IRB Transfer
Date: Thursday, December 08, 2016 11:53:00 AM
Attachments: [redacted]

Dear [redacted],

56.115(b) states “The records required by this regulation shall be retained for at least 3 years after completion of the research, and the records shall be accessible for inspection and copying by authorized representatives of the Food and Drug Administration at reasonable times and in a reasonable manner.”
FDA’s regulations do not address transfer of studies and their associated records between IRBs.

The answer to your question depends on whether the original IRB transfers all of the documents and responsibility for study oversight to the new IRB, and whether or not the new IRB accepts this responsibility, or whether the two IRBs share responsibility for the study.

Study records must be retained for at least 3 years after completion of the research, but this can be accomplished in a variety of ways, some examples of which are addressed in the guidance, *Considerations When Transferring Clinical Investigation Oversight to Another IRB*, which can be found at http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-afda-gen/documents/document/ucm307779.pdf .

As noted in the guidance, “Because FDA may require access to the records at any reasonable time, it is important for the agency to know whether the original IRB, the receiving IRB, the institution that housed the original IRB, a CRO or other responsible third party will maintain the records once clinical investigation oversight has been transferred. The party that assumes responsibility for the records is responsible for ensuring that they are retained in accordance with 21 CFR 56.115(b).”

If the original IRB elects to retain their documents for the required period, copies of pertinent documents should be given to the receiving IRB for their records, with concurrence of the study sponsor.

I hope this information is helpful to you. If you need further assistance, please feel free to contact the GCP mailbox at gcp.questions@fda.hhs.gov .

Best regards,

Sheila

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From: [redacted]
Sent: Tuesday, December 06, 2016 2:01 PM
To: OC GCP Questions
Subject: IRB Record Retention after IRB Transfer

Hello,

I'm hoping that you could clarify something for me regarding IRB record retention. When IRB oversight is transferred to a new IRB, is the original IRB still obligated to retain records for 3 years after the completion of the research? or would it be for 3 years after the transfer of oversight?

Thank you in advance for any help you can offer,

[redacted]