

Closing a Study with the Emory IRB

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Emory IRB Webinar

April 14, 2016

General Considerations

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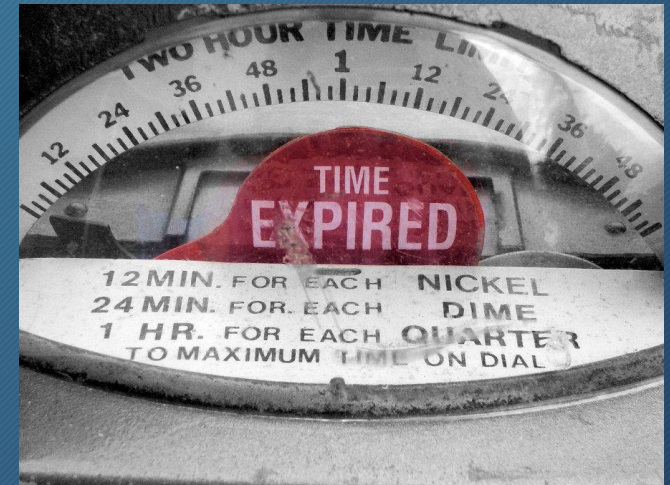
- The completion or closure of a study is a change in activity that must be reported to the Emory IRB at the time that it occurs. If you are planning to close out the study, make sure you are also gathering documents for the close out, so you are prepared!



General Considerations

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- Don't let your study lapse! You need to submit a continuing review application, even if your study is about to close. Alternatively, you may submit a close out request before study approval expiration
- Any premature completion or closure of a study should be reported and explained to the IRB.



When should I close my study?

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- It will depend on your study status and sponsor requirements, if any
- Examples when a study should be left open
 - Studies still collecting follow up data
 - Studies from sponsors still reviewing collected data(for example, asking study teams to verify in the medical record data already collected)

When should I close my study?

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- Examples when a study should be left open (cont...)
 - Studies submitted for publication when is likely that the publisher will ask for additional data
 - Studies in data analysis with identified data (containing PHI)
 - Studies under an Emory sponsor, that need to submit final IND or IDE reports (after the study ends) to the FDA

My study is ready for closeout, now what?

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- Submit a Close-out submission under the study history
- The form will ask you if you are still collecting data, etc.
- Add information about the study status, any publication or results
- Do not continue with research activities (including data analysis) with identified data

eIRB close out form

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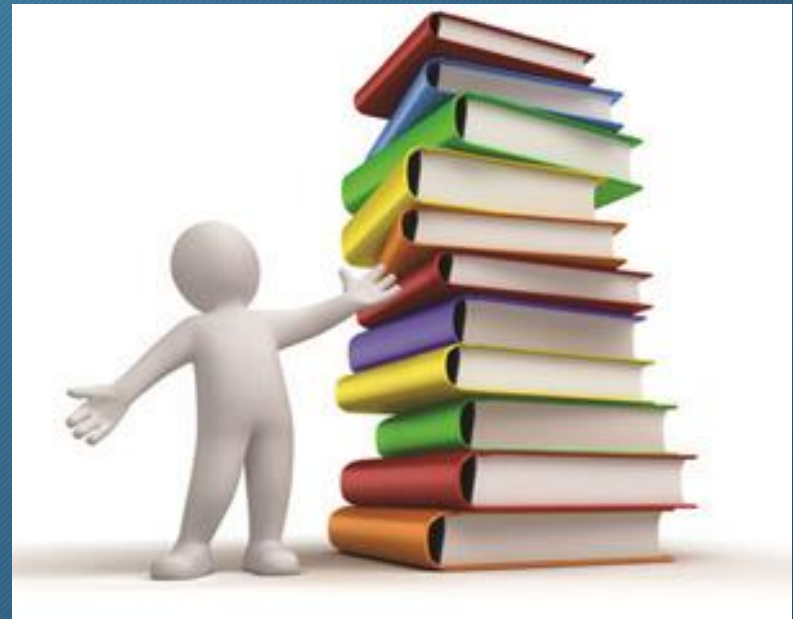
- The form will ask you the following about your study status:
 - Subject enrollment has ceased
 - Blood or tissue has ceased
 - Data collections has ceased
 - No subject follow-ups will occur for research
 - All reportable events were already submitted



eIRB close out form

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- A point of confusion in the form:
 - The form asks to verify if all data has been published. You do not need to have the study open for publishing purposes unless there is a chance the publisher will ask you to obtain additional data, or to verify in the medical record information already collected.



eIRB close out form

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- At the end of the form, we ask: *Upload a short narrative summary of the conclusions of this study. Include any comments on adverse events that occurred, and the significance they had on your conclusions.*
- Here, you should upload:
 - Any publication (if any), abstract with results, IND/IDE withdrawal requests and final reports

My sponsor has additional SAEs reportable at CR, should I keep the study open?

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- You do not need to keep your study open because you need to submit related internal SAEs at continuing review.
- Related, internal SAEs can be reported with the close out, and they will be part of the close out record



What about if I have NC or UP to report?

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- In that case, you cannot close the study until the potential unanticipated problem or noncompliance are reviewed by the IRB
- Submit a reportable event submission and explain that you are in the process of closing the study.

After closing my studies, can I destroy collected data?

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- No, you cannot, and the retention of the data will vary per study. For example, for FDA studies(using a drug/device/biologic), you cannot destroy the data until 2 years after the drug/device/biologic have been marketed in the US.
- Even then, Emory has more strict rules about retention of certain documents, such as ICFs. For more information, use this link:
<http://records.emory.edu/retention-schedules/categories/research.html>

I closed the study, and now the sponsor wants to see my stored data

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- If the data that you are providing does not have identifiers (as it is the case with a lot of case report forms) this may not be a HIPAA issue, but more about your contract with the sponsor, and the staff effort needed for it.
- Make sure you are not providing new information about the patient, for example, current test data
- Note: for FDA studies, the sponsor may request information for safety reasons, and that is covered by HIPAA/FDA.

I closed the study but now I need to collect more data

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- In special circumstances, the IRB may allow you to re-open your study. The study will need to be renewed with a CR application before re-starting the research.
- You need to provide a written statement clarifying the reasons for reopening, and disclosing if any research was done during the time the study was closed.

What happens in FDA regulated studies?

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- For investigators: they need to submit a final report to the IRB and the sponsor within 3 months of completion of the investigation



What happens in FDA regulated studies?

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- For sponsors (industry or S-I): they need to submit a final report to all reviewing IRBs within 6 months after termination or completion.
 - For Emory sponsor IDE studies: study should remain open until the final report is submitted to the FDA, and IDE is closed.
 - For Emory sponsor IND studies: If IND is not used in other protocols, IND should be closed and final report submitted before closing study with IRB

Special considerations for the research done at the AVAMC

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- If your study took place at the VA (or done with VA resources), you need to submit the VA closeout form with the eIRB submission.
- The form can be found at:
http://www.atlanta.va.gov/Docs/Closeout_Summary_for_Human_Subjects_Research.docx
- In addition, you should know that the VA has their own data retention schedule. Please consult with the VA before closing a study.

If you have additional questions...

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