



EMORY UNIVERSITY

Institutional Review Board

Research Administration

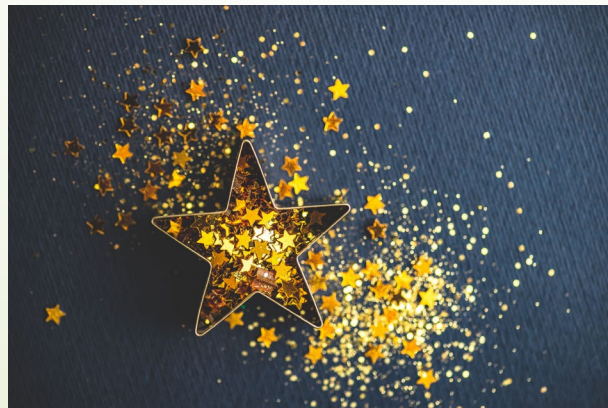
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Type all your questions in the Q&A space (not in the chat window). We will answer all your questions at the end of the webinar



Requirements for updating and cleaning existing submissions: Make IRB part of your New Year's resolutions!

Jackson Parker, CIP
Lead QA/Education Analyst
Emory University IRB
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Topics Covered

- Requirements for updating study submissions
- Guidance on administrative clean up
- Closing studies with the IRB
- Reminder to inform IRB when PIs leave the Emory
- Reminder that the old eIRB (RX) system will be offline and inaccessible

Why is this Important?



To facilitate pre-review and continuing IRB review

To ensure that the study continues to meet approval criteria

To remove documents and information no longer relevant to current study

To ensure the IRB is consistent when requiring updates by using clear guidelines

Studies That *May* Require Updates

- ▶ Originated in the old eIRB (pre-2020) and have not been placed on our protocol templates
- ▶ Have outdated/incorrect information in the protocol, eIRB submission or consent form
- ▶ Missing key information (e.g. drug attachments, questionnaires, site monitoring plan, etc.)
- ▶ The specific updates will depend on several factors...





Examples

- ▶ Requests will vary depending on type of study
 - ▶ Multi-site Clinical Trial with a study-wide protocol open to enrollment
 - ▶ Will require a “supplement” protocol to provide Emory-specific details (e.g. enrollment goal, data management)
 - ▶ Chart Reviews
 - ▶ May only require clarification on data storage and management
 - ▶ Repository/Registry studies
 - ▶ May need specific information added based on our Repository/Registry template
 - ▶ Recruitment/Screening studies
 - ▶ Will need to ensure the information is clear and up-to-date if study is still active and enrolling participants.



Required Updates

- ▶ May not be required for studies in certain statuses
 - ▶ Study in data analysis only or long-term follow-up with no research interventions occurring
 - ▶ May not require any update unless the follow-up procedures are not adequately described in the current protocol/submission
 - ▶ Study that has not been active for many years and includes dated information
 - ▶ Should either be closed or updated before being reactivated
- ▶ Stay tuned for comprehensive guidance on our website!



When To Update?

- ▶ At the time of Continuing Review (CR) or submission of a Modification to “other parts of the study” you may receive feedback from analyst
 - ▶ The analyst working on the study will advise when a follow-on submission is received if additional information/updates are required.
 - ▶ If discovered during CR, to prevent a lapse in approval, the IRB will only require that a modification be submitted (in pre-review state) to move forward with review of CR.
- ▶ During RNI review
 - ▶ The RNI review process sometimes requires diving deep into submission. This may also be a time when updates are required and will be communicated as part of a corrective and preventative action plan (CAPA).
- ▶ During routine internal quality review
 - ▶ The IRB routinely performs quality reviews of submissions. As part of this review there may be a requirement to update portions of the submission to meet our requirements. This will be communicated to the study team following the review.



When To Update? (continued)

- ▶ Study Teams are encouraged to be proactive and review study submissions to see if they need to be updated at any time.
- ▶ Please reach out to the assigned analyst if you have questions on whether updates are necessary.
- ▶ It is important to acknowledge that mistakes are made. If you notice that incorrect/incomplete information is in the submission, please submit a modification to make the necessary corrections.

Administrative Clean-up During Mod or Mod/CR

- ▶ Remove old documents no longer in use
 - ▶ They will still be available via version control
- ▶ Studies with lay summaries that are incomplete or do not align with IRB guidelines
- ▶ Studies with incomplete information in the smartform (e.g. missing drug information and/or required questions unanswered)

Drugs ⓘ

1. * List all drugs, biologics, foods, and dietary supplements to be used in the study:

[+ Add](#)

Generic Name	Brand Name	Drug Type
✎ Update pembrolizumab	Keytruda	Drug

2. * Will the study be conducted under any IND numbers? ⓘ

Yes No [Clear](#)

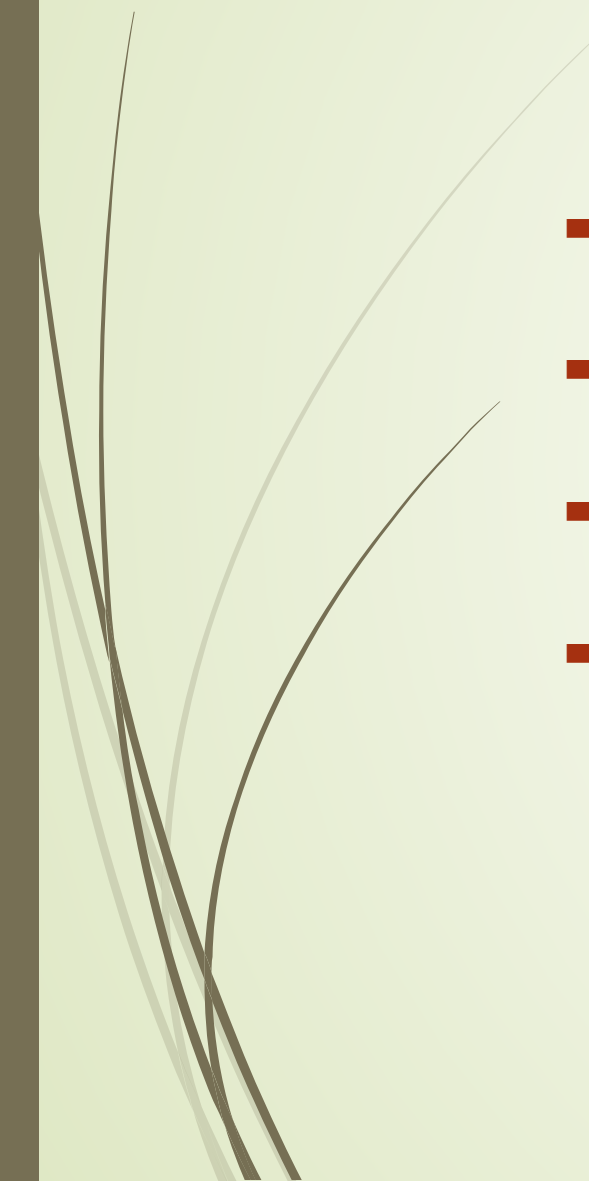
3. * Identify each IND:

[+ Add](#)

IND Number	IND Holder
There are no items to display	




Administrative Clean-up (continued)

- ▶ Communicated by analysts during continuing review or modifications to “other parts of the study”
 - ▶ We encourage teams to be proactive and update submissions when items are noticed
 - ▶ Make sure that questionnaires that are being used as part of the study are submitted to the IRB for review
 - ▶ Reminder: eIRB is not a document repository for studies; be sure to store copies of all materials locally (regulatory binder, study records, master file, etc.)
- 



Closing studies in eIRB

- ▶ Studies not requiring CR still need to be closed in the eIRB system
- ▶ Studies should be closed when they meet the following criteria:
 - ▶ Study is permanently closed to enrollment
 - ▶ All subjects have completed all study-related interventions
 - ▶ Collection of private identifiable information is complete
 - ▶ Analysis of private identifiable information is complete
- ▶ Details on how to submit a study close-out are provided on our website on the [eIRB page-level help](#) section.
- ▶ Note: Close-outs use the CR submission type (there is no separate Close Out submission)
- ▶ Notify the IRB as soon as you become aware that a Principal Investigator is leaving the institution



Emory IRB Process when a Principal Investigator (PI) Leaves Emory

- ▶ It is important to notify the IRB as soon as you become aware that a PI is leaving Emory IRB (ideally 30-45 days before leaving)
- ▶ Email the IRB listserv (irb@emory.edu) and include the name of the specific PI
- ▶ Develop a plan on how active submissions will be handled following departure and provide these details in the PI transfer form.

Emory IRB PI Transition Form

- PI transfers study to another Emory faculty member (may require Department Approval if current PI does not initiate the change)
- Continue study at new institution and Emory (may require reliance or a separate application at the new institution and a change of PI locally); or transfer study to the new institution (Emory no longer a participating site, will need to keep Emory IRB submission active until approval is established at other site)
- Close study at Emory
- [Emory IRB PI Transition Form](#)

EMORY IRB PI TRANSITION FORM					
Instructions: Only needed with a PI leaving or coming to Emory AND 1) taking or bringing IRB approved studies to/from the other institution, or 2) Will remain engaged in research (with the other institution) to be able to continue the study at Emory/Other Institution or 3) if they are taking/bringing the study grant with them. Make sure to submit this form 30 to 45 days before the PI is leaving or coming to Emory.					
PI Name:		Effective Date of Move:			
Name of Institution I am Leaving:		Name of Institution I am Moving To:			
List Below The Affected Studies:					
IRB Number	Study Title	Current Status of Study	Actively Federally Funded?	This study will end at Emory or other institution after I leave	My research activities after I leave Emory/Other institution



Old eIRB will no longer be available after January 2024

- ▶ The old eIRB system will be taken offline and will not be accessible to researchers after January 2024
- ▶ IRB Staff will have access to archived documents from the old system for internal processes
- ▶ Some requests to access old documents may be honored by the IRB
- ▶ If you need to retrieve documents from the old system, please do so in the next couple weeks to ensure you have all you need within your current study files

Questions?



Contacts

- ▶ Call or email [your study analyst](#) directly, for specific study question.
- ▶ Call [any of our staff](#) for general questions.
- ▶ For Education/Outreach questions, Complaints from study participants, Compliance, and Adverse Event issues, please contact the [Education and Quality Assurance Team](#).
- ▶ General inquiries: IRB@emory.edu

