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IRB Turnaround Times and Ways to Streamline Review

Emory University IRB

September 8th, 2022

Agenda

- IRB Target Turnaround Times
- Factors Impacting Overall Timeline
- Ancillary Reviews
- Special Handling Requests
- Website Resources
- Questions

IRB Target Turnaround Times

The IRB sets target turnaround times for initial screening, screening of changes, expedited review, and producing correspondence after review.

The other main element in the overall IRB timeline is the time it takes the study team to respond to IRB requested changes. In addition, the following items are important to consider as they relate to turnaround times:

- Submit early and plan for expected turnaround times to ensure deadlines are met.
- The time to IRB review is not the same as time to approval. There are often changes requested.
- We always try to beat these targets, but the chart is a reasonable expectation.
- **Note:** Repeated calls or emails when the IRB is within our targets may delay your and others' studies.

Type of Submission	IRB Staff Screening	Time until review after receipt of complete submission	Follow up/Letter after review
Full Board new studies and amendments[1]	Pre-screening within two weeks; screening of responsive changes 1-2 weeks depending on complexity of changes	1-3 weeks (i.e. next available meeting)	2 days after IRB meeting
Expedited new studies and amendments	Pre-screening within two weeks; screening of responsive changes around one week, depending on complexity	5 days	2 days after review
Continuing Review *(when submitted at least **45 days** before expiration)*	Pre-screen 3-4 weeks prior to expiration (if submitted in time); sooner if Grady site	2 weeks before expiration Earlier if Grady site	2 days after meeting or expedited review
"Does my study need IRB review?" inquiries (aka NHSR determination)	Immediate: Use our online tool		
Exempt New Studies	Pre-screening within two weeks (often less right now with use of consultants) Screening of responsive changes 1-7 days depending on complexity	5 days	2 days after review

**All times are in business days

IRB Target Turnaround Times

- The IRB meets 6 times a month, and there are up to 5 new studies on each agenda.
- Expedited review means review by one designated reviewer, instead of review at a convened meeting (does not always mean "faster").
- Most IRB reviewers are full-time faculty/clinicians, and while they have target turnarounds, delays sometimes occur.
- Continuing reviews are handled based on expiration date unless Grady ROC review is needed (in which case processed more quickly).
- Modifications for local study team member changes are typically screened within 3 days of receiving the submission.

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Check Status in eIRB

- Always check eIRB for the status of submissions that are in progress.
- Find your assigned analyst listed in the workspace under “IRB coordinator”. If no one is listed email the IRB listserv for updates.

STUDY00004662: Test

Principal investigator: Jackson Parker
Submission type: Initial Study
Primary contact: Jackson Parker
PI proxies:

IRB office: Emory IRB Office
IRB coordinator:

Factors Impacting Overall Timeline

Submission quality

- **New Studies**
  - Use our informed consent templates on our website (ICF/HIPAA templates)
  - See our guidance information for new studies, and our Protocol templates for investigator-designed studies
  - There are Instructional videos to assist with the eIRB submission process and eIRB help pages that provide step-by-step instructions for submissions
  - Include any specific handling instructions in a logged comment when submitting the study
  - Provide a point-by-point response when addressing IRB requested changes

- **Modifications (other parts of the study)**
  - Provide clear and meaningful summaries that highlight the major updates
  - Ensure the enrollment status and subject notification are provided when submitting
  - Ensure documents are uploaded in the correct section and in the correct way (“Update” button used for revised Word documents)

- **Continuing Reviews**
  - Ensure you are submitting around 30-45 days prior to the expiration date
  - Reconcile numbers between last CR and current enrollment totals.
  - Include copies of DSMB memos or other items that were left unchecked in question 6, or provide explanation if not present

Factors Impacting Overall Timeline

Avoid Modification Delays

Clearly summarize what is changing

- Even if including a "summary of changes" document from sponsor, briefly summarize the main changes in the Modification summary
- The IRB is *most* concerned with changes that significantly impact risk or study design (e.g., IB updates, ICF risk updates, etc.)

*We no longer request a "tracked-changes" version of **word documents***.

- Instead, use the "Update" button next to the existing version to submit revised, clean documents.
- eIRB can then automatically create a "compare" or "track-changes" version for the IRB
- Only works for Word documents, not PDF's
- Remember to *update version dates* in footers, file names, and display-names of updated documents

Also, take the opportunity to remove outdated documents from older studies and refresh lay summaries

Factors Impacting Overall Timeline cont.

Other items that can delay submissions:

- Whether grant/contract negotiations and any ancillary reviews are still outstanding
  - Submit to other offices in parallel whenever possible
- How quickly the study team replies to requests for clarification or changes – communication is key for both the study team and IRB staff via eIRB, email, or phone
- Spikes in submissions to the IRB

Currently, the IRB has several vacancies. We are filling in partially with outside consultants and are recruiting new hires as quickly as possible in this environment.

Ancillary Reviews

The following ancillary reviews are required before final IRB approval can be issued:

- **Department Review:** Required for all studies except RSPH grad student studies. The IRB staff can select for you, or you may do it as well.
- **Faculty Advisor Review:** Do not use Ancillary Reviews for this. Instead, please list your faculty advisor as PI and we will request Department Approval. For RSPH, the student can be PI, with the advisor as "Co-Investigator" in the Local Study Team Members section of the smartform. RSPH advisors will be asked to log a comment issuing their approval.
  - Note: For other undergraduate and graduate projects, the faculty advisor needs to be listed as PI, and the study will go through department review. SOM requires a faculty member to be the PI, and studies to go through department review.
- **Conflict of Interest:** Required if an investigator or their immediate family member meets the threshold for financial interest (see Help on the first page of smartform, in question about PI financial interest.)
- **Controlled Substance Consult:** Required if protocol includes the use of any controlled substances.
- **EHSO Biosafety:** required if you answered "Yes" to any of the two options under question 2, in the "Ancillary Review Information" section. For more information about human gene transfer studies review this Emory Biosafety Review Guidelines (PDF) or email EHSO at biosafe@emory.edu if you selected the second checkbox (Any of the following: microorganisms or infectious materials; human cells...).
- **PRMC:** Required for all cancer-related research involving Emory (not solely studies taking place at Winship Cancer Institute; includes chart reviews, public health studies, surveys, etc.). Please see Winship Clinical Translational Review Committee for information and electronic PRMC submission form (submit to PRMC directly, outside of eIRB; may be done prior to eIRB submission but you must have first created a new study, to generate an eIRB number).
- **EHSO - Radiation Safety:** Required for protocols that include any type of radiation, whether scans, radioactive drugs, or radiation therapy. See Study Submission for guidance.
  - If this is a study conducted only at the VA, the VA radiation safety officer has a separate process.
- **REMS Consult:** Required for all protocols using a drug under a REMS (Risk Evaluation and Mitigation Strategy, imposed by the FDA).
- **S-I Advisory:** For IRB office use only, when an Emory researcher holds an IND or IDE.
- **VA R&D:** Required for all Atlanta VA Research. The Atlanta VA's Research and Development Committee must review all VA Research after it is approved by the IRB.

Other Reviews that Impact IRB Approval Timelines

- Emory Office of Information Technology, CHOA, or Grady Security Review
  - Should be submitted at the same time as the IRB submission to reduce delays
- Research with Tribal Nations
  - May require internal or outside counsel consult to ensure all Tribal regulations are followed
- Other Collaborative Research where single IRB review is indicated
  - May take extra time to get reliance agreement(s) in place (or sites may be added later)
  - Consult IRB Reliance Team early (pre-proposal) if wondering whether Emory IRB can be the single IRB
- International Research
  - When you have travel-restricted research, make sure to communicate that in the submission right away. For example, *this research is supposed to take place when I'm in X in the next two months.*
  - Include the Letter of Cultural Context early
  - Upload (when relevant) your export control approval in the local study documents

Requests for Accelerated Handling

The IRB receives these requests frequently so we must evaluate them carefully. Taking items out of the queue must be for a truly urgent matter that may adversely affect study subjects. Contact the IRB Director or ADs to provide justification.

Reasons why a study ***may*** receive priority consideration:

- Immediate Public Health concern (e.g. Rapid Response Treatment Protocol)
- Study requires travel for research that takes place internationally (important to **submit early** for studies that are under time constraints due to travel)
- Student research with very limited timeframe (note that when submitting)

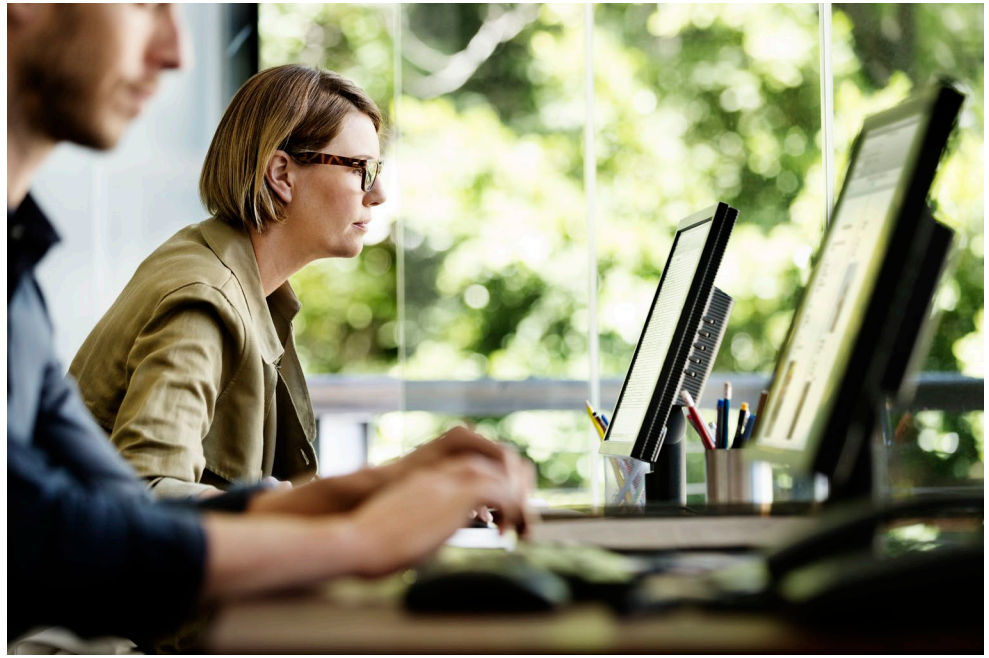
Website Resources

To assist in submission preparation for the IRB:

- Study Submission Guidance
- Protocol Templates
- Consent Toolkit
- eIRB Page Level Help
  - New Study
  - Continuing Review
  - Modification
  - Study Closeout

IRB review schedules, timelines and miscellaneous:

- IRB Target Turnaround Times
- Meeting Teams and Schedule
- Frequently Asked Questions



Questions?

Contact Us

Emory Institutional Review Board

irb@emory.edu

(404) 712-0720