



EMORY UNIVERSITY

Institutional Review Board

Research Administration

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The IRB's Post-Approval Monitoring

Emory University IRB

August 11, 2022



Agenda

Authority and Scope of IRB's Post-Approval Monitoring

Collaborators

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Informed Consent Process Monitoring





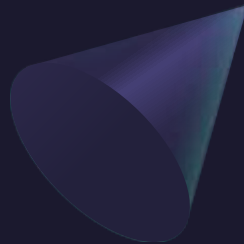
Authority and Responsibility of the Emory IRB

Oversee the conduct of Research protocols to assure compliance with approved protocols and applicable regulations, including the conduct of periodic reviews of Research protocols where required; **the conduct of appropriate for-cause, directed, and not-for-cause audits or compliance reviews; the observation of the consent process and the Research** by the IRB or a third party retained by the IRB to verify that no material changes have occurred since the last Approval; the conduct of inquiries into issues or complaints that arise concerning Research protocols; and/or the referral of such issues or complaints, or findings regarding such, to other appropriate Emory University committees or administrative personnel.

IRB's Post-Approval Monitoring Scope



- All studies approved by the Emory IRB
- All studies determined exempt by the Emory IRB
- Projects determined to be “not human subjects research” by our online determination tool
- Even studies taking place at Emory sites that are approved by an external IRB



Collaborators in the HRPP

Emory IRB collaborates with other oversight offices at Emory and with our partner institutions to share information and protect research participants:

- Emory's Research Compliance & Regulatory Affairs (RCRA)
- Emory's Clinical Trials Audit and Compliance (CTAC)
- Children's Healthcare of Atlanta
- Grady Health System
- Atlanta VA Healthcare System

And others! Each group conducts their own post-approval monitoring and may share information as applicable.

Not-For-Cause Record Reviews



- Not meant to be punitive!
- Provides the IRB with insight into how things are working in the real world
 - IRB may identify quality improvement growth areas and needed adjustments to IRB processes and guidance
 - IRB can answer questions and make suggestions for improvement
 - Ensures study objectives are met while subjects' rights, safety, and welfare are protected
- Scope of review:
 - Regulatory documentation, including approved protocols and informed consent documents, IRB approval letters, delegation of authority logs, clinical trial-related documentation as applicable
 - Subjects' study records
 - Signed informed consent documents (and HIPAA authorization, if applicable)
 - Reportable event information (if any)

Not-For-Cause Record Review: Participation Options*

VIRTUAL

- Provide IRB access with all documents in the scope of review through OneDrive, REDCap, etc.
- We will conduct the review over a period of about 1 week
- May ask questions during review, good to nominate a point of contact
- The IRB will schedule a debriefing meeting with the team to go over any findings and next steps
- Some studies that don't require continuing review may instead be asked to participate in a survey about study status

IN-PERSON

- Reserve a local conference room for IRB staff (usually 2-3 staff) to review all study records
- Bring all study records to the conference room in advance of the review
- Once we arrive, study staff can leave
- IRB staff will call with any questions and when we are ready to debrief with the study team and go over findings or next steps

*The PI does not need to be present for a record review



Not-For-Cause Record Reviews

- Studies randomly selected based on criteria in the IRB's Annual Quality Plan
 - Ex: a chart review that has been approved >5 years, two studies that take place at an external-to-Emory location, etc.
- Email notification sent to the PI and PI Proxy/Primary Contact, as applicable
- Notice period: about one week
 - Usually at least three different dates and times offered for the team to select for in-person review
 - **Can only be delayed for very extenuating circumstances, and only for another week**



Not-For-Cause Record Reviews: Outcomes



- If any findings are identified during our review, we will verbally go over them during a debriefing meeting with the study team at the conclusion of the review
- In addition, we will draft a report with details about the findings, and suggested corrective and preventive action (CAPA)
- Study team's report response:
 - **Five business days to:**
 - 1) disagreement with the findings, if any;
 - 2) accept our proposed CAPA with revisions you feel are necessary, if any; and
 - 3) a plan to successfully implement the CAPA.
 - **Ten business days** to report any findings to the IRB via RNI



For-Cause Record Reviews

- Usually prompted by an allegation, participant complaint, or information from another compliance group
- Cannot delay: the IRB must review study records promptly in order to investigate and prevent harm to participants
- When appropriate, the IRB may share some detail about the cause for our review

For-Cause Record Reviews: Process and Outcomes



- If the IRB considers there to be a possibility of **immediate harm** to study participants, we may ask you to **voluntarily** stop study activities
 - If necessary, the IRB can formally **suspend** a study
- Record review and investigation will take place as soon as possible, either virtually or in-person, with or without study PI's participation
- Similar to not-for-cause reviews, IRB will send you a report and the same follow-up deadlines for a response and RNI are in place
- Findings may be shared with other compliance groups, but we do not provide a report of review outcomes to a complainant

Informed Consent Process Monitoring

Ensuring adequacy of the informed consent
process and documentation



Informed Consent Process Monitoring



- IRB staff will reach out to notify the study team of our intent to observe the next informed consent process for a study
- When the next participant is scheduled to provide informed consent, IRB staff will arrange to be there.
- In private, the person obtaining consent will explain the IRB is on site to observe and ask the prospective participant for permission to observe the consent discussion
- Participants' preferences stand: the IRB will not observe any informed consent process without a participant's permission

Informed Consent Process Monitoring: How It's Done

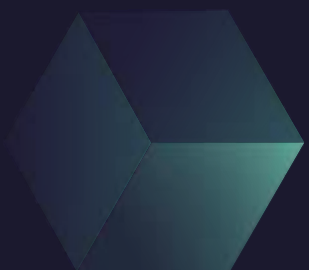
- Informed consent discussion occurs as usual (including Q&A), while the IRB representative observes silently
- The prospective participant is free to ask IRB staff questions.
- At the conclusion of the discussion, the IRB representative will thank the participant and person obtaining informed consent and will leave the room.



Informed Consent Process Monitoring: Outcomes



- IRB staff will follow up with a report describing the deficiencies from the observation, if any, within three business days. Recommendations for improvements will be included in this letter.
- If deficiencies in the consent process are noted, the IRB staff member may refer those findings to the IRB Compliance Review team, require additional education on the consent process, or provide on-site informed consent training for the study staff



Contact Us

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