Welcome to the March 2022 Emory IRB Webinar!

Welcome to this IRB webinar session!

My name is Briana Rotterman, and I am with the Education and QA team here at the IRB.

Today's session will cover the Emory Self-Assessment tool for Data and Safety Monitoring.

Enter questions at any time in the Q&A window.

We will answer all questions at the end of the webinar.

The recording of this webinar will be available on our website shortly after this presentation.

Please make sure to adjust your volume settings to experience the best audio quality.

Emory Self-Assessment Tool for Data and Safety Monitoring

Now on REDCap!

Objectives

- Refresher on studies that can include self-assessment monitoring in the data safety monitoring plan
- Introduction of the tool on REDCap
- Navigating the tool and related information
- Contact Information
- Questions

Emory IRB Monitoring Requirements

Emory IRB requires the following for all medium and high-complexity studies:

- Real-time review of participant data for safety, welfare, and to ensure data integrity during initial data collection
- Site Monitoring at pre-determined intervals
  - For medium-complexity studies, as well as high-complexity “Category B” studies, the IRB may approve a monitoring plan that relies on “self-monitoring.”

Studies that Can use the Self-Assessment Tool

Medium-Complexity: Studies involving behavioral interventions, sample collection or imaging done during a single interaction, probability of harm is limited to the immediate circumstances of the research encounter;

Examples: Otherwise NMTMR with an MRI with contrast, research bone marrow sample collection, clinical encounter cerebrospinal fluid or biopsy material collection

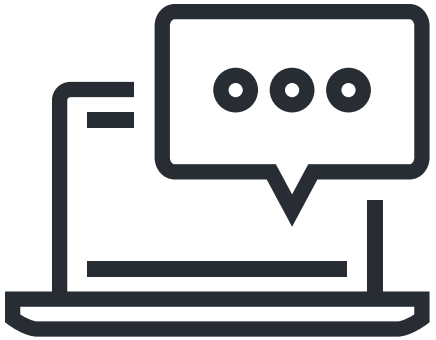
High-complexity category B: Phase I-III clinical trial using a drug or device under its FDA-approved indication such as a comparative effectiveness trial of two standard-of-care interventions.

Please see the detailed monitoring requirements here and please note there are additional monitoring requirements for FDA-regulated trials and studies that include international sites.

Navigating the Tool

Emory Self-Assessment Tool

- Biomedical Test Sample
- Social-Behavioral Test Sample



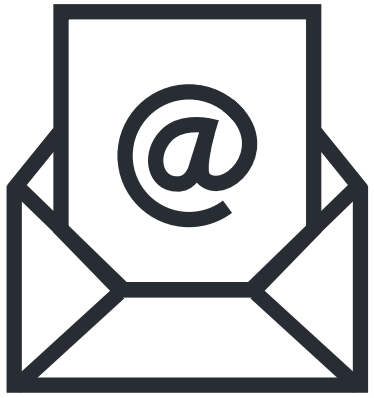
Additional Information

Tool Features:

- Save and return later function allows you to complete over time
- Input your email to receive a link back to the form and/or bookmark/save the link
- Branching, N/A, and comment functionality allows you to complete only the components that apply to your study
- CTAC will receive your report automatically when you submit via the tool, so you don't have to send the self-assessment monitoring reports manually
- At continuing review for the IRB, you will just need to note to your analyst that you are submitting your monitoring reports to CTAC or submitting via the self-assessment tool depending on your study. You will no longer need to upload the email receipts from CTAC
- Print as a PDF and save the completed pages for your records

Keep in Mind:

- CTAC will reach out if CTAC has questions/concerns, sees a pattern of problems, or for training purposes
- Editing data in a link overwrites the previous information. Start a fresh link for a fresh monitoring assessment



Questions?

For assistance with the Emory self-assessment and If you would like to request a compliance review of your study, please contact Emory's clinical trial resource, the CTAC:

Stephanie deRijke, Clinical Trials Audit and Compliance at smickle@emory.edu

For questions regarding Sponsor-Investigator documentation, please contact:

Margaret Huber, Office of Research Integrity and Compliance at mhuber@emory.edu

For IRB Questions, please contact:

General: IRB@emory.edu

Reliance: irb.reliance@emory.edu

Study Specific: assigned IRB analyst

Thank you for attending!

Thank you for taking the time to listen to this presentation.

The webinar slide deck, video, and survey link will be available on our site.

We would appreciate your feedback on our survey to help us identify areas we could improve and ideas for future topics.

We will now conclude this presentation, but if you have additional questions, please visit our website at www.irb.emory.edu, or call the main IRB line at 404-712-0720.

Our contact information is available on the website as well as within the current presentation.

Thank you for your attention to this webinar.
We hope it was helpful.
See you next time!