## Fall 2025 Update from the Environmental Medicine IRB Team

In this newsletter edition, we thought it would be helpful to address some common queries regarding IRB submissions. Below are frequently asked questions. We've provided answers which may be helpful.

1. **What research trainings are required for IRB submissions?** All research trainings are to be conducted through the CITIProgram.org. The following trainings are required for each member of the study team:
    - Basic course for investigators/ research staff (*refresher needed every 3 years*)
    - Data Security and HIPAA training
    - HIPAA for research update
    - Rigor, Reproducibility and Ethical Behavior in Biomedical Research (*only for faculty, students, residents, fellows*)
    - GCP for Clinical Trials with Investigational Drugs and Biologics (*if your project is FDA regulated or if required by external sponsor*).

    The CITI program will send email reminders at *30, 60, and 90 days* before your training is up for expiration.

2. **What is a Triggering Event and when do I need Financial Conflict of Interest Review?** In order to initiate a research project, a Triggering Event (TE) must be completed in the eDisclosure Management System (eDMS). All projects must have a current TE Form completed in the eDMS system. A Triggering Event Number (TE) is *required* for new RUTH submissions, with a new funding source, and at the time of continuing review.

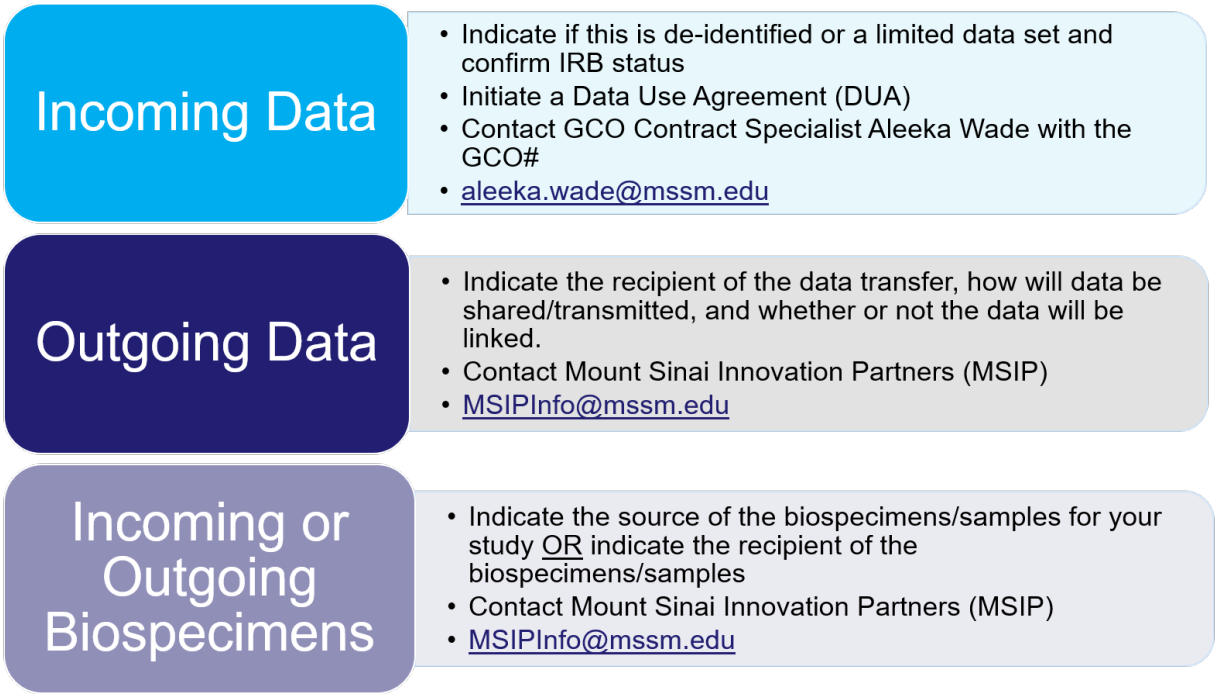
    For modifications, include the Triggering Event number in the "modification summary" section in the RUTH Smart Form. You can modify an existing Triggering Event if adding or removing personnel.

    FCOI (Financial Conflict of Interest) review is required for *every* submission (initial, modifications, and continuations). For modifications, FCOI review is required for changes in funding and/or adding new study personnel. While in RUTH, use the "Manage Ancillary Reviews" button on the submission workspace to assign the FCOI office to review your study.

3. **What should I do if I have a change in funding?** If funding for your research changes, this requires a modification in RUTH. If the modification is adding new funding, then a new TE number is required. A TE number corresponds to a funding source for a study. You will also need to complete HRP-215 - FORM - Comparative Review for the change in external funding. If funding changes from external funding to internal funding, select "Icahn School of Medicine at Mount Sinai" in the drop down list in RUTH.

4. **If I want to collaborate with an investigator at another institution and share data or biospecimens, how can I accomplish this?**

    If you are planning to share data/biospecimens with another institution and collaborate on research, you will need to work with Mount Sinai Innovation Partners (MSIP) and establish an agreement.




As a reminder, if you require any assistance with your IRB application, please contact Ilene Wilets Ilene.wilets@mssm.edu and Holly Miller holly.miller@mssm.edu.