

IRB 101- A Comprehensive Checklist

This is a checklist to help you navigate the multiple on-line systems involved in the IRB process. Please see the “IRB Tips” document for advice on filling out the text sections, deciding whether your project is exempt, expedited or standard, etc.

Whether you’re a novice or an expert, the IRB process can be quite overwhelming with many moving parts. IRB submissions fall into one of three categories; Exempt, Expedited (minimal risk) and Standard (full board review). Irrespective of the category under which your study falls, all of the steps below will apply. Although these can all be done concurrently, we suggest the following order:

TO BE DONE EVERY 3 YEARS:


CITI Program-Intended for anyone involved in research studies with human subjects.

(<https://about.citiprogram.org/en/homepage/>)

- Use your existing credentials or register as a new user
- You must affiliate with the appropriate institution (Icahn School of Medicine at Mount Sinai) in order to complete the training modules specific to your institution’s educational/research requirement.
- When you log on to the main page, please select your institution. You will then see your learner tools for the institution to which you affiliate. Select “add courses” to add the following modules:
 - Data Security and HIPAA Training
 - GCP (Good Clinical Practice)
 - HIPAA Research Update
 - Investigators/Research Staff
 - This is perhaps the most time-consuming of the four processes; we suggest you break up the modules rather than attempt to complete in one sitting.
 - CITI certificates expire every three years after which you are only required to complete a refresher course which is considerably less time consuming than the initial training.
 - Please forward copies of your completed certificates to my attention- Nordia Morrison (Nordia.morrison@mountsinai.org).

Sinai Central-to identify and manage potential conflicts of interest (<https://sinaicentral.mssm.edu/>)

This portal is used to identify both institutional and research specific potential conflict of interest (COI).

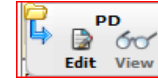
- TO BE DONE YEARLY BY EVERYONE: Institutional COI form. Please use the following path:
 - Log in to Sinai Central using your institutional credentials
 - On the homepage, click on COI>Annual Report of Outside Relationships then review status of your report statement. If your status is “Not submitted “or “Started”, please finalize by clicking on the folder icon next to your name  and answer the relevant questions. Please remember to certify and submit.
- TO BE DONE FOR EACH PROJECT: research specific COI
 - Log in to Sinai Central using your institutional credentials
 - On the homepage, click on COI>Investigator Forms>New Investigator Form (also accessible from the GCO tab as well).
 - Complete the relevant information; by selecting a “Remind Day” the system will generate automatic emails daily until it is completed by each personnel named on this form.
 - Please ensure that you change the name of the PI if you are the coordinator initiating this. **For the purposes of the IRB application, there must always be a faculty PI.**
 - Proposal Type for initial submission should be “New or Transfer”
 - Funding Agency by default is: Internal (Formerly Mount Sinai School of Medicine) unless externally funded.

- Funding Agency Type: Internal (formerly MSSM)
- Human Subjects: Yes
- To add additional personnel, click on “add investigator”, identify their role and save.
- The system generally loads the last known date of CITI training/refresher for each personnel named; CITI certificates expire every three years.
- If you need to make changes to an Investigator Form after the status indicates “With GCO Coordinator”, please contact the GCO at Ext 58300 (212-824-8300) to request manual changes.

InfoEd- Routing electronic research to the GCO (<https://eresearch.mssm.edu/>)

- THIS NEEDS TO BE DONE UNDER THE ACCOUNT OF A FACULTY “PI”. The resident can facilitate by preparing the portions highlighted in blue below. Advice on developing these is in the “IRB Tips” document.
- In order to access InfoEd; you *must* attend a training session. Please see the following link for schedule of classes: <http://osticket.mssm.edu/support/pages/infoed-and-ideate-schedule-of-classes-and-open-help>
 - When you have acquired a username and passport, log in and initiate a new submission by clicking on “create new proposal” under My Proposal on the homepage.
 - Confirm the intended PI
 - Create a New Proposal
 - From drop-down, select “setup proposal manually”
 - Proposal Type: New Proposal
 - Sponsor: Icahn School of Medicine at Mount Sinai
 - Enter proposal title (title should be consistent across all systems)
 - Select a start and end date (this does not have to be concrete)
 - Budget period: Default 1
 - Confirm all of the above is correct then click “yes create proposal”
 - Please check to ensure that you are not creating a final report; if the system reverts to a final report by default, please change submission mechanism/screen template to New (non –S2S, no budget). Check off “no” to both cover letter and training grant fields then save.
- Upload lay summary to the “lay summary” tab and a more detailed description of your research protocol to the “research or program plan” tab then always remember to check off “completed” in the upper right hand corner of the page after completing each section. Uploaded documents are automatically converted to pdf.
- Use “personnel wizard” to identify all personnel who will be on this study. If they’re not found in the system, open a new InfoEd IT ticket (<http://osticket.mssm.edu/support/open.php>). From Help Topic select: InfoEd /New Personnel Request.
- Disregard the “classification codes” tab by checking the “completed” box.
- To answer the set-up questions under the Internal Documents tab, click on the blue hyperlink “add institution forms/supporting documents”
 - Add form name “new/competitive renewals/resub v 1.6.2 by checking in the box then click “add”
 - A paper/pencil icon will appear next to incomplete, click on it and enter the IF# from Sinai Central and answer the list of questions then save and complete
 - To finalize, you will need to build the “form page” after which the PI should submit for internal review by clicking the thumbs up icon and re-entering his/her credentials to attest to the submission
 - Make note of the proposal – PD # on the upper right hand corner

- ❑ To revisit and edit a proposal, under My Proposal, click on “show list”; identify your proposal ; click on the folder icon, PD then Edit.



IDEATE- routes to PPHS aka IRB (ideate.mssm.edu)

- ❑ Ideate must be accessed via FireFox browser
- ❑ Please forward me your life # and network username so that I may request courtesy access on your behalf if you are unable to attend the class in a timely manner.
- ❑ Upon first log in, click on Manage>My User Profile to upload your CV; all tabs are not mandatory in order to update your profile.
- ❑ To initiate a new protocol, click on “Create New” >PPHS Protocol and fill in each field accordingly.
- ❑ The PPHS has migrated from paper forms to a free text platform via IDEATE; the only forms that are still relevant should be “consent forms” and the “informational sheet” for exempt studies.
- It is not reasonable to provide general instructions for completing your protocol in IDEATE as each study differs in design; for case by case assistance, please contact Nordia Morrison-
Nordia.morrison@mountsinai.org

Disclaimer: The above instructions are intentionally “general”; should you require more specific assistance, please contact Nordia.morrison@mountsinai.org (eg. for proposals involving budgets, other sites within the health continuum, IRB renewals, final reports, etc.

Note: Studies involving personnel who are not CITI trained will automatically be rejected by the IRB. All four steps are interdependent.