



MOUNT SINAI  
SCHOOL OF  
MEDICINE

# MSSM-IRB E-Newsletter

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## IRB Website

[www.mssm.edu/irb](http://www.mssm.edu/irb)

## Contact Us

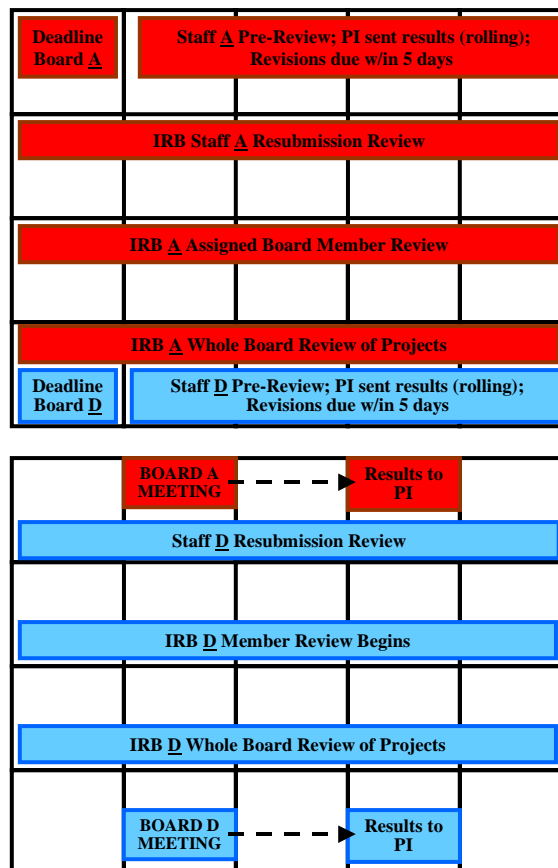
[www.mssm.edu/irb/general\\_info/staff.shtml](http://www.mssm.edu/irb/general_info/staff.shtml)

## New IRB Schedule

[http://www.mssm.edu/irb/pdfs/meeting\\_dates\\_2006.pdf](http://www.mssm.edu/irb/pdfs/meeting_dates_2006.pdf)

## New IRB Schedule Starts APRIL 1 - This is NOT a Joke!

The IRB review process will be altered as we convert to a multiple board system. Submissions will undergo **pre-review** by the IRB staff and feedback will be given to the PI to make revisions/clarifications **PRIOR** to the project being reviewed by the Board. Once the PI responds to the requested modifications, the project will be sent to the Board for review at a meeting. Therefore, it is anticipated that most "administrative" issues will have been identified and resolved prior to review at the Board meeting. The intention is to decrease the number of protocols "deferred" at IRB meetings and maximize the use of IRB member review efforts. To accomplish this additional work prior to each IRB meeting, the deadline/review timeline will be changed as of April 1. The schematic below demonstrates the project submission and review timeline for two Boards (A and D). Remember, there are two other boards (B and C) whose schedules could also be superimposed on this diagram (but aren't, for greater clarity's sake).



It is extremely important that Investigators and their staff understand the new process. New and continuation projects must be still be logged in with GCO, but no copies will need to be brought to the IRB at that time. Soon after IRB receipt of the submission, an email explaining the next part of the process and corresponding dates will be sent out to you. You will then receive an administrative review of your project generally within 5 working after the deadline.

## NEW FORMS:

### Retrospective Data Review Forms (e.g. Medical Record Reviews)

<http://www.mssm.edu/irb/docs/RetroResData.doc>

AND

<http://www.mssm.edu/irb/docs/RetroClinData.doc>

### Retrospective Tissue Review Forms

<http://www.mssm.edu/irb/docs/RetroResSpec.doc>

AND

<http://www.mssm.edu/irb/docs/RetroClinicalSpec.doc>

## NEW GUIDANCES:

### Just-in Time Policy

[http://www.mssm.edu/irb/pdfs/just\\_in\\_time.pdf](http://www.mssm.edu/irb/pdfs/just_in_time.pdf)

### Certificates of Confidentiality

[http://www.mssm.edu/irb/docs/COC\\_Guidance.doc](http://www.mssm.edu/irb/docs/COC_Guidance.doc)

### Research Personnel Changes

[http://www.mssm.edu/irb/pdfs/personnel\\_changes.pdf](http://www.mssm.edu/irb/pdfs/personnel_changes.pdf)

After receiving your administrative IRB review, **YOU WILL HAVE FIVE (5) DAYS TO RESPOND TO THE IRB with your corrections, responses, and any copies of documents requested from you. FAILURE TO RESPOND COMPLETELY WITHIN THIS TIME FRAME WILL REMOVE YOUR APPLICATION FROM THE CURRENT CYCLE. THIS COULD RESULT IN UP TO AN EIGHT (8) WEEK DELAY IN PROCESSING YOUR APPLICATION!**

Your updated documents will then be forwarded to the individual IRB members who will review them over the next week. During this time, you may be requested to answer questions or make further revisions by the IRB Administrator working in conjunction with the IRB Board member(s), in order to further prepare your project for the meeting. After the entire Board has reviewed all of the projects on the agenda, the actual Board meeting will take place the following week.

We are committed to creating a comprehensive yet expeditious review system. Please pay attention to the deadlines ([http://www.mssm.edu/irb/pdfs/meeting\\_dates\\_2006.pdf](http://www.mssm.edu/irb/pdfs/meeting_dates_2006.pdf)), and instructions that accompany all communications from the IRB. We request everyone's cooperation as we undertake this major alteration in IRB functioning, and we welcome constructive feedback in making the new system run as smoothly as possible.

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## InfoEd Project - You have to be in it to use it!

Over the next few months, we will be installing the **InfoEd electronic research administration software** for submission management. When installed, all GCO, IRB, IACUC and Biosafety applications will have to be entered and managed through this system. A Clinical Trials module will also be available. In order to use the system, **Investigators and their staff must have an InfoEd profile.** The following instructions will enable you to set up a minimal InfoEd profile.

To Access InfoEd:

1. Log into MSSM Home Page ([www.mssm.edu](http://www.mssm.edu))
2. Click on Research
3. Click on Grants and Contracts Office
4. Click on Funding Opportunities
5. Click on InfoEd under Funding Resources
6. Click on GENIUS/SMARTS
7. Click on Create a New Profile

Administrator New Profile Registration:

1. Pick an Institution – Select Mount Sinai School of Medicine
2. Enter in name and email address
3. Select your Primary Department at MSSM
4. Do not include your social security number
5. Select a user name and password and submit (We suggest using your Mount Sinai network login ID as your Genius/InfoEd ID)

Under Required for GENIUS & SMARTS section:

1. Select the General category
2. Click on the blue Department word-select your primary department making sure you check the box for the department and the circle for Primary. Save Changes.
3. Leave Social Security # blank
4. Enter in Administrative Title
5. Select NO for Private Profile
6. Enter in Work address and Work phone number
7. Skip all the boxes and go to the questions at the bottom
8. Question 1 regarding availability of profile information change to Global
9. Leave the rest of the answers to the questions as they are
10. Click on save changes then return
11. Log out of the system

If you have any questions or would like to sign up for an InfoEd training session to you can receive funding opportunities to your email, call Melissa Ducker at extension 88976.