



MOUNT SINAI
SCHOOL OF
MEDICINE

MSSM-IRB E-Newsletter

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IRB Website

www.mssm.edu/irb

Contact Us

www.mssm.edu/irb/general_info/staff.shtml

IRB Schedule

Old system– 4/1/06

www.mssm.edu/irb/pdfs/meeting_dates_2006.pdf

New schedule- stay tuned!

New IRBs Alter Submission/Review Process & Schedule

The Human Subjects Protection Program is pleased to announce our expansion to five Boards (four regular and one Executive IRB). The 4 regular IRBs will each meet once monthly, on consecutive weeks of the month. This board expansion is driven by the need to provide more rapid and standardized reviews, to decrease the workload on IRB members, and to assure that thorough reviews are accomplished in compliance with federal regulations. We are currently recruiting and training new IRB members to serve on these panels.

The IRB review process will be altered as we convert to a multiple board system. Submissions will undergo **pre-review** by the IRB administrative staff and feedback given to the PI to make revisions/clarifications **PRIOR** to the project being reviewed by the Board. Once modifications are completed by the PI, 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).



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

Certificates of Confidentiality

http://www.mssm.edu/irb/docs/COC_Guidance.doc

Research Personnel Changes

http://www.mssm.edu/irb/pdfs/personnel_changes.pdf

We will be providing more specific guidance about the upcoming changes via written communications and in-services as the time grows closer toward the transition. We appreciate that there will be some difficulties during the transition period, and we will work with everyone to minimize potential disruptions. We request everyone's cooperation in advance as we undertake the most significant alteration in IRB functioning since its inception at Mount Sinai, and we welcome your constructive feedback in making the transition process and new system run as smoothly as possible.

MSSM Selects InfoEd for Research Administration

MSSM has purchased a suite of software products from InfoEd International (www.infoed.org) to manage research administration and facilitate the conduct of clinical trials. The Info software will provide web based protocol development and submission to GCO, IRB, IACUC, Biosafety and Conflicts of Interest in Research. Full submission of grants to the NIH via grants.gov is incorporated into the software. The software project is due to be installed and configured over the next few months with general use expected in June or July. This is a major investment on the part of MSSM to improve service to investigators throughout the school.

Combined with the alterations to our review processes, the implementation of InfoEd will allow researchers to track their proposals, receive notifications regarding upcoming compliance dates and maintain all communication associated with a project in a single repository.

Security Fair Scheduled for March

MSSM will sponsor a security fair on March 1, 2006. In response to a number of incidents in which protected health information collected for research purposes has been lost (on desktop computers, laptops, and palm devices), the security committee has developed policies and suggested procedures. The information will be described in detail and vendors will be present at the Security Fair – keep a look out for further information.

New 2006 IRB Members

The IRB currently has a number of dedicated members who have served for many years. To this group, we now welcome additional volunteers for the upcoming board expansion to allow each department's expertise to be adequately represented. The following faculty are new additions in the 2006 year:

Altman, Ken: Otolaryngology
Biggs, Carina: Surgery
DeBoccardo, Graciela: Intl Med, Neph, Transpl
Farkouh, Michael: Cardiology
Fischer, Gregory: Anesthesiology
Godfrey, Tony: Hem/Onc
Mansfield, Robert: Pediatrics
Podos, Steven: Ophthalmology
Scher, Corey: Anesthesiology & Pediatrics
Smith, Rebecca: Psychiatry
Vezina, Maria: Nursing Education

Ames, Scott: Kidney/Pancreas Transplant
Chahinian, A. Philippe: Oncology
Edye Michael: Kidney/Pancreas Transplant
Filsoufi, Farzan: Thoracic and Cardiovascular Surgery
Gabrilove, Janice: Hem/Onc
Grosskreutz, Celia: Hematology/BMT
Morland, Kimberly: Epidemiology; public health
Reich, Lawrence: Internal Medicine, Primary Care
Shemesh, Eyal: Pediatrics and Psychiatry
Tagawa, Scott: Oncology
Weintraub, Andrea: Pediatrics, Neonatology

If you would like to volunteer for service in the human research subject protection program, please contact the IRB for further information.