



MOUNT SINAI
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MEDICINE

Mount Sinai Medical Center Program for the Protection of Human Subjects (formerly known as the IRB) E-Newsletter

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WHAT'S IN A NAME? IRB changes name to PPHS

With the expansion to five review boards (four general IRBs and one policy IRB), it was becoming confusing to refer to the entire program as "the IRB". Therefore, we have changed our departmental title to the "Program for the Protection of Human Subjects" (PPHS). We feel this new title concisely reflects our raison d'être. You will be seeing our updated documents and website reflecting this new title in the near future.

DATA SECURITY

As of April 17, 2007, the Data Security module of the educational courses required by the IRB will become **MANDATORY** in order for a researcher or research staff to participate in human subject research. This is true for researchers submitting new applications as well as continuation applications from 4/17/07 onward. The online education session describes how research data can be managed in ways to better protect subject privacy and data confidentiality. In order to fulfill the requirement, go to http://www.mssm.edu/irb/edu_req/ and click on "Data Security" and follow the instructions.

NEW DEVICE GUIDANCE and FORMS

Our policies and procedures are constantly under revision. We are very pleased to announce the release of an **updated policy** on the use of devices in research. In the guidance document, we describe the federal requirements for use of devices in research (both approved and investigational devices) and the procedures that both the researchers, and the PPHS, will follow in order to allow the use of devices.

Two new device forms are also now available. One form is called the "**Device Form**" and is to be completed when a device (FDA approved or investigational) is to be used in the context of a research project. The second form is for devices that fall under the "**Humanitarian Use Device**" (HUD) regulations. In addition to proposals to use HUDs in research, the use of HUDs in standard medical care must also be reviewed by the PPHS per federal regulations. Completed forms should be included as part of a total application. If you're not sure which form to fill out, please call the PPHS office and we will assist you.

CERTIFICATES OF CONFIDENTIALITY UPDATE

When preparing an application for a Certificate of Confidentiality, please be aware that the Mount Sinai Institutional Official for human subject research has changed. Rather than Dr. Kenneth Davis' name and titles, you will need to use Dr. Dennis Charney's name and titles in the applications going forward. Dr. Charney, the Dean of the Mount Sinai School of Medicine and Executive Vice President of The Mount Sinai Medical Center, now serves as the Institutional Official with regard to human subject protection program. Please refer to page 2 of our updated guidance "**Certificates of Confidentiality: The Why and How**", to see how the correct information should be presented in future applications. As usual, these applications should only be submitted directly to the PPHS, not to the Dean's office.

[LINK TO NEW GUIDANCES:](#)

Device Guidance

[Links to NEW FORMS:](#)

Device Form

Humanitarian Use Device Form

Updated Waiver of Informed Consent

[Link to:](#)

IRB Schedule

[Link To:](#)

Contact Us

WAIVER OF INFORMED CONSENT

We have modified the “[Request for Waiver of Informed Consent](#)” form to better clarify the information that is being requested from the PI. Please use this version from now on. We hope that the new form makes the process easier to understand. Your feedback about this form, and any other form or process, is always welcome.

REVISIONS to APPROVED RESEARCH

Reminder: In the new review system, when you submit a request to modify your approved project, 3 copies are no longer required for the initial submission. Only one original set of documents is needed for initial review. The PI will be contacted at a later point to bring in additional copies (if needed). Also, please note that the timing of revision reviews follows the same schedule as new projects. Refer to the online [schedule](#) for submission deadlines.

APPROVED PENDING no more

When an IRB reviews a project it can take a number of actions. If everything substantive is in order, an IRB can issue a conditional approval *pending* the approved resolution of the remaining minor issues. For years we have called this status “approved pending”. However, some investigators interpreted this status as “fully approved” and began conducting the research. Therefore, in order to avoid confusion in the future, all projects which are judged to have this conditional status will be recorded as the following:

Your project was reviewed at the IRB meeting of XX/YY/200Z. All substantive issues have been reviewed. The following minor issues must be addressed in order for the IRB to issue a final status letter. NOTE: This project cannot proceed (i.e. you may not enroll patients, collect samples, or review data, etc.) until the IRB has reviewed and approved all minor revisions.

Investigators should submit the changes requested and they will be reviewed and approved in the PPHS office (unless further changes are necessary). We will not be handling these projects any differently than we have, but this terminology change is designed specifically to avoid investigators mistaking an “approved pending” designation for a “full approval”. Please let us know if you have any questions.

PROFILING OUR NEWEST PPHS STAFF MEMBERS

[Elena Sunland](#) holds an MBA in non-profit and health care administration from the University of St. Thomas in St. Paul, MN, with an undergraduate degree in Speech Pathology from the University of Minnesota. She has extensive experience in IRB administration, with nine years at a teaching hospital (Regions Hospital, St. Paul) and two years with the social sciences IRB at NYU. Her special interests include women’s health, PTSD, HIV/AIDS and education. Elena currently works with IRBs B and D.

[Rebecca Banchik](#) holds a BA both in psychology and Spanish from Lafayette College in Easton, PA. Her research background includes working in an infant perception and vision lab as well as a year-long honors thesis which focused on the theory of implicit racism and anti-Semitism. Rebecca also studied abroad in Madrid, and is a singer and actress. Rebecca currently works with IRBs A and C.

[Eliana Meiorowitz](#) graduated Columbia College with BA in American Studies, which culminated in her thesis on the portrayal of gay men with AIDS in American film. She has put her liberal arts degree to good use in advertising, journalism, dotcom startups, and as a personal organizer. Her interests include media studies, New York history, politics, and her hometown Boston Red Sox. Eliana currently works with IRBs B and D.

Please introduce yourself to these staff members!