



MOUNT SINAI  
SCHOOL OF  
MEDICINE

# Mount Sinai Medical Center Program for the Protection of Human Subjects E-Newsletter

January 2010

Volume 5, Number 1

## In This Issue

- [We've Moved!](#)
- [Updated Paper Forms](#)
- [Which form?](#)
- [Application Deadlines](#)
- [Education Sessions 2010](#)
- [PPHS Staff](#)

[Link to:  
PPHS Website](#)

[Link to:  
IRB Schedule](#)

[Link To:  
Contact Us](#)

## We've Moved; Come Visit Us!

The Program for the Protection of Human Subjects (PPHS) office and the Grants and Contracts office (GCO) have moved to at 3 East 101st, First Floor.

Please come to our **Open House**

Wednesday, Jan. 20th from 3:00 - 5:00 p.m. Refreshments will be served!

## Updated IRB Paper Forms

Changes have been made to the following forms:

- 1) The Standalone Consent documents (Form 2B English/Spanish)
- 2) The Combined Consent/HIPAA Authorization forms (Forms 2A English, 2A Spanish, 2E, 2F, and 2G) have been updated.

Changes to the consent templates include a new required statement in the "Ending Participation In the Study" section, modified template language in the HIPAA section, addition of the word "date" in the form header (please use a date to record your consent version), and modified PPHS office number. Please use the 01/2010 templates form going forward.

## Which form should I use?

For human research studies that involve Protected Health Information, which means most of the medical-oriented research that is done at Mount Sinai, the PPHS strongly recommends using the combined informed consent/HIPAA authorization form (Forms 2A, 2E, 2F, or 2G on our Forms page). Using the combined form presents less potential for forgetting to address (and document) both informed consent and HIPAA authorization. While the "standalone" consent form (so called because it does not contain HIPAA authorization) is still available for studies that do not collect PHI, it should generally not be used for studies that do involve PHI, unless sufficient justification has been made to the IRB for using two separate documents. Please contact the PPHS if further clarification is needed regarding your particular research.

## AAHRPP Accreditation Beginnings

Mount Sinai has started preparing to apply to the Association for the Accreditation of Human Research Protection Programs later this year, in order to achieve accreditation for our human research protection program. We will be evaluating the institution's policies and procedures over the next year and meeting with investigators and research staff to obtain feedback. Stay tuned for more!

## IRB Application Deadlines

Please see the [2010 Schedule](#) on our website for IRB submission deadlines. The document also contains dates of IRB meetings and dates to expect certain feedback from IRB analysts. Please refer to this document often—it's your friend!

## Educational Sessions Led by PPHS Team Members

### **IRB Submissions 101 Course:**

The PPHS office offers basic training for IRB submissions to researchers and coordinators submitting their first application to the IRB. Topics discussed during this 2 hour presentation include: research oversight; Institutional Review Boards in general and specifically Mount Sinai's IRBs; our goals and challenges; PPHS human subjects resources; categories of review; required documentation for

submissions; PPHS submission timeline; how to submit a complete application; completing the protocol summary form and the consent form. You can register for classes beginning on the 1st day of the month that you would like to attend or look for the email invitation sent out monthly.

Dates for this class are:

January 25, 2010 – (11am – 1pm)

February 22, 2010 – (2pm – 4pm)

March 29, 2010 – (11am – 1pm)

April 26, 2010 – (2pm – 4pm)

May 24, 2010 – (11am – 1pm)

June 28, 2010 – (2pm – 4pm)

July 26, 2010 (11am – 1pm)

August 23, 2010 – (2pm – 4pm)

September 27, 2010 – (11am – 1pm)

October 25, 2010 – (2pm – 4pm)

November 29, 2010 – (11am – 1pm)

### **Resident Training Schedule**

If you are a resident planning to conduct research using human subjects (from medical record reviews to participating in clinical trials), the PPHS office invites you to informal individual meetings to ask IRB managers questions about your human subjects study, the application paperwork and get answers about how to make this process as smooth as possible. You can register for a meeting beginning on the 1st day of the month that you would like to attend or look for the email invitation sent out monthly.

Dates for this sessions are:

February 10, 2010 – (5:30 – 6:30pm)

March 16, 2010 – (5:30 – 6:30pm)

April 15, 2010 – (5:30 – 6:30pm)

May 12, 2010 – (5:30 – 6:30pm)

June 7, 2010 – (5:30 – 6:30pm)

July 12, 2010 – (5:30 – 6:30pm)

August 12, 2010 – (5:30 – 6:30pm)

September 13, 2010 – (5:30 – 6:30pm)

September 30, 2010 – (5:30 – 6:30pm)

October 13, 2010 – (5:30 – 6:30pm)

November 15, 2010 – (5:30 – 6:30pm)

**Registration** will be accepted in the same month as the date of the class. Space is limited so please contact Lori Jennex at [Lori.Jennex@mssm.edu](mailto:Lori.Jennex@mssm.edu) or Rebecca Banchik at [rebecca.banchik@mssm.edu](mailto:rebecca.banchik@mssm.edu) to reserve your spot. If you do not believe you are on the PPHS email list, please send a request to [Angela.Khaimova@mssm.edu](mailto:Angela.Khaimova@mssm.edu) in order to add you to the “CRC” email list.

## **PPHS Team Happenings...**

We would like to announce the following PPHS staff **promotions!** Please congratulate them...

**Rebecca Banchik** - IRB Manager

**Liz Carroll** - Sr. IRB Specialist

**Lori Jennex** - Associate Director, PPHS/Director of Operations

The PPHS office would also like to feature the following PPHS staff members....

**Jessica Huening** joined the PPHS in May 2009. She holds a BA in Psychology from North Carolina State University in Raleigh, NC and a certificate in Paralegal Studies from Fairleigh Dickinson University in Teaneck, NJ. She comes to Mount Sinai after working in psychiatric research at the Nathan Kline Institute in Orangeburg, NY. Jessica currently works with IRBs A and C.

**Sara Lewis** received her MPH from Boston University School of Public Health in 2009. During graduate school she worked at Children's Hospital Boston as a research assistant, and primarily focused her academic work on maternal health policy. Prior to graduate school, Sara served in the AmeriCorps obtaining medical services for children on Medicaid. In 2006 she graduated with a Bachelors degree in History & Policy, with a secondary major in International Relations from Carnegie Mellon University. Sara joined the PPHS in July 2009 and works with IRBs B and D.