



MOUNT SINAI
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MEDICINE

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

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Accreditation Update

In February, the PPHS began its accreditation efforts with a self-assessment. We have spent the past few months redesigning our system and completing the initial application submission to AAHRPP (the Association for the Accreditation of Human Research Protection Programs). AAHRPP accreditation is the “gold standard” in human research protections. The process of applying the accreditation standards to our program will result in a number of significant changes for our office, and for those who engage in human subject research.

Website Update

All sections of the PPHS website are being updated. Please visit the website frequently during August and September.

Updated Forms and Submission Requirements

On August 16, 2010 the PPHS made available its new application forms, templates and guidance for investigators. The use of the new forms **will be mandatory as of August 30, 2010**, so please visit our website to use the appropriate forms before making your submission to the IRB. The forms will be updated as needed, so you are strongly encouraged to always download the current form before you begin. Do not use the forms you have saved from previous submissions.

The new forms can be located on the [PPHS Forms page](#). All individuals involved in the submission process are strongly encouraged to read the [Investigator Manual](#) and the [Frequently Asked Questions](#) documents in advance of preparing a submission to the PPHS and to attend a training session on the use of the new application materials. PPHS training sessions are discussed below.

New Submission Process

The Grants and Contracts Office will be switching to an online submission process (InfoEd Protocol Development module) on August 23rd. The PPHS applications will continue to use paper and the submission process to PPHS will be changing. **All human subject applications must be brought directly to the PPHS office for log-in.** All submissions must include the “IF number” (number assigned through the Sinai Central [FCOI submission process](#) (http://sinaiknowledge.mssm.edu/sinai_central/conflict-of-interest/gco) written on the top right corner of the Human Subjects Application form. In addition, the **deadline dates for submissions to the PPHS office will be changing from Mondays at 5:00 p.m. to FRIDAYS at 5:00 p.m. The deadline change will be effective September 3rd.** A new deadline schedule will be available soon.

Process Updates

Here are a few new processes that you will become familiar with in the new PPHS system:

- ✓ All submissions will be screened for missing information. The PI and contact person will receive an email and an opportunity to provide any missing information. Choices presented to the research team in emails are situation-specific, so please read them carefully.
- ✓ New projects will also receive a pre-review from an IRB analyst that will assess whether the project is likely to meet the regulatory criteria for IRB approval, and will suggest any modifications that would make it more likely to achieve IRB approval. The PI and contact person will receive an email regarding the results of the pre-review and an opportunity to respond/revise the submission.
- ✓ Research team response-time to PPHS communications will determine when the project re-enters the IRB review queue.

Policy Updates

- ✓ The PPHS office will now require documentation that references the IND number (e.g. sponsor protocol, sponsor correspondence or FDA correspondence referencing the IND number) or IND exemption; if this is an investigator-held IND, PPHS submissions will need to include a copy of FDA correspondence documenting the IND number or the FDA correspondence that an exemption has been granted. Any waiver (exemption) of IND or IDE requirements must be granted by the FDA. The previous process by which an IRB would accept an investigator's contention that a project met criteria for a waiver has been abandoned. If you believe a waiver is appropriate, you must submit this position to the FDA for their acceptance (or rejection).
- ✓ For significant risk devices, the PPHS office will require documentation of the IDE number.
- ✓ If a continuation application or final report is not received prior to the expiration of IRB approval for a study, the Investigator will not be able to receive IRB review for any other new project submissions until the proper reporting has been processed by the IRB.
- ✓ All personnel involved in the design, conduct and reporting of the human subject activity on a research project must be listed on the new Application form, fill out FCOI disclosures, and complete PPHS education requirements. *This includes research coordinators.*
- ✓ If ANY member of the study team has not completed the education requirements, IRB approval will not be released.
- ✓ Evidence of personnel qualifications for each project must be provided with the application. Biosketches, resumes, summaries of qualifications in the protocol template or separately, or CV's are acceptable.
- ✓ PPHS will now give time periods during which certain responses or actions from PIs are expected. Failure to respond may have a consequence ranging from withdrawal from the review queue to a finding of non-compliance. This information will be embedded in the PPHS correspondence.
- ✓ Department Chair signature is required on the PPHS Human Research Application Form for new project submissions only. This is in addition to other requirements (e.g. approvals for the GCO eSubmission process)
- ✓ The definition and reporting timeframe has changed for "reportable events" such as unanticipated problems and certain adverse events. Please see "Reportable New Information Form" for details.

InfoEd Update

As of Monday, August 16, 2010, the PPHS no longer has a separate process or form for retrospective studies. Retrospective studies will be submitted using the same application form and template protocol as prospective studies in the new PPHS system. Submission to the InfoEd Human Subjects Development module will be progressively disabled to enable site reconstruction. Therefore, **submissions will need to be made in paper to the PPHS office as indicated below.**

The last day to submit previously-unsubmitted continuations, modifications, or final report applications through InfoEd Human Subject Development module will be Monday, August 30, 2010. For projects expiring after 9/30/10, please plan to submit a continuation application through the paper-based process.

We would like to encourage you to log in to InfoEd and review your projects to address any outstanding issues that have been requested from the PPHS. Projects currently in review will be finalized in the InfoEd system. Please call the PPHS office at 212-824-8200 for further information and guidance.

After Monday, August 30, 2010, all active retrospective studies currently in InfoEd will transition to paper applications at the time of the next modification request or continuation. All final reports must be submitted in hard copy on the new Continuing/Final Review Report Form, after August 30, 2010. A copy of the approved e-forms must be printed out and submitted with the application to the PPHS.

New Education Requirements

There are three PPHS education course requirements for all individuals who engage in the conduct of human subject research: 1) Human Research Subject Protection, 2) HIPAA for Research, and 3) Data Security for Research. The PPHS office has updated the requirement for the Human Research Subject Protection. Effective August 18, 2010, the only training course that will be available through the PPHS office to meet the Human Research Protection requirement will be the CITI program. **All personnel will need to complete the CITI program course requirement** (in addition to meeting the education requirements for HIPAA for Research and Data Security for Research).

HOW TO COMPLETE THIS REQUIREMENT:

You can register to fulfill this new requirement at www.citiprogram.org. Choose "Mount Sinai School of Medicine NYC". [Take care not to choose one of the other "Mount Sinai" choices] Further information will be available on the [PPHS Educational Requirements website](#).

HOW THIS AFFECTS YOU:

If the PPHS office has your information **on file for having previously** completed the Human Subjects in Research requirement, ***you have until December 31, 2010 to complete the CITI training***. Beginning January 1, 2011, the PPHS office will not process any further submissions until this training has been completed. Please make sure all research faculty and staff complete this requirement. No one will want to spend New Years Eve doing these modules to avoid having a project be suspended on January 1, 2011.

If the PPHS office **does not have your information on file** for having completed the Human Subjects in Research requirement, or you are new to the Institution, you ***must complete the CITI training curriculum before you can engage in any human subjects research***. The PPHS office will not process any submissions until this training has been completed.

If you have **previously completed CITI training for any other project or institution**, please log in to CITI and ***add "Mount Sinai School of Medicine NYC" as an affiliate in order for any of your credits to transfer***. You will be required to complete the course curriculum for your credits to transfer.

HOW LONG WILL IT TAKE TO COMPLETE THE COURSE:

The Basic Human Subjects course is expected to take **4-6 hours** to complete. The average user breaks this down over 5 sessions. ***All modules must be passed and completed in order for you to fulfill the education requirement.***

WHAT TO DO WHEN THE COURSE HAS BEEN COMPLETED:

Please retain your certificate. You do not have to send it to the PPHS. We will be notified by CITI when you have completed the course.

HOW LONG WILL THE COURSE REMAIN VALID:

Beginning in January 2011, ongoing education in human subjects research will be required every 3 years. Refresher courses will be offered through the CITI program to meet this new requirement.

Updated HIPAA for Research and Data Security for Research training modules are anticipated in September. These courses will also be mandatory for everyone.

New Educational Sessions Led by PPHS

PPHS Outreach – Step Right Up!

PPHS sets up in the Guggenheim Pavilion Atrium (next to the Cafeteria) on Thursdays between 12 and 1 PM. PPH staff members are available to answer questions about how to submit applications to the IRB, the status of existing IRB applications, and anything in between. Researchers will have the opportunity to submit IRB paperwork at this location. Our goal is to bring our expertise outside of the confines of our office and to be accessible to the wider Mount Sinai community. Step right up and talk with us! Look for the Circus Tent Poster!

PPHS Training Sessions: New Forms and Processes

The PPHS office is holding training sessions on the new application materials, new policies, and new system. These training sessions include a detailed tour of the new forms. All researchers,

coordinators and others involved in human subject research submissions are encouraged to attend. Training courses are available (space permitting) on:
Thursday, September 2 - 1:30-3:30
Wednesday, September 8 - 3:00-5:00
Friday, September 10 - 10-12
Tuesday, September 14- 9:30-11:30
Thursday, September 16- 2:30-4:30
Monday, September 20- 1:30-3:30
Thursday, September 23- 11-1
Tuesday, September 28- 9:30-11:30
Wednesday, September 29- 11-1
Please contact William.Benjamin@mssm.edu to reserve a seat.

PPHS Team Happenings...

Avery Block and **Kacey Feasel** have earned their Certified IRB Professional Certification (CIP) this spring and have recently been promoted to Lead Analyst positions. Congratulations Avery and Kacey!

PPHS Staff Profiles:

Fernando Baez joined the PPHS in November 2009 as an Administrative Coordinator. He holds a BA in Media Studies and Psychology from Hunter College/CUNY. Prior to joining Mount Sinai, Fernando did volunteer work for the Center for HIV Educational Studies and Training (CHEST). At CHEST, he helped recruit and conduct interviews with persons living with HIV. Fernando's hobbies include traveling, cooking, music and languages. Fernando speaks Spanish and German. You will most often find him greeting you when you call or visit the PPHS!

William Benjamin joined the PPHS team in May of 2010. He holds a Bachelor of Science degree in Accounting from the University of Scranton, Scranton PA. Prior to Mount Sinai, William worked as a Supervisor at a Community Bank in Pennsylvania. William currently works as the IRB's Financial Coordinator.

Manjit Gill joined the PPHS in November 2009. She holds a degree in Chemistry from California State University, Fresno. Prior to Mount Sinai, Manjit worked at Manhattan Vision Associates - Institute of Vision Research for 3 years as a research associate on projects sponsored by Johnson & Johnson. Manjit currently works with IRB's A and C.

Andrea Goosen joined the PPHS in January 2010. She holds a Bachelors of Business Administration and a Masters of Public Health from the University of Florida, in Gainesville, Florida. Prior to joining Mount Sinai Andrea worked on a research project that evaluated a nutrition campaign used in Florida. Andrea is currently developing a manuscript based on the findings of the evaluation to submit for publication. Andrea currently works with IRB's A and C.

Stacy Jankauskas re-joined the PPHS family in February. Stacy previously worked at Mount Sinai as an IRB analyst for 3 years, becoming a Certified IRB Professional (CIP). Stacy earned her masters in nutrition at Columbia University and worked in the IRB office at Columbia University Medical Center. Stacy has taken on the role of IRB Manager. Welcome back, Stacy!

John Roberts joined the PPHS in July 2009. He holds a degree in Environmental Science & Policy from Duke University in Durham, North Carolina. Prior to Mount Sinai, John worked at RTI, International (previously Research Triangle Institute) in the Research Triangle Park of North Carolina as a research associate and project manager on projects funded by the CDC and U.S. Departments of Justice and Education. John currently works with IRB's A and C.