



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

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PPHS Retreats In Order to Advance

The Program for the Protection of Human Subjects will hold an educational retreat on November 8th for all of its IRB members and department staff. We will be addressed by medical ethicist Arthur Caplan, Ph.D., on "Phase I trials: Ethical Concerns and What To Do About Them.", Dr. Warren Olanow, on "Gene Transfer Therapy Research", Dr. Jeff Silverstein on "Safety Monitoring: Evaluation of DSMPs and DSMBs" and Carol Bienstock on "Consent Short Forms: Policy in the Making." There is limited availability for others to attend. If interested, please contact Ilene.Wilets@mssm.edu for further information. While the PPHS office will be closed that day, GCO (next door) has generously agreed to accept PPHS submissions.

2008 IRB Deadline Schedule Available

The deadline schedule for the 2008 calendar year (and final meetings for 2007) is available on the PPHS website "[Application Info](#)" page under "Meeting Dates, Deadlines, and Results" (item D.)

Stating Dollar Amounts in Advertisements

The PPHS recently modified its recruitment policy to allow for mention of dollar amounts in advertisements with some important conditions.

While the PPHS prefers that ads simply mention that "compensation for time and effort may be available", the mention of specific monetary amounts may be permitted, provided that monetary incentive be neither the focus of the advertisement (such as being in the center of the ad with other information peripheral) nor be specifically emphasized (e.g. multiple dollar signs, different or larger font than the rest of the ad, flashing text on websites, etc.). Additionally, if the approved research plan provides that monetary incentives be pro-rated over the course of several research visits etc., then the phrase "up to \$X may be available" should be used when possible. Ads should make clear that eligibility criteria must be met. The PPHS asks that researchers carefully consider the impact of placing a specific monetary amount in an ad; such considerations should include whether the information would unnecessarily influence the target audience.

All forms of advertising or dissemination of information for the purpose of recruitment of subjects into a research protocol must be approved by the PPHS prior to distribution or publication of the material. This includes, but is not limited to, newspaper advertisements/articles/publicity, radio or television announcements, Mount Sinai Weekly Bulletin advertisements/publicity, posters, fliers, or web-based ads. The PPHS will review the final version of advertisements, as is our current procedure, to make case-by-case decisions about the appropriateness of both the information, and its presentation, in advertisements.

Advertisements: Save a trip & submit electronically!

Most advertisements for study recruitment can be submitted online via Sinai Central. In order to be able to post advertisements online, however, you need to *first contact the PPHS* so that we can give you access to the online advertisement module. Once you've been given access you can go to the Clinical Trials Advertisement Approval System to submit your ads. There is a link on the Guidance page of the PPHS website (<http://www.mssm.edu/pphs/guidance> under item 2.a.ii). Web ads are automatically posted on the clinical trial websites of mssm.edu and mountsinai.org, and you also have the option of posting to CenterWatch website.

Educational Opportunities

If you're new to human research or need a refresher on the basics of IRB application process, please attend our monthly "Basic IRB Training" courses. The next session will be given on: November 19, 2007. If you're interested in attending, please contact Lori.Jennex@mssm.edu.

[Link to:
PPHS Website](#)

[Link To:
Contact Us](#)

*Program for the
Protection of
Human Subjects*

*1425 Madison Ave 4-
78*

*1 Gustave L Levy Place
Box 1075*

New York, NY 10029

Ph: (212) 659-8980

Fax: (212) 876-6789

Not Just A Form: Informed Consent

It is critical to remember that “Informed Consent” is not simply a document – it is an interactive, ongoing decision-making process that takes place between study team members and participants, as well as their family members and medical caregivers in some instances.

There is a minimum amount of information that must be included in the conversation about the research, which is dictated by federal regulations. There are 8 basic elements that must be presented to potential participants: 1) the purpose of the research and a description of what is involved, 2) potential risks/discomforts, 3) potential benefits, 4) alternatives to participation in the research, 5) measures that will be taken to protect subject confidentiality, 6) information regarding injuries resulting from participation, 7) contact information for the study staff, and 8) a clear statement that participation in the research is voluntary.

The federal regulations also require that additional information is presented when applicable to the research, including: 1) a statement about risks that may be unforeseeable, 2) description of circumstances when a subject’s participation might be terminated without their consent, 3) additional costs the subjects may incur from participation, 4) potential consequences if the subject withdraws from the research before completion, 5) a statement that relevant new findings about the research will be provided to them, and 6) the number of subjects to be enrolled.

In order to assist researchers in meeting the federal requirements, the “informed consent template” document was created to guide researchers toward covering all of the basic, and some of the additional, required elements. The informed consent form reminds researchers about the minimum information that should be discussed with a subject, provides a place to record the agreement of a subject to participate, and provides a reference tool the subject can refer back to later. While the consent document serves these very important purposes, the meaningful discussions with subjects are crucial to achieving a truly informed consent, which is at the heart of human subject protection.

Not Asking: Waiving Informed Consent

There are some circumstances in which IRB’s can consider a researcher’s request to NOT obtain informed consent of prospective human subjects. (Note: a human subject includes any living person about whom a researcher obtains private identifiable information, such as in most reviews of medical records). The federal regulations provide a mechanism for an IRB to approve of such a “waiver” of the informed consent process, if an IRB can determine that a researcher’s request for a waiver meets the following criteria:

- 1) the research involves *no more than minimal risk* to subjects,
- 2) the research could not *practicably* be conducted if informed consent was required,
- 3) the rights and welfare of the subjects would not be negatively impacted by not asking for consent to participate; and
- 4) when appropriate, subjects will be “debriefed” after participation

The regulatory term “practicably” (in criteria #2) is interpreted to mean that obtaining consent from subjects would be highly unfeasible or impossible, not just inconvenient.

When requesting to waive informed consent, be sure to justify the request by explaining how the project meets each of the criteria to waive informed consent [[See page 35 of the Guidelines and Policies Manual](#)]. To request to waive informed consent, complete the IRB [Form 7](#), and include it with your project application. Please feel free to contact the PPHS for more information.

Profiling our Newest PPHS Staff Members

- [Jenny-Pingling Ng](#) holds a MS in Clinical Nutrition from New York Institution of Technology. She graduated with her bachelor degree from St. John’s University with a major in Biology and a minor in photography. Her interests involve nutrition, preventive medicine, traditional/ Eastern medicine, transplantation research, OB/GYN medicine, photography, journalism, creative writing, poetry, and music. Currently she is working on her credentials towards Registered Dietician licensure and Nutrition Specialist Certification. She previously worked at Mount Sinai in the Recanti Miller Transplant Institute in 2000 and 2002. She is excited to be back with Mount Sinai and looks forward to making a contribution to the PPHS.
- [Scott Beardsley](#) is the most recent addition to the PPHS team. He graduated from the U of Buffalo in 2004 with a BA in Biomedical Sciences. Scott worked in clinical research studies in the emergency department of the Erie County Medical Center, and also an IRB specialist at the Roswell Park Cancer Institute in Buffalo, NY. In October 2006, he passed the Certified IRB professional (CIP) examination. Scott hopes his experiences can contribute to the Mount Sinai community, and he's looking forward to working and living in NYC for the first time.



Congratulations!

Kudos to Ilene Wilets, Ph.D., Chair of IRB D, and Elena Sunland, M.B.A., IRB analyst, on passing the Certified Institutional Review Board Professional (CIP) exam. The exam is rigorous and requires extensive knowledge of the human research protection administration field. The PPHS now has seven staff members who have achieved certification status!