



MOUNT SINAI
SCHOOL OF
MEDICINE

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

August 2007

Volume 2, Number 2

In This Issue

- [The Marriage of Consent and HIPAA Authorization](#)
- [DSMP vs DSMB](#)
- [Change to Come in Adverse Event Reporting Requirements](#)
- [Educational Requirements: Are You in Good Shape?](#)
- [A Good Idea](#)
- [Educational Opportunities](#)
- [New PPHS Staff Members](#)

[Link to:
PPHS Website](#)

[Link to:
IRB Schedule](#)

[Link To:
Contact Us](#)

Consent and HIPAA Authorization: Upcoming Marriage

Due to popular request, the PPHS is working on a form that incorporates the informed consent document and the HIPAA authorization into a single unified document. This will allow researchers who wish to utilize only one form when obtaining consent and authorization from their potential subjects to do so. The PPHS anticipates that this change will help researchers more easily maintain their source documentation. The "standalone" consent forms and HIPAA documents will still be available. Minor improvements to the formatting and instructions will be included with the new combined form, as well as in updated versions of the standalone forms. Stay tuned for the release of the combined consent/HIPAA form.

DSMPs vs DSMBs: Battle of the Acronyms

Did you know there is a difference between a "DSMP" and a "DSMB"? A data and safety monitoring plan (DSMP) is a general term meaning a proposal to protect participant safety and data. DSMPs can contain a variety of measures to address data quality and confidentiality, safety monitoring (of adverse events, new information, risk/benefit ratio), adverse event reporting plans, and (when appropriate) the inclusion of a data and safety monitoring board (DSMB). A DSMB is a set of individuals whose task is to evaluate study design and data in order to monitor the safety of the subjects and determine if a study needs to stop. DSMB members should be independent from the direct management of the research and not have conflicts of interest. Boards are generally made up of experts knowledgeable in the specific field, in clinical research, and/or in biostatistics. Whether a study needs a DSMB is based on a variety of factors—study risk, study population, design (double-blinded, etc.) size, and complexity. It is important to note that all studies require a DSMP, but only some kinds of studies require a DSMB (board).

Impending Revolution in Adverse Event Reporting

Both the Office of Human Research Protections and the Food and Drug Administration have recently issued long-awaited guidance that clarifies the intended definitions of "unanticipated problems" and how this concept relates to the reporting of adverse events by PI's to IRBs, and IRBs to FDA/OHRP. It is well-known that the absence of this guidance until now has resulted in an enormous volume of information being submitted to IRBs, who are not equipped to track, monitor, or make sense of much of the adverse event data (particularly in multi-center trial where we do not have all data from all sites). OHRP and FDA have now indicated that protection programs can decide whether the reporting of a subset of adverse events and unanticipated problems will better protect the human subjects at their institutions.

The Mount Sinai PPHS believes that reducing the information required for adverse event reporting will achieve greater human subject protection. The PPHS will be able to receive higher quality, higher priority data from PIs, and the limited PPHS resources will be spent evaluating the most critical safety issues. The PPHS will be releasing an updated adverse event reporting policy and form in the near future that addresses what needs to be reported to the PPHS going forward.

Did I Complete All 3 of My Educational Requirements?

In order to participate in human research at Mount Sinai, **three (3) separate education courses must be completed**. Two of them are narrated PowerPoint® presentations given by Dr. Glenn Martin. Let's clarify them:

- 1) Research Data Security. If you didn't attend the presentation Dr. Glenn Martin gave on this topic in March 2006, you must watch the presentation on MSSMTV. This is the most recent requirement announced 18 months ago; many still have not completed this module. To fulfill this requirement, please click [here](#).
- 2) Research HIPAA. This is also a narrated PowerPoint presentation given by Dr. Martin that addresses HIPAA in the context of human research at Mount Sinai. *[Note: this is NOT the institutional video every MSMC employee watches about the concept of HIPAA, and please do not fax over that certificate to the PPHS].* If you didn't attend the conference given on this topic in March 2003, you should watch the presentation on MSSMTV. To fulfill this requirement, click [here](#).
- 3) Human Subject Protection: a standard course about human research protection. To fulfill this requirement, click [here](#).

If you have any questions about whether you have fulfilled your educational requirements, please contact angela.khaimova@mssm.edu at the IRB (x88980).

A Good Idea...Version Dates/Numbers on Study Docs

Putting a version date on your documents (especially protocol summaries, consent forms, and investigator-initiated protocols) is a good practice to more easily track which document is the right one to give to research participants or to submit to the PPHS. While headers and footers can be good places for version dates, these "lesser trafficked areas" can sometimes be missed when you update your documents. Putting them near the main text where you won't miss them is often a good idea. [Reminder: please do not alter the version date in the section at the bottom of the consent document that is marked "IRB Official Use Only". That is how we keep track of our document versions!]

Additional IRB Educational Opportunities

If you are new to human research at Mount Sinai or need a refresher on the basics of IRB application process, please attend one of our "Basic IRB Training" courses which are given monthly. The next sessions will be given on: August 20, 2007, September 17, 2007, October 15, 2007, and November 19, 2007. If you're interested in attending, call the PPHS office at 212-659-8980 or email Angela.Khaimova@mssm.edu and let us know which course you'd like to attend.

Profiling our Newest PPHS Staff Members

Rachel Lally graduated from Colgate University with a BA in Behavioral Neuroscience and a minor in Education. She has worked at Mount Sinai for four years at the Family Studies Research Center in the Psychiatry department as both a research coordinator and grants manager. She has experience in Alzheimer's disease and autism research in addition to IRB and grant submission, and she looks forward to enhancing her Mount Sinai experience by working at the IRB.

Ari Rubinstein completed his BA in Biomedical Ethics at the University of South Florida and will receive his MA in Bioethics and Medical Humanities from the USF College of Medicine in the Fall. Ari comes to us after having worked as the Project Coordinator for the Program in Narrative Medicine and Summer Intern for the Clinical Ethics Committee at The Columbia University Medical Center. Ari's special interests include internal, emergency, and sports medicine as a former medical team member for the Tampa Bay Lightning (NHL), NY Yankees, and Disaster Medical Assistance Team (FEMA).

Please introduce yourself to these staff members!