



MOUNT SINAI
SCHOOL OF
MEDICINE

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

August 2008

Volume 3, Number 2

In This Issue

- New Forms and Guidance
- Data & Safety Monitoring Plans
- Combined Consent/HIPAA Authorization
- Updated Standalone Consent Form
- Non-Standard Consent Situation Documentation
- Protocol Summary Form
- Drug/Biologic Information Form
- Emergency Use of Unapproved Drugs, Biologics and Devices
- Future Use HIPAA Language
- Engagement in Research Form
- Education Requirement Website Change
- IRB Education
- New PPHS Staff Members

A Time of Change...

A number of new and updated forms and policies have been developed for paper-based submissions (everything except InfoEd retrospective studies). The use of these forms and policies goes into effect immediately. In order to assist in the transition to the new form set, **audio-visual presentations** have been developed to help highlight changes from previous form versions, and to introduce new forms. These presentations are available on the IT website at <http://eolas.mssm.edu/e-learn/> under the heading "New and Updated IRB Paper Forms". This newsletter highlights the new or updated forms and policies, with links to the actual documents and forms in **blue**. The new policies and forms are also identified on the **PPHS website** with a **NEW!** icon. If you have any feedback about the new forms and policies please email irbstaff@mssm.edu with your comments, or call 212-659-8980.

Data & Safety Monitoring Plan Guidance & Form

As a complement to our new **Adverse Event Reporting policy**, we are now releasing the **Data and Safety Monitoring Plan guidance** and **form**. As indicated in this new guidance, all human research protocols conducted under the review of the PPHS must include a formal Data and Safety Monitoring Plan (DSMP). The intention of this plan is to contribute to the appropriate oversight and monitoring of the safety of participants, conduct of the study, and the validity and integrity of the data. It should be noted that a data and safety monitoring PLAN (DSMP) is different from a data and safety monitoring BOARD (DSMB), the former being the guiding principles for monitoring, and the latter being a body of individuals convened to do monitoring. The new guidance describes minimum requirements for a DSMP, additional requirements that may be necessary based on risk and complexity of the research, and suggested approaches to the creation, review and oversight of DSMPs. DSMP's should be tailored to the appropriate circumstances of the research and generally involve:

1. A process to monitor the progress of research and the safety of participants.
2. A process for assuring compliance with requirements regarding the detection and reporting of adverse events (AEs) and unanticipated problems.
3. A process for assuring data accuracy and protocol compliance.

A DSMP form has been created for those investigators whose research requires more than the minimum plan level, and who wish to use the form format. Other DSMP formats are acceptable as well, as long as they contain the required information present in the IRB form. Please refer to the DSMP **policy** and the **DSMP form** on the PPHS website under Guidance item 5c. The protocol summary form has also been modified to ask about the DSMP for the research study. **All new and continuation applications will need to provide information about their data and safety monitoring plan using the DSMP form and/or updated protocol summary.**

Combined Consent/HIPAA Authorization Form

Researchers now have the **option** of using a **combined consent/HIPAA authorization form** instead of the individual "standalone" consent and HIPAA authorization forms. In the "combined" form, a modified version of the previous HIPAA authorization language has merged with the consent "confidentiality" language, and the whole section has been moved prior to the documentation page. Researchers with already IRB approved consent and HIPAA forms can choose to submit a revision to combine the two documents together. However, **PLEASE NOTE** that the HIPAA text in the combined form is DIFFERENT than in the current HIPAA standalone form, so a simple "cut and paste" cannot be done. In order to transition from the standalone HIPAA to the combined HIPAA/Consent, one needs to follow the imbedded instructions provided in the combined form, maintaining the new boilerplate language as applicable. It is highly recommended to watch the audio-visual presentation on this form at

[learn/](#) under the heading “New and Updated IRB Paper Forms”. The link to the new combined consent/HIPAA form is available on the [IRB application form webpage](#) and the combined template is available in [Spanish](#) there as well.

Updated Consent Form Template

The consent form template (both on the combined consent/HIPAA and standalone consent) has been updated to include some new pieces of information, including:

- 1) The consent version information;
- 2) Modified header titles;
- 3) A new header title describing the duration of the study;
- 4) Modification of some of the template language;
- 5) The back page of the consent document is different. For standard consent situations, the new consent documentation page should be used. For consent situations that are more complicated, such with a person who is illiterate or visually impaired, there is a new back page to assist with the proper procedure in those scenarios. See next section.

The updated standalone consent form template is also available on the PPHS website in [English](#) and in [Spanish](#). **Any new or continuation application that involves consent documents will require use of the updated consent template (either standalone or combined). Further, any revision made to an approved consent document will require submission of the updated consent template, so it is recommended that researchers submit their updated consent documents as soon as possible.**

Consent Documentation Options Expanded

Previously, there were two pages in the back of the consent form template to document the subject’s written consent to participate and the consent delegate signature. There was also a box on this page that was intended to deal with unusual situations. The IRB has removed the “special situation” box and consolidated the subject and consent delegate signature sections onto one page. This change has been made on the combined and standalone consent templates. If an investigator has an English speaking subject who cannot read or see the consent document, or cannot sign the consent document due to physical incapacity, we have developed 2 special consent documentation pages to assist researchers in these situations. [IRB Form#2C Consent Documentation For Subjects Unable To Read](#) and [Form #2D Consent Documentation for Subjects Unable to Sign](#) are available on the [IRB Application Form webpage](#) and the audio-visual presentation is available at <http://eolas.mssm.edu/e-learn/> under the heading “New and Updated IRB Paper Forms”.

Protocol Summary Form

The [Protocol Summary Form](#) (IRB Form 1) has been modified regarding question #19 (Data and Safety Monitoring) as well as the addition of form fields. Otherwise, the 8/2008 form remains the same. The requirement to use the new form goes into effect immediately, and the form is available on the [IRB application form webpage](#), as well as the link above.

Drug/Biologic Information Form

The [Drug/Biologic Information Form](#) (IRB Form 3) has been modified to include several additional questions including the nature and location of drug and biologic administration, and information related to exemption from IND requirements. The requirement to use the new form goes into effect immediately, and the form is available on the [IRB application form webpage](#) and the audio-visual presentation is available at <http://eolas.mssm.edu/e-learn/> under the heading “New and Updated IRB Paper Forms”.

Emergency Use Guidance/Form/Web Interface

The PPHS is providing an [expanded guidance](#) and additional forms for physicians wishing to provide an [unapproved drug, biologic, or device](#) to a patient in a life-threatening/debilitating medical situation in which no standard acceptable treatment is available and there is not enough time to obtain prospective IRB review. If the physician thinks that using a drug, biologic, or device that is NOT FDA APPROVED may provide some potential benefit, and there is insufficient time to obtain prospective IRB approval, there is an emergency use provision in the FDA regulations that may allow an exemption from prior review and approval by the IRB. The exemption, which may not be used unless all of the conditions are met, allows for one

[Link to:
PPHS Website](#)

[Link to:
IRB Schedule](#)

[Link To:
Contact Us](#)

[Have Questions?
Call 212-659-
8980](#)

emergency use of an unapproved drug, biologic, or device per condition *per institution* without prospective IRB review. Subsequent uses of the investigational product must have prospective IRB review and approval at the institution. In addition to the updated guidance, a checklist form has been developed (one for drugs/biologics, one for devices), that must be filled out by the physician and department Chair. Additionally, a consent template has been developed for physicians to customize appropriately and use with their patient once the emergency use is approved by the institution; this template replaces the previously used Permission Sheet #3. There is also now a PPHS website link for physicians to verify if a drug/device/biologic has been used by a Mount Sinai physician in such an emergency situation previously. Physicians are encouraged to contact the PPHS regarding any intent to use an unapproved product for emergency use as soon as the product is being considered. The guidance and forms are available on the [IRB application form webpage](#) under item #6. The audio-visual presentation is available at <http://eolas.mssm.edu/e-learn/> under the heading "New and Updated IRB Paper Forms".

Engagement in Research Form

When non-exempt human research is taking place at an institution and the researchers would like an individual at *another* institution to conduct only a component of the overall research project (i.e. as opposed to being a designated site conducting the full research), it must be determined whether the component activity meets the definition of engagement in research. If it does, then IRB review is required at that institution as well. The Engagement in Research form is a tool developed to help determine whether a researcher is considered to be engaged in human research at Mount Sinai when the Sinai investigator is only conducting a component of research being done at another institution. The [form](#) is available on the [IRB application form webpage](#) (Form 26).

Updated Suggested Text: HIPAA Future Use

Researchers are reminded that the language has been updated in the suggested HIPAA "future use" questions related to requesting subject permission for future uses of collected data and specimens. This language should be customized for consent forms when data or specimens will be banked for future use beyond the current research project. Please update your consent forms at your next opportunity to align with the newest version of the text, as applicable. You can find the updated language on our website by clicking on the following links: [Blood/Tissue Future Use](#); [Data Future Use](#)

Education Requirement Website Change

The website for completing two of the three IRB educational requirements has now changed. The link to the IRB section of the new website is: <http://irb.cmeoutreach.com>. At this time, the two educational requirements on CMEoutreach are the **HIPAA for Human Research** course and the **Data Security in Human Research** course. (*The third requirement, the Human Research Protections course, is still available at the NIH: <http://phrp.nihtraining.com/users/login.php>*) If you have already fulfilled your 3 IRB educational requirements you need do nothing at this time; future requirements will be available through this website. New faculty or staff participating in human subject research should go to this new site to fulfill 2 of their 3 requirements.

The username and password that you used for the previous MSSMTV site will not work on this new site. You will be required to register the first time that you use it. After you register for the first time, an email will be automatically generated with your password. Subsequently, you can set your password to anything you like. When you register for the first time, it will take you directly into the site, under the "Completed Activities" tab. Click on "Activities and Tests", and you will see the links for the Data Security video as well as the HIPAA and Research video link right below it. You can view the presentations and then click on "View tests" to take the quiz and generate your certificate.

You can find the links to this website on our PPHS website at http://www.mssm.edu/pphs/edu_req/ under Research HIPAA and Research Data Security. For user assistance regarding the CME Outreach website, please contact the Mount Sinai School of Medicine web department: 646.688.1660, ext. 226, or jack.aiello@mountsinai.org.

IRB Education Courses

[Link to:
PPHS Website](#)

[Link to:
IRB Schedule](#)

[Link To:
Contact Us](#)

[Have Questions?
Call 212-659-
8980](#)

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.

Dates for this class are:

September 22nd - 11:00 - 1:00 p.m.

October 27th - 2:00 - 4:00 p.m.

November 24th - 11:00 - 1:00 p.m.

To sign up, please email lori.jennex@mssm.edu or suzanne.caruso@mssm.edu.

IRB Adverse Event Policy Training:

The PPHS office offers a one-hour presentation to researchers and coordinators on the new Adverse Event and Unanticipated Problems Policy. This in-depth presentation reviews the purpose of the new policy; understanding current definitions; requirements for reporting AEs and unanticipated problems and death on protocol.

Dates for this class are:

Sep 18 - 10:30 - 11:30 AM

Oct 17 - 1:00 - 2:00 PM

November 10th – 10:30-11:30 AM

December 11th - 3:30-4:30 PM

To sign up, please email suzanne.caruso@mssm.edu or lori.jennex@mssm.edu.

PPHS Staff Additions

We welcome the following new additions to the wonderful PPHS team:

Liz Carroll holds a BA in Political Science from Hunter College. She came to Mount Sinai from The New York Academy of Medicine where she served as the IRB administrator for two years, focusing on Social/Behavioral public health research studies. She also has experience as a grants administrator and research assistant.

Elise C. Sackmann holds dual Master's degrees in French Literature from New York University and in English studies from the Université de Nice, France, where she grew up. Her interests include all forms of art and aesthetics, from literature and fine arts to lifestyle (fashion, interior design, gardening, as well as theater and travel), which captivate her for their evolving means of expression and sense of culture.