



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

March 2009

Volume 4, Number 1

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InfoEd Continuation & Final Report Applications for Retrospective Studies Now Available

If you submitted a retrospective human subjects protocol using InfoEd, you now have the ability to create a continuation or final report application for those original submissions using InfoEd. When it's time to submit these applications, please go to the Research IT e-learning/reference document website and print out the instructions related to the application type. The process is no more complicated than the original submission.

The instructions can be found on the Research IT e-learning/reference site by the following route:

1. Please go to <http://eolas.mssm.edu/e-learn>.
2. Select "Click here to access the InfoEd reference materials."
3. Select "Human Subjects Module."

When you select the Human Subjects Module folder, you will be prompted to either log in or create a login for the site. You must register to access the InfoEd reference materials on the site; the site contains proprietary information about InfoEd. The login that you use for the support site is only for that site; it is not your InfoEd login. If you haven't already, you will need to create a login for the support site. The process is the same as creating a login for many other Web sites, like Facebook or Amazon. You will get to choose your own username and password. You just need a Mount Sinai email address to create your account. As always, when you need assistance please email the InfoEd support team as infoed@mssm.edu.

New IRB Paper Forms

- A new Combined Consent/HIPAA authorization form for CHILDREN IN RESEARCH is now available on the [PPHS application form page](http://www.mssm.edu/irb/docs/IRB2FCombined_child.doc) at http://www.mssm.edu/irb/docs/IRB2FCombined_child.doc. Form 2F can be used for studies involving the enrollment of children as research subjects when the researchers wish to combine the parental permission and HIPAA authorization processes into one form.
- Have you received an updated Clinical Investigator's Brochure (CIB) from a sponsor? A new form is now available for submission of an updated CIB. Form 27 is available on the [PPHS application form page](http://www.mssm.edu/pphs/docs/CIB_change_form.doc) or at the following direct link: http://www.mssm.edu/pphs/docs/CIB_change_form.doc. The CIB update form must be completed whenever a new CIB is being submitted following a project's initial IRB approval.

Updated IRB Paper Forms

- The "Engagement in Research" Form 26 has been updated based on the OHRP release of the final guidance document on this topic. It can be used as a worksheet that will help the PPHS determine if you or your collaborators are engaged in research and therefore need oversight. It is available on the [PPHS Application form page](http://www.mssm.edu/irb/docs/IRB26EngagementResearch.doc) under Form 26 or at the following direct link: <http://www.mssm.edu/irb/docs/IRB26EngagementResearch.doc>.
- An updated continuation checklist is available on the [PPHS Checklist page](http://www.mssm.edu/irb/pdfs/IRBcheck_continuation.pdf) or at the following direct link http://www.mssm.edu/irb/pdfs/IRBcheck_continuation.pdf. It has been updated to clarify when the device form is necessary, and the kinds of research for which some documents are unnecessary in the continuation application.
- Small changes have been made to the informed consent template (both the combined authorization/consent and standalone consent). These updated forms will be made available over the next few weeks, and their use is recommended but not required at this time.

Keeping The Data Secure: A Vital Element of Human Subject Protection

This is a written description of current expected data security standards that is posted on our website at http://www.mssm.edu/pphs/docs/data_security_standards.doc :

As a general practice research data (information collected/generated about individuals) should be stored separately from direct identifiers e.g. name, address, DOB, MRN, SSN) that can link the data to a person's identity. Instead, research data files should be stored using a unique "code" instead. The "linking code file" (code breaking list) should be maintained separately.

Securing the linking code file: The file that links the code to the person's identity (direct identifiers) should be maintained securely: if it is on paper it should be in a locked, secure place separate from the research data; if it is electronic, it should be encrypted, wherever it is stored.

Securing the research data file: Research data files may currently be stored in various places, and their security requirements are different. Any research file stored on a desktop hard drive, stand alone server, laptop, flash drive, floppy disk, etc MUST be encrypted. If the research data file is kept on a personal network drive on the Academic Computing or Hospital IT file server located in the medical center's secure data center, encryption is not required, but still advisable. If the research data file is stored on a "departmental" network drive (a general drive for a whole department on the Academic Computing or Hospital IT file server located in the medical center's secure data center), access to the data files should be limited to the research team, either through restricted view access to team members set up by Academic Computing or Hospital IT (recommended) or password protection on the file. If this cannot be done, the files should be encrypted. Remember it is the location of the file, not the location of the computer that counts.

Did You Know? Annual IRB Review is a Federal Reg!

The Health and Human Service regulations for the protection of human subjects ([45 CFR Part 46](#)) require that, among other things, an IRB conducts continuing review of research at intervals appropriate to the degree of risk, but **not less often than once a year** (45 CFR 46.109(e)).

Continuing review of research must be substantive and meaningful. In accordance with HHS regulations continuing review by the convened IRB is required unless the research is otherwise appropriate for expedited review. Furthermore, HHS regulations at 45 CFR 46.111 set forth the criteria that must be satisfied in order for the IRB to approve research. These criteria include, among other things, determinations by the IRB regarding risks, potential benefits, informed consent, and safeguards for human subjects. The IRB must ensure that these criteria are satisfied at the time of both initial and continuing review. In particular, when conducting continuing review, the IRB needs to determine whether any new information has emerged either from the research itself or from other sources that could alter the IRB's previous determinations, particularly with respect to risk to subjects. Of note, information regarding any unanticipated problems involving risks to subjects or others that have occurred since the previous IRB review in most cases will be pertinent to the IRB's determinations at the time of continuing review.

In conducting continuing review of research not eligible for expedited review, all IRB members receive and review a protocol summary and a status report on the progress of the research that includes:

- the number of subjects accrued;
- a summary of any unanticipated problems and available information regarding adverse events (in many cases, such a summary could be a simple brief statement that there have been no unanticipated problems and that adverse events have occurred at the expected frequency and level of severity as documented in the research protocol, the informed consent document, and any investigator brochure);
- a summary of any withdrawal of subjects from the research since the last IRB review;
- a summary of any complaints about the research since the last IRB review;
- a summary of any recent literature (the PI's research OR anyone else's on the topic) that may be relevant to the research and any amendments or modifications to the research since the last IRB review;

- any relevant multi-center trial reports;
- any other relevant information, especially information about risks associated with the research;
- a copy of the current informed consent document and any newly proposed consent document.

At least one member of the IRB must also receive a copy of the complete protocol including any modifications previously approved by the IRB. Further, upon request, any IRB member has access to the complete IRB protocol file and relevant IRB minutes prior to or during the convened IRB meeting.

When reviewing the current informed consent document(s), the IRB must ensure:

- The currently approved or proposed consent document is still accurate and complete;
- Any significant new findings that may relate to the subject's willingness to continue participation are provided to the subject in accordance with HHS regulations.

Review of currently approved or newly proposed consent documents must occur during the scheduled continuing review of research by the IRB, but informed consent documents should be reviewed whenever new information becomes available that would require modification of information in the informed consent document.

Furthermore, the minutes of IRB meetings should document separate deliberations, actions, and votes for each protocol undergoing continuing review by the convened IRB.

When reviewing research under an expedited review procedure, the IRB Chair (or designated IRB member(s)) should receive and review all of the above-referenced documentation, including the complete protocol.

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.

Dates for this class are:

March 23, 2009 – 2 pm – 4 pm
 April 27, 2009 – 2 pm – 4 pm
 May 18, 2009 – 10 am – 12 pm
 June 22, 2009 – 2 pm – 4 pm
 July 27, 2009 – 2 pm – 4 pm
 August 31, 2009 – 11 am – 1 pm
 September 28, 2009 – 2 pm – 4 pm
 October 26, 2009 – 11 am – 1 pm
 November 30, 2009 – 2 pm – 4 pm

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:

May 15, 2009 – 4:00 – 5:00 pm
 July 16, 2009 – 11:30 am – 12:30 pm
 October 15, 2009 – 11:30 am – 12:30 pm

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 an informal meeting 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.

Dates for this sessions are:

April 13, 2009 - 5:30-6:30 pm
 May 15, 2009 - 5:30-6:30 pm
 June 8, 2009 - 5:30-6:30 pm
 July 7, 2009 - 5:30-6:30 pm

August 13, 2009 - 5:30-6:30 pm
September 14, 2009 - 5:30-6:30 pm
October 14, 2009 - 5:30-6:30 pm
November 13, 2009 - 5:30-6:30 pm

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 or Suzanne Caruso at suzanne.caruso@mssm.edu to reserve your spot.

Meet PPHS Team Members..

Avery Block holds a BA in psychology from Connecticut College in New London, CT. She graduated with a certificate with the Program in Community Action and Public Service for her work regarding the quality of life of college students who have Type 1 diabetes, which culminated in her senior honors thesis. Avery has worked at Joslin Diabetes Clinic in Boston, MA as a research assistant with the Mental and Behavioral Health Research Department and most recently worked at the Institutional Review Board at Dana Farber Cancer Institute in Boston. Avery currently works with IRBs A and C.

Stephen W. Hayes holds a BA in English and Psychology from Merrimack College in North Andover, MA. He comes to Mount Sinai after working in Multiple Myeloma research at the Dana-Farber Cancer Institute in Boston for the past four years. He has also worked for Monster.com and in a brain injury rehabilitation program. He enjoys playing guitar and is an avid Boston sports fan. Stephen currently works with IRBs B and D.