



HUMAN SUBJECTS RESEARCH NEWSLETTER COMMITTEES ON HUMAN RESEARCH

SERVING THE UNIVERSITY OF VERMONT
AND FLETCHER ALLEN HEALTH CARE
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INFOED IS COMING!

We are making great progress in our transition to our new data management system (InfoEd) for the human subject protection program. We successfully converted our human subject protocol data into a test area at the end of August and have been testing ever since. We are scheduled for a final conversion the week of December 6 and will begin use the week of December 13.

The Committee will now have the ability to generate and forward correspondence via email. Some of the correspondence, for example, the continuing review notices are automated while others are manual and require a “push” from the RPO staff. Protocol principal investigators, designated contacts and faculty sponsors will receive all the correspondence, similar to the way it is handled now through interoffice mail, with the exception that all correspondence will now be sent via email. These emails may come from different people within our office however the subject line of all the emails will always include the word ***IMPORTANT*** and the **IRB file number**. **Please do not disregard these emails as we will not be sending hard copies of the correspondence that have been emailed to you.**

At this time, if your reply requires a form submission, or if you are submitting a new protocol, we still require paper copies to be submitted for review. Paper submission instructions are located on our forms web page at: http://www.uvm.edu/irb/?Page=m1_forms.php&SM=humanmenu1.html. We plan to release the electronic submission portion of the system sometime in the future. You will be notified when that is ready.

To prepare for this new email process, we have undertaken a huge data analysis and have been contacting PIs, contacts, and faculty sponsors who have discrepant emails in our current system. We are confirming their preferred email address and are entering it into their InfoEd Profile. The InfoEd Profile is where all of your demographic information is kept. Since most of you are not using the InfoEd system at this point your Profile information is minimal.

At this time, UVM active PIs, contacts, and faculty sponsors have the ability to login to InfoEd using their UVM NetID and password to view and edit their InfoEd Profile information. You may change any of the fields in the Profile. Warning: The Profile fields are shared across OSP Pre-Award, and both the IACUC and IBC committees. This means that all the Infoed correspondence, including grant proposal, IRB, IACUC and IBC correspondence will go to the same email address.

To find some additional information and step-by-step guides for viewing and editing your InfoEd Profile go to <http://www.uvm.edu/~infoed/?Page=InfoEdUserProfile.html>.

Note: If you are a Fletcher Allen Employee only or are an external researcher, you are not able to login to InfoEd at this time. However, we have already emailed you separately to establish your preferred email address, so you are set. We are working on a process to allow access for you in the future.

Thank you for your patience during this time of change. Please do not hesitate to contact us with any problems or concerns. The earlier we are made aware of any problems with this process the sooner we can address them.

Closing Protocols

If you are closing your protocol at time of continuing review or with an amendment you must be sure to complete either of the two forms in their entirety. All information is required as part of your final report to the IRB.

Human Subjects Training Changes

Along with the InfoEd implementation, we are updating our Human Subjects Tutorial registration process. The current software that supports the registration data is being retired so we will be moving the registration portion of the training into “Limesurvey”, a survey software tool supported by UVM ETS.

We have over 4,000 people in our database. Identifying people in our database and associating those same people with a protocol has proven extremely difficult over the years. We have therefore decided with this new implementation that people will need to login (authenticate) using a UVM NetID and password prior to completing the registration portion of the training. Requiring authentication as part of the registration will resolve much of the confusion around this issue. It does, however raise a couple of other issues as follows:

1. For non-UVM employees, there will be an additional step that needs to be taken. You will need to provide the RPO office with some information about you so that a UVM NetID can be granted for this purpose. We have determined this to be a small percentage of the total number of people. The instructions will be at the beginning of tutorial.

2. We have also found that some of you do not realize that you have a UVM NetID. To address this, we will have a step-by-step instruction at the beginning of the tutorial to help you make the determination as to whether you have a UVM NetID or not and what to do if you do not.

You should have your UVM NetID and password ready before you begin the training as you won't be able to register your completion without them.

To allow us some time to finalize the new registration process, we have recently sent out anniversary reminders to those expiring through April 2011. We would appreciate it if you would complete it now.

We will send another notice regarding this when the new process is in place. Thank you for your patience in this regard.

ETHICAL ISSUES IN GENETICS RESEARCH

P. Pearl O'Rourke, MD
Director of Human Research Affairs, Partners
HealthCare Systems
Tuesday, November 16, 2010
UVM Medical Education Conference Room 300
4:45-5:45pm EST

The explosion of genetic research and personalized medicine presents a number of challenging ethical issues for researchers, participants and oversight bodies such as the IRB. Many of these issues are not new – but are simply exaggerated when seen through the lens of genetics.

This session will be didactic with some case presentations. The overall teaching goal is to increase awareness regarding the ethical issues confronted in genetics research.

Learning Objectives: At the end of this presentation, participants will be able to:

1. Discuss the nuances of identifiability of genetic information and the impact on regulatory oversight of this research.
2. Understand the pros and cons of returning genetic research results to individuals
3. Recognize the effect of direct-to-consumer genetic testing on biomedical research.

Target audience: Principal Investigators and other Research personnel

Accreditation:

The Dartmouth-Hitchcock Medical Center, Center for Continuing Education is accredited by the Accreditation Council for Continuing Medical education to provide continuing medical education for physicians.

The Dartmouth-Hitchcock Medical Center designates this educational activity for a maximum of 1 *AMA PRA Category 1 Credit*[™]. Physicians should only claim credit commensurate with the extent of their participation in the activity.

Contact Julie with any questions regarding this educational opportunity.

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