



HUMAN SUBJECTS RESEARCH NEWSLETTER COMMITTEES ON HUMAN RESEARCH

SERVING THE UNIVERSITY OF VERMONT
AND FLETCHER ALLEN HEALTH CARE
ISSUE 33, WINTER 2011



CHANGE TO KEY PERSONNEL ROSTERS AT TIME OF CONTINUING REVIEW

Beginning with continuing review notices for February, March, and April you will no longer need to fill in the names of all your key personnel. We will provide, along with your continuing review notice, a roster of all key personnel that will reflect what the IRB currently has on file. You will need to print that page, complete the form, and attach it to your continuing review submission. We will continue to maintain the list of tutorial completions on our website for your convenience, but you will no longer be required to provide tutorial completion dates back to us on the roster form. If you need to add a new person to the roster at the time of continuing review you will need to submit a [Request for Change in Key Personnel](#) form and attach it to the continuing review submission. Key personnel updates will be held until the training has been completed by the new person and that person must not begin until you are notified that the new person has been added.

During the transition, both the old and the new continuing review forms will be available on our website, the “old” one with a roster included for those in transition and a “new” one that does not have a roster (instead references the new process.) Please make sure that you are using the correct form and process. We cannot reapprove a protocol without a key personnel roster.

Why Don't I Have To Include Tutorial Completion Dates Anymore At Time Of Continuing Review?

The Committee is no longer associating the completion of the training requirement to the continuing review process of specific protocols. The new system tracks an individual's training expiration date. If an individual listed as key personnel has not completed the required training prior to their training expiration, the IRB will administratively remove their name as key personnel on all protocols on which they are listed and notify the affected PI(s). This means that those individuals removed can no longer work with human subjects or human subject data. This will allow individual protocols to continue without interruption, maintain our compliance with training requirement, and help the IRB to maintain a current list of personnel for each protocol.

In an effort to avoid this IRB action, we developed an automated reminder system. Key personnel, as well as the contact for each protocol on which the individual is listed as personnel, will receive multiple email notices of this requirement as the individual's anniversary date nears. The database will comb through those individuals requiring completions on a nightly basis, select those that are nearing their anniversary date, and then email reminders will be sent to the individual with a copy to each protocol contact. These notices will be sent at 90, 60, and 30 days, with one final notice again at 7 days prior to expiration. The final 7-day notice will also be copied to the PI(s) to give them an opportunity to assist in meeting the requirement.

If the individual's training expires, as stated above, the IRB will administratively remove them from active status on the protocol(s). This action will be documented and forwarded to the PI. This means the individual can no longer do humans subjects work on the protocol.

Given this improved notification process, we expect that we will not need to remove key personnel from protocols for failure to comply with this requirement. It is important, however, that PIs keep their key personnel lists up-to-date. If someone is no longer working on the protocol, PIs should submit a Request for Change in Key Personnel form so that individual is removed from the protocol(s). The Request for Change in Key Personnel form has been modified so that removal of a single individual from multiple protocols can be done with just one form. If the individual is not removed from a protocol real-time, they may run through this entire reminder process, resulting in possible unnecessary actions. Attention should be given to these email reminders as these are the official reminders and the only notices that will be provided.

Human Subjects Training

Just prior to the holiday break we revised our tutorial to require a UVM NetID and password to register the training completion. We want follow up on this change in process for human subjects training as we have had a couple of unintended consequences.

We found that many people outside the UVM/FAHC community were using this as an educational tool. While we are no longer able to open registration to everyone, there is still open access to review all of the training slides prior to the registration area. We welcome and encourage that continued use for educational purposes.

Another issue is when non-UVM employees plan to be involved in UVM/FAHC research and have not as yet been added to an individual protocol. All non-UVM employees who require this training need a UVM NetID to register their completion. However, we are only allowed to request a UVM NetID for key personnel listed on a protocol.

There have been instances when a person has been requested by their PI to take training prior to the PI's submission of an amendment to add them to the protocol - a clear catch 22! They need to complete the training and they can't do so because they don't have a UVM NetID, but they can't obtain a UVM NetID because they are not listed on a protocol.

Please note that for personnel who do not have a UVM NetID, it is important to submit your request to add them to your protocol **as soon as possible** so that they can in turn complete their training requirement. The request doesn't have to be approved just received in the RPO office. We have modified the Request for Key Personnel form to have a column to identify, in lieu of a training date, a date of request for UVM NetID.

B. Add Personnel		Not applicable		
Last Name	First Name	Email Address	Date of Request for UVM NetID (Only necessary if you can't complete training for lack of UVM NetID.)	Will this person be delegated to consent subjects? Yes/No
			Date of Tutorial Completion	

Check tutorial completions at <http://www.uvm.edu/~irbeducation/TutorialCOMPLETION.htm>

InfoEd Updates

We successfully converted our data prior to the holiday break and are utilizing the new web-based human subjects data management system. We have created our first sets of meeting agenda for the Behavioral and Medical Sciences IRBs with a click of a button.

We used the system to send our continuing review notices out for February, March and April. Be looking for those in your email. We have found that some folks within the College of Medicine do not have their emails forwarded appropriately to their "med" addresses and weren't receiving their email. Please make sure that you have forwarded your email so that you don't miss any IRB correspondence. The COMIS help desk can assist you if necessary.

We would remind you that 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 protocol correspondence will go to the same email address.

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. If you need to make changes to your name or email, send an email to IRB2@uvm.edu.

We would request that if you have a change in your name that in addition to changing your profile that you let our office know. We need to have this information so that we can revise our paper files accordingly. You may email IRB2@uvm.edu with this information.

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>.

FDA Amends Informed Consent Regulations

At the beginning of this year the Food and Drug Administration (FDA) announced that it is amending the current informed consent regulations to require that informed consent documents and processes for applicable drug (including biological products) and device clinical trials include a specific statement that clinical trial information will be entered into a databank. The databank (ClinicalTrials.gov) referred to in this final rule is the clinical trial registry databank maintained by the National Institutes of Health/National Library of Medicine (NIH/NLM) which was created by statute. The submission of clinical trial information to this data bank also is required by statute. This amendment to the informed consent regulations is required by the Food and Drug Administration Amendments Act of 2007 (FDAAA) and is designed to promote transparency of clinical research to participants and patients.

Given this, all new protocols that require clinical trial registration on ClinicalTrials.gov must now also include a statement regarding this registration in the informed consent document. This applies to all informed consent documents and processes related to a clinical investigation that is initiated on or after March 7, 2011. This amendment is not retroactive to currently approved protocols as the FDA has stated that "we do not believe that the benefit outweighs the difficulty, cost, and complexity of requiring revision to all existing informed consent documents."

Our existing Common Protocol Cover form includes a question to assist PIs in determining if the protocol requires registration on ClinicalTrials.gov. To assist in ensuring that investigators now also include the appropriate language in the consent form, we have revised the form to provide you with the required consent form language.

d.	Is this protocol either a
	<ul style="list-style-type: none">• Trial of Drugs and Biologics: controlled clinical investigations, other than Phase 1 investigations, of a product subject to FDA regulation• Trial of Devices: Controlled trials with health outcomes of devices subject to FDA regulation, other than small feasibility studies, and pediatric postmarket surveillance
<input type="checkbox"/>	Yes
<input type="checkbox"/>	No
If yes, prior clinical trial registration is required by FDA and inclusion of the following language in your consent form is required:	
"A description of this clinical trial will be available on http://www.ClinicalTrials.gov , as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time."	
Please note that prior clinical trial registration may also be required for publication in many journals but would <u>not</u> require the above FDA statement in the consent form. For guidance see Clinical Trials Registration Information located in the "news" section of our website.	

This will be added as part of our review of all new clinical trials beginning immediately.

Fletcher Allen Investigational Drug Service Expands

Fletcher Allen's Pharmacy department has opened the Fletcher Allen Outpatient Investigational Drug Service (IDS). This service has been offered to some research programs for several years, and the department will now offer assistance with drug research on a wider basis.

The IDS offers secure storage for drugs and records, study review and budgeting for all studies, dispensing and compounding for oral and sterile agents, appropriate and complete record-keeping and regular monthly statements for accounting purposes. The office is permanently staffed by a pharmacist and pharmacy technician and is open 20 hours per week and by appointment for site visits.

For more information, please contact the investigational pharmacist, Elizabeth Rodriguez, Pharm. D., at 847-2610 or elizabeth.rodriguez@vtmednet.org; or Diana Dutkiewicz, CPhT, at diana.dutkiewicz@vtmednet.org. You may also stop by the office on the first floor of the UHC campus during office hours: Tuesdays and Wednesdays, 8:30 am-5 pm and Fridays, 8:30 am-1:30 pm.

PI Grand Rounds Series from Dartmouth Hitchcock via Video Conference

Time: Tuesday, Feb. 15th from 4:45 to 5:45 PM

Location: Medical Education Conference Room 300

Featuring: Greg Koski, MD, Associate Professor of Anesthesia, Harvard Medical School and former Director of OHRP

Topic: Investigator Responsibilities

Editor: Donna.Silver@uvm.edu

Web Site: <http://www.uvm.edu/irb>

Newsletters archive:

<http://www.uvm.edu/~irb/?Page=education/newsletter.htm>