



HUMAN SUBJECTS RESEARCH NEWSLETTER COMMITTEES ON HUMAN RESEARCH

SERVING THE UNIVERSITY OF VERMONT
AND FLETCHER ALLEN HEALTH CARE
ISSUE 36, FALL 2011



CHANGES PROPOSED FOR HUMAN RESEARCH PROTECTION REGULATIONS

The Department of Health and Human Services (DHHS) recently published an advanced notice soliciting comments on the DHHS proposal to improve the rules protecting human research subjects.

In the notice, entitled "Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators," the government seeks the public's input on an array of issues related to the ethics, safety, and oversight of human research, before making changes to the regulations, which have been in place since 1991. Although this advanced notice is very early in the rule-making process, this proposal suggests a sweeping overhaul of these regulations with the intention of strengthening protections for human research subjects.

If you are interested in more information, the Office of Human Research Protection (OHRP)'s web page has links to the news release, the full proposal, a 4-page summary table of the proposed changes, and FAQs: <http://www.hhs.gov/ohrp/humansubjects/anprm2011page.html>.

The comment period has been extended to Wednesday, 10/26/11 and the Research Protections Office is developing comments on behalf of the University. If you would like to send us your thoughts or concerns for us to consider as we develop our response, please send them to the RPO office, 213 Waterman Building or to irb@uvm.edu no later than 10/12/11. Additionally, any member of the public is permitted to submit individual comments and we would encourage you to do so if you have specific points you wish to convey. If you do decide to comment, we suggest that you to read the entire proposal, as there are questions imbedded within the document for which specific comments are requested.

IRB Invoicing

When you are submitting the Common Protocol Cover form and the protocol is billable for IRB fees, please contact your sponsor prior to completing the Sponsor section to obtain the correct sponsor contact information. We are finding that sponsor invoice contacts are incorrect. Unfortunately, it is only identified by the sponsor after the invoice has already been sent to them. In some cases, it may be incorrect and the invoice isn't forwarded to the correct person. This holds up payment and thus holds up release of your IRB approval.

InfoEd Update

Things seem to be going well after our data conversion. We are still working through some internal processes but we are now in a place to consider moving on to the next task which is electronic protocol submission. We have some initial internal training sessions scheduled with the vendor this month.

Once this initial introduction to the product is done, we will be assessing feasibility and timelines. We will be forming a focus group of you, the user community, to help us troubleshoot issues, develop processes and test those processes, and provide opinions for a rollout and training plan. We want to make sure that we have considered as much as possible prior to implementation. The focus group will include people with diverse roles within both the University and Fletcher Allen. Although there will be a time commitment, it is difficult to predict how much time at this point. We foresee different levels of involvement based on your particular role in the institution. If you are interested in participating in this endeavor with us, please contact Donna.Silver@uvm.edu.

A Look At Continuing Review and Reminders

Every non-exempt protocol requires review at a minimum of once per year. The IRB for years has provided 90, 60, 30 day reminders for when continuing review materials are due. While these reminders are not a regulatory requirement, we find that providing these reminders helps us all keep on track with the continuing review requirement. Unfortunately, many researchers wait until the last reminder and in some cases the very last minute to submit their continuing review materials.

As you know, most recently we have moved to automatic reminders from the InfoEd system. This has helped tremendously, however, we still have researchers who are not timely with their continuing review submissions. To help us make sure that we all stay in compliance with this requirement, we have been adjusting our reminder dates and time periods in an attempt to receive the materials in enough time for our review. The IRB needs approximately 21 days to prepare for a full continuing review (more than minimal risk activities) and approximately 7-10 days for an expedited (no more than minimal risk activities). Of note, we are aware that the date changes may result in some duplicate reminders or missed reminders short term. Ultimately it is the PI's responsibility to make sure the continuing review materials are submitted in a timely fashion.

We ask that while we continue to adjust our reminders to improve this service, that you submit your continuing review materials following the first reminder. This will ensure that your protocol obtains the review that is required within the required timeline.

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

Informed Consent Compliance

Informed consent must be obtained **prior** to any research procedures. Use of improper consent procedures is considered noncompliance regardless of whether there was intent or whether there was any increased risk to the subjects as a result of the improper consent procedures. Depending on the situation, consent noncompliance may result in additional reporting to others entities outside of the IRB such as the sponsor or the institutional official.

To properly obtain consent you must

1. Validate that you are using the correct consent form by doing the following:

- You have pulled the consent form that matches the protocol version for which you trying to enroll;
- You have confirmed that the IRB date stamp is present and completed with a date on last page, and that that date has not expired;
- You have confirmed that the version of the consent, if revisions have taken place, is the one you are going to use (indicated by a letter designation within the IRB stamp)
- There are no handwritten notes or strikethroughs on the IRB approved consent form. (No alterations of this kind can be made to an IRB approved consent form without prior review and approval by the IRB.)

2. The person obtaining consent must:

- be the PI or an appropriate delegate who is listed on the protocol roster;
- assess the subject's understanding during the informed consent discussions and answer any questions;
- sign and date the consent form after the subject has signed and dated the consent form;
 - Note: Pre-signing and dating consent forms is NOT allowable. The PI or delegate, by signing and dating the form at the same time as the subject, is attesting that they have reviewed the protocol with the subject and conducted the informed consent process.
- provide a complete (include all pages) copy of the fully executed consent to the subject;
- and document the consent process by maintaining a complete (include all pages) copy of the executed consent form and making a note to your research files.