HUMAN SUBJECTS RESEARCH NEWSLETTER
COMMITTEES ON HUMAN RESEARCH
SERVING THE UNIVERSITY OF VERMONT
AND FLETCHER ALLEN HEALTH CARE
ISSUE 31, SPRING 2010

IMPORTANT IMMEDIATE FEE POLICY CHANGE

A revised policy for charging fees for IRB review is attached. This revision implements a change in process, not in fees, at the request of FAHC administration.

Effective immediately, the IRB will reinstitute the practice of holding the documentation of **initial** IRB approval until the review fee has been paid by the sponsor. On July 1, 2009, the IRB began releasing documentation of IRB approval before payment was received and this has created a serious delay in sponsor payment to Fletcher Allen. This process change required by FAHC is intended to correct this delay.

We regret any inconvenience that this change may cause. Please see the policy for more details and answers to FAQs on this policy.

Items Worth Mentioning

If you intend to provide monetary compensation of any kind (i.e., gift cards, savings bonds) to a subject, you need to provide private information, including the social security number, to procurement services. You must let the subjects know about this process within the consent form. There is language you may use in the consent template.

If you are submitting a protocol that can be expedited, you only need submit one copy and there is no submission deadline. They are accepted and reviewed on a first-come first-serve basis and are not tied to a convened meeting.

If you use email to correspond with subjects, either individually, or in a group email, please remember to use appropriate email etiquette. When sending to a group make sure you blind cc the group so that you are not sending the names of other subjects to the group. Also, you should be careful about the content of your email. Once you hit the send button, there is no pulling it back. If the content is sensitive, you should seek a different means of communication.

As of July 1, 2010 IRB Institutional Numbering Will Change

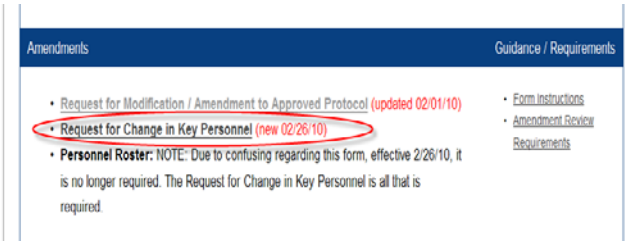
As we move towards converting all our humans subjects data into the new InfoEd system we need to modify our institutional numbering system. Currently some of our numbers include symbols or acronyms which will not be practical moving forward. For any new protocols received for review in the new fiscal year, 7/1/10, the following will be the new numbering system:

Behavioral Protocols
B11-001, B11-002, B11-003, etc
For current behavioral protocols the "*" will be removed from the end of the number and a leading "B" will be placed in front of the number.
Medical Protocols
M11-001, M11-002, M11-003, etc
For current medical protocols that have symbols or acronyms, we will maintain those numbers manually until the study closes.

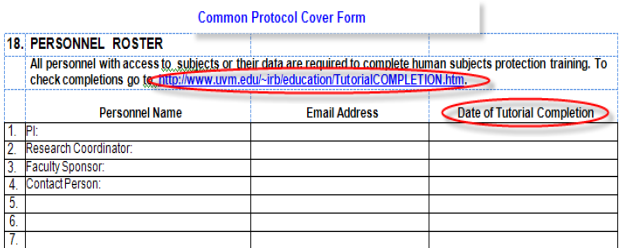
Review and Approval of Key Personnel Changes Update

In our last newsletter we notified researchers of a process change regarding key personnel. We found that this change created confusion and hardship for all involved. Therefore we retracted much of the process change.

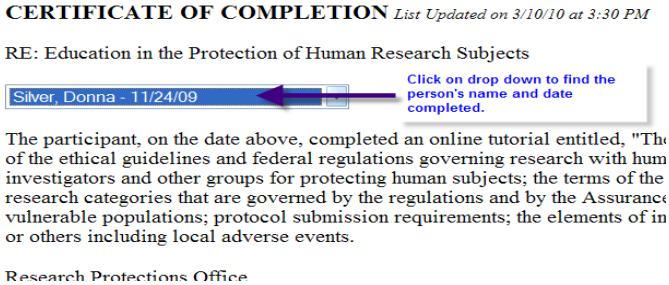
Two changes remain. To request a key personnel change you use a new form not the amendment form. This will be administratively signed off by staff in the office.



The second change is a request for additional information about key persons' training. The PI is responsible to ensure that all key personnel have completed their human subjects training. Below is an example of the Common Protocol Cover Form.



To find the tutorial completion dates click on the link provided in the form and search by the person's name. If they are out of compliance with this requirement, we expect the PI to request that it be done either prior to submission or at the same time of the review.



We hope this helps to clarify the requirements going forward.

GINA

We are well on our way to revising current consent forms to include the GINA language. A couple of questions have come up that we thought we would disseminate.

1. The law is not specific in regards to whether subjects who have previously consented to the use of genetic materials, have to re-consent. The law increases the protection to the subject and therefore the IRB will not require that you have subjects re-consent for this purpose.

2. Some of you have contacted us for help with establishing whether GINA applies to your research study or not. In some cases it is very clear that genetic materials are being collected and used in the research but in others it is not as clear. In these cases, the PI or sponsor needs to answer this question and revise the language accordingly.

3. If the basis for the genetic research is on samples which do not have any identifiers, GINA does not apply.

Below is a link where more information can be found.
Genetic Information Nondiscrimination Act (GINA)

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