HUMAN SUBJECTS RESEARCH NEWSLETTER
COMMITTEES ON HUMAN RESEARCH
SERVING THE UNIVERSITY OF VERMONT
AND FLETCHER ALLEN HEALTH CARE
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InfoEd

InfoEd is a web-based software designed to allow researchers to submit their grant proposals and protocols electronically.

At this time, the move to electronic submission of **proposals** is almost complete. The RPO has successfully converted **protocol** data for the Institutional Biosafety Committee and the Institutional Animal Care and Use Committee. We are now focusing on conversion of our human subject protocol data from its current database into InfoEd. There is quite a bit of work to a data conversion especially given the complexity of a human subject research protocol. There are many decisions about internal processes that need to be made even prior to a conversion. We are in the process of identifying potential problems or shortfalls with the new system and are making decisions about how those will be handled. This reflection on our day-to-day activities has allowed us to re-think and make improvements. Most of the resulting changes initially will affect only our staff, however we have noted below some initial changes and some issues that will require some forethought by you the investigator. We will strive to keep you abreast of changes as they occur. The following are some recent process changes and other that are in the works.

1. We no longer accept IND safety reports. Policy was changed in Spring 09. We are returning those IND reports to you, unreviewed.

2. We are changing our review process for key personnel changes. See page three of the newsletter for details.

3. Moving to electronic means that "paper" documents need to be scanned and uploaded to the InfoEd system. You are all aware of the reams of paper this process requires. In the future, scanned documents will be required for submissions. What this means for investigators is that if you do not currently have a scanner that is adequate to scan all of your protocol materials, you may want to consider purchase of a scanner in the future.

4. Move to electronic also means that email will be used to exchange information. If you are a UVM employee or have a dual appointment (email addresses for both UVM and FAHC) and prefer to use the vtmednet address, you should establish that email coming into your UVM email box is being forwarded appropriately to the vtmednet address. The success of electronic exchange of email heavily depends upon the receipt of email from our office and therefore we want to make sure that you are receiving protocol email correspondence. See the following link on UVM's site to forward your email, http://www.uvm.edu/account/. Email addresses on file for all investigators will be verified prior to email exchange of protocol correspondence.

5. We will be deciding shortly on a new IRB protocol numbering system. The current use of symbols and acronyms within our numbers will no longer be practical in the InfoEd system. We will not implement this change until the new fiscal year (new protocols coming in for July 2010.) As long as you use the number we have provided, there should be no problem.

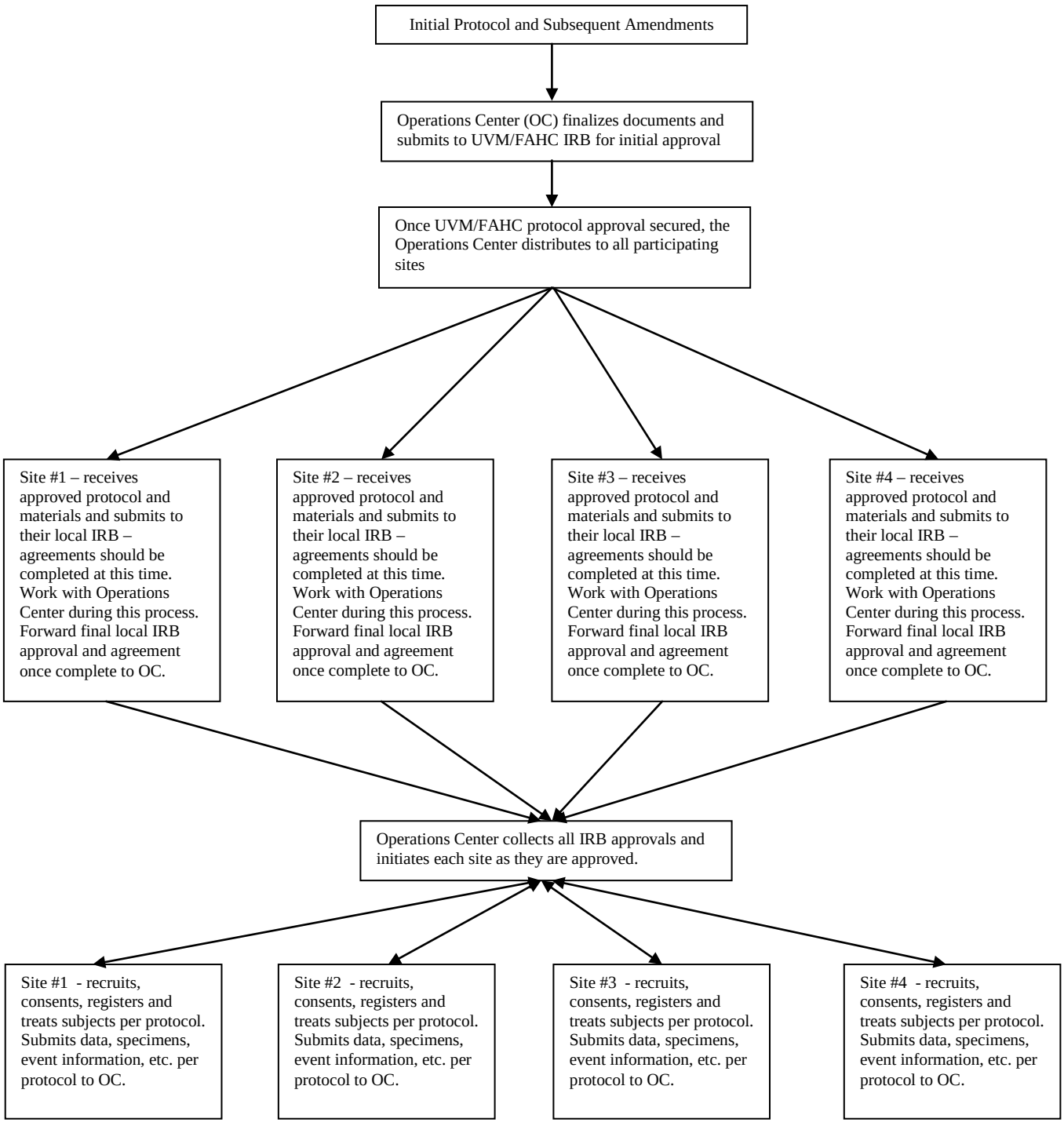
IRB Review of Cancer Center Protocols

Due to recent difficulties in tracking the review, approval, and sequence of different versions of Cancer Center protocols, the IRB has instituted the practice of requiring cancer-related protocols to have prior Protocol Review Committee (PRC) approval or approval pending clarifications that do not require additional full PRC review. In other words, if the protocol needs to go back to PRC for additional full committee review prior to approval and it is already on our agenda, that protocol will be removed from the IRB agenda until there is a PRC approved version of the protocol. The PRC meets one full week prior to the IRB and we expect this will eliminate IRB review of versions of the protocol that have already been deemed as needing significant changes.

Revision to IRB Policy Related to Multi-Institutional Studies under UVM/FAHC Leadership

The Committee is seeing increasing numbers of protocols in which a UVM/FAHC researcher has taken on the responsibility of the "Operations or Coordinating Center" in multi-institutional clinical trials. In these cases, the UVM/FAHC researcher is ultimately responsible for the conduct of trials at all participating sites. This requires that the UVM/FAHC researcher have processes and oversight mechanisms to ensure proper study management.

We have revised Section 13 of our research manual to assist researchers in knowing what their responsibilities are in this situation. Below is a high level flow chart. Please refer to the full policy to obtain details.



Review and Approval of Key Personnel Changes

Recent draft guidance from OHRP allows IRBs latitude in developing procedures for how certain materials are reviewed, such as designating individuals to review responsive materials from the investigators and to make determinations as to whether the IRB's conditions for approval have been met or to review minor administrative changes.

The guidance provides examples to illustrate the types of conditions IRBs may stipulate when approving research, as well as the type of individual designated to confirm conditions have been met. One example provided related to "credentialing" of the listed investigator(s). Credentialing often refers to the completion of the human subjects training requirements for all key personnel. Therefore, we have changed our operating procedures to allow qualified IRB administrative staff to review and sign off on key personnel changes.

This new process will relieve the IRB chairperson the task of reviewing and approving every change in key personnel for every active protocol. This will allow for a quicker response of such requests.

To accomplish this change in procedure, we have created a new Personnel Roster form. This form captures the list of key personnel working on your protocol. This new form needs to accompany the initial cover form and all subsequent continuing review submissions. Please utilize the footer within this form so that you and we are always working from the current version.

If you wish to add or delete a person, you must now submit the "Request for Key Personnel Change" form and attach the updated "Personnel Roster" form. You are no longer allowed to make changes to the list using the amendment form.

Some of you will recognize these forms, as last fall we successfully instituted this process change in both the IBC and IACUC Committees. Don't hesitate to contact our office if you have any questions.

Staff Changes

Please welcome RPO's newest addition, Laurel Nolet. Laurel now handles all the safety submissions in our office. She also comes to us with great experience in data management and data conversions. She will play an integral role in the data conversion and implementation of the Human Subjects module of InfoEd.

GINA

A new federal law, call the Genetic Information Nondiscrimination Act (GINA), makes it illegal for health insurance companies, group health plans, and most employers to discriminate based on a person's genetic information. It prohibits health insurers or health plan administrators from requesting or requiring genetic information of an individual or an individual's family members, or using such information for hiring, firing, or promotion decisions, and for any decisions regarding terms of employment.

Given that GINA has implications regarding the actual or perceived risks of genetic research and an individual's willingness to participate in such research, OHRP Guidance has indicated that investigators and IRBs should be aware of the protections provided by GINA as well as the limitations in the law's scope and effect. They note that IRBs should consider the provisions of GINA when assessing whether genetic research satisfies the criteria required for IRB approval of research, particularly whether the risks are minimized and reasonable in relation to anticipated benefits and whether there are adequate provisions in place to protect the privacy of subjects and maintain the confidentiality of their data. GINA is also relevant to informed consent. When investigators develop, and IRBs review, consent processes and documents for genetic research, they should consider whether and how the protections provided by GINA should be reflected in the consent document's description of risks and provisions for assuring the confidentiality of the data.

All health insurance companies and group health plans must follow this law by May 21, 2010. All employers with 15 or more employees should have been in compliance with this law as of November 21, 2009.

GINA does not protect persons against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. GINA also does not prohibit discrimination on the basis of an existing genetic disease or disorder.

GINA changes the criteria for IRB approval and the requirement for obtaining informed consent and therefore, the IRB has modified the common protocol cover form and the continuing review form to ask the PI a specific question about genetic materials. If genetic materials are collected, stored or analyzed, the consent form must include information about GINA. Refer to the IRB consent template document for the standard language.

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