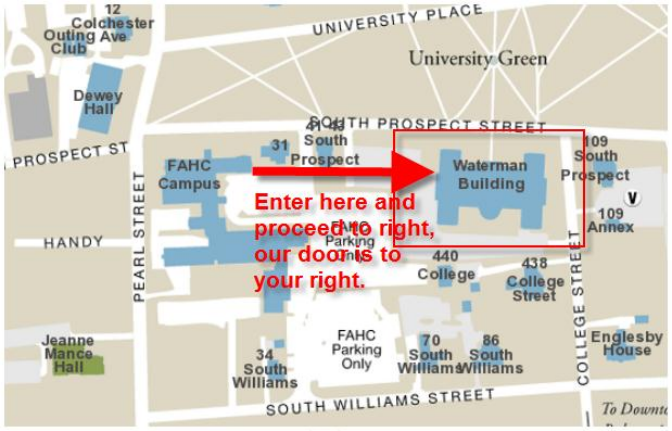
HUMAN SUBJECTS RESEARCH NEWSLETTER
COMMITTEES ON HUMAN RESEARCH
SERVING THE UNIVERSITY OF VERMONT
AND FLETCHER ALLEN HEALTH CARE
ISSUE 35, SUMMER 2011

Post Move Information

We have made it! 500 boxes and at least 30 rolls of tape later it would seem that we have landed. While we are physically in place, changes to our internal procedures and processes are minute to minute.

COLCHESTER

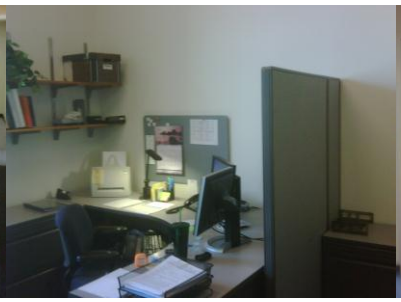
Our new office is in the Waterman Building. For those who do not know where we are now, please see the map below.



Our signage is forthcoming. You will enter through the door indicated, bear to your right and our door is to the right. A temporary sign is in place. Please call us at 656-5040 if you have problems finding the office. For those dropping off submissions or meeting with RPO research review administrators, please first check in with RPO front office staff which will be on your right after you have entered the office.

Please do not leave submissions with anyone other than our staff or the staff in the adjoining Sponsored Project Administration (SPA) office in room 217. This will help to avoid misplacement of submitted protocol paperwork. We are looking into whether we are permitted to place a secure drop box outside of our office for after hour submissions. We will keep you abreast of that decision.

WATERMAN – A work in progress!



REMINDER: FOR ALL NEW UVM AND FAHC PROTOCOL SUBMISSIONS (EFFECTIVE SINCE JULY 1, 2011)

As per our June 9, 2011 Special Notice, there is a new version of our protocol cover form posted on the Forms Page of our website that now includes a question asking if the proposed study will involve "any FAHC patients or any equipment, facilities, supplies or personnel of FAHC, whether standard of care or protocol-driven, such as laboratory, pharmacy, imaging, EKGs, or other diagnostic or therapeutic items or staff." If the answer to any part of the above question is "Yes," the FAHC Compliance Office must approve a "billing plan" designed to ensure compliance with hospital billing requirements prior to the release of IRB approval.

If you answer "yes" to this question, the IRB will notify the FAHC Compliance Department who will in turn be in touch with the Principal Investigator (PI) or Contact to determine what type of billing plan is required. **Submission of an electronic copy of the cover form to compliance@vtmednet.org at the time of IRB protocol submission will help facilitate this process.**

This applies to all new UVM and FAHC human subjects protocols. Failure to use the new version of the Common Protocol Cover form, which includes the new billing question, may result in delay of IRB review.

Please contact the Fletcher Allen Compliance Department at 847-7726 or compliance@vtmednet.org if you have any questions.

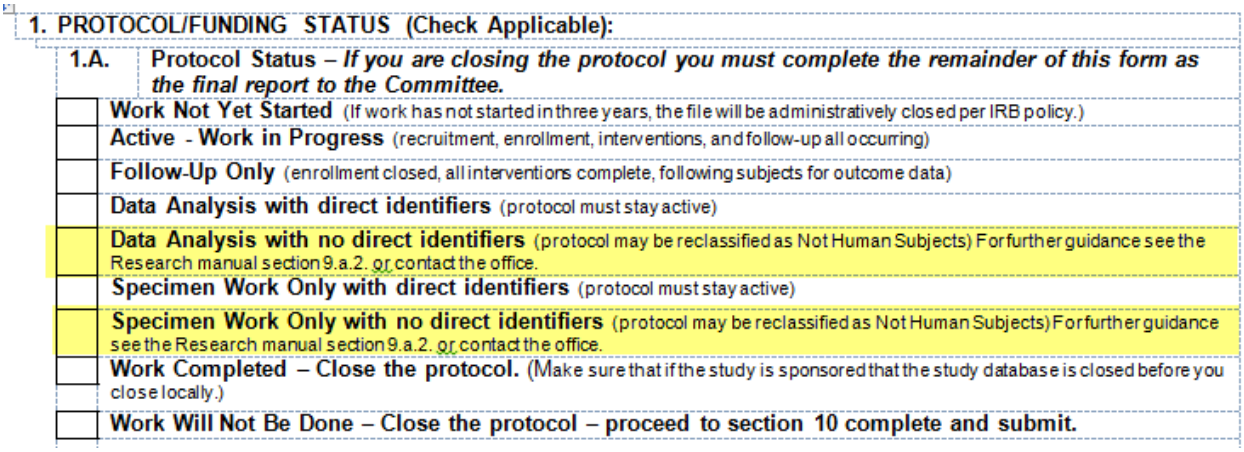
The Research Manual has been recently updated. Please link to the following page to see the summary of changes since the last version and the full manual.
http://www.uvm.edu/~irb/?Page=education/researchmanualintro.htm

Identifying the Point When Continuing Review is no Longer Necessary

Recent OHRP guidance has allowed us to change our policy regarding continued review of projects that no longer involves human subjects. See Section 9.a.2. in the updated Research Manual.

Once investigators have finished obtaining data through interaction or intervention with all subjects or obtaining identifiable private information about all the subjects, including the use, study, or analysis of identifiable private information the project may be reclassified as "Not Human Subjects" if identifiers are no longer associated. If the project can be reclassified as "Not Human Subjects" the research project no longer needs to undergo continuing review. For example, when the only remaining activity of a research project involves the analysis of aggregate data sets without individual subject identifiers, no further continuing review is necessary. Of note, only protocols which were initially approved with a waiver of consent can be reclassified, as consent forms contain identifiable information. If the IRB can formally change the protocol designation to "Not Human Subjects" for that project, the investigator will be notified and continuing review will no longer be necessary.

The IRB has added new status options on the continuing review form to assist in determining if the project meets "Not Human Subjects" criteria. **For clarity, only protocols that were initially approved with a waiver of consent can check either of the options that include "no direct identifiers". If a consent form was signed, there will always be identifiers.**



1. PROTOCOL/FUNDING STATUS (Check Applicable):

1.A. **Protocol Status – *If you are closing the protocol you must complete the remainder of this form as the final report to the Committee.***

- ☐ **Work Not Yet Started** (If work has not started in three years, the file will be administratively closed per IRB policy.)
- ☐ **Active - Work in Progress** (recruitment, enrollment, interventions, and follow-up all occurring)
- ☐ **Follow-Up Only** (enrollment closed, all interventions complete, following subjects for outcome data)
- ☐ **Data Analysis with direct identifiers** (protocol must stay active)
- ☐ **Data Analysis with no direct identifiers** (protocol may be reclassified as Not Human Subjects) For further guidance see the Research manual section 9.a.2. or contact the office.
- ☐ **Specimen Work Only with direct identifiers** (protocol must stay active)
- ☐ **Specimen Work Only with no direct identifiers** (protocol may be reclassified as Not Human Subjects) For further guidance see the Research manual section 9.a.2. or contact the office.
- ☐ **Work Completed – Close the protocol.** (Make sure that if the study is sponsored that the study database is closed before you close locally.)
- ☐ **Work Will Not Be Done – Close the protocol – proceed to section 10 complete and submit.**