The University of Vermont

THE University of Vermont MEDICAL CENTER

HUMAN SUBJECTS RESEARCH NEWSLETTER
COMMITTEES ON HUMAN RESEARCH
SERVING THE UNIVERSITY OF VERMONT
AND THE UNIVERSITY OF VERMONT MEDICAL CENTER
ISSUE 43, SPRING 2016

Change in Submission Deadlines

Beginning with the July 2016 CHRMS and CHRBSS meetings, the deadlines for submission of new protocols requiring full committee review will now be three weeks prior to the meeting date. This is to enable a more thorough pre-review of protocol submission materials.

As part of this new process, RPO staff will review incoming submissions to confirm that necessary documents are included and will correspond with the researchers or research staff to obtain any missing documents. Incomplete submissions will not be forwarded to the Committee for review. RPO staff may also ask for clarification if any inconsistencies or problems are noted during this pre-review.

As missing information can delay the Committee review and decision-making process, we expect this pre-review will result in a smoother and faster path for researchers to obtain final approval of their protocols. Additionally, we hope the pre-meeting review will enhance the reviews done by the Committees and thus the overall protection of the human subjects in our studies.

Please see our website for the revised submission deadlines.

New Health Records Review Protocol

In our winter newsletter we informed you that we were in the process of developing a specific form for record review projects that involve protected health information.

As noted previously, the HIPAA regulations that govern how protected health information (PHI) is obtained and used for research purposes are very prescriptive. The Research Protections Office has been meeting regularly with representatives from UVMMC Integrity and Compliance, the Jeffords Institute for Quality, and the IRB Policy & Procedure subcommittee, to refine our guidelines in keeping with the requirements of the HIPAA regulations and to reduce regulatory burden to investigators.

Health record reviews are typically not more than minimal risk and fall under the expedited review category #5 *(research materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis)*). As a result of our collaboration, we have revised the procedures and developed one comprehensive submission form to address all HIPAA and research records review needs of both UVM and UVMMC. We expect this will improve our ability to safeguard privacy while supporting better access to PHI for researchers.

The Health Records Review Protocol form is now on the forms page of our website. Please use this form when the **only** **"procedure"** is review of identifiable protected health information. If your research involves other procedures in addition to records review, please use another appropriate form. As part of your submission, you must provide documentation of permission/approval to access the data from the source/custodian. The same Health Records Review Protocol is to be used regardless of the source of the data. If the source of the data is the Jeffords Institute for Quality, you must obtain approval from that office prior to submission to the IRB, using the same form.

RPO has developed a specific continuing review form for records review research. Please use this new form for the continuing review of any of your ongoing projects involving health records review.

If you have any questions, please do not hesitate to contact the RPO at 656-5040 or email any of the contacts listed on Page 3 of this Newsletter.

News from the RPO Director

Nancy Stalnaker

RPO Redesign Initiative:

In 2013 the Research Protections Office (RPO) began a major process improvement initiative. The RPO Redesign, as we fondly call this initiative, is a collaborative and comprehensive process involving RPO staff and constituents. Our focus, and the lens through which we evaluate this project, is on the researcher community, the efficiency and accuracy with which we conduct and report on our work, the integrity of the research review process, welfare and safety, and staff development.

For over a year, we have focused on implementing change in key areas of our work. We have celebrated many successes to date, including:

- We tested and upgraded InfoEd to the version that will facilitate electronic submissions.
- We are making a number of process improvements within the IBC, including the development of an electronic form for the submission of protocols.
- In collaboration with the IRB, IACUC, and IBC, we are working toward implementation of a new research training system using an on-line platform by the Collaborative Institutional Training Initiative (CITI) Program, which will eventually replace the current required trainings for working with human subjects, working with laboratory animals, and laboratory biosafety.
- With the UVM Cancer Center, we implemented a process to respond to the September 2015 mandate to use the National Cancer Institute Central IRB for adult oncology group trials.

Currently we are focusing on improvements to our workflow and systems, including electronic submissions for IRB protocols. After a robust testing process, our goal is to pilot the electronic submission process in the fall of 2016. Stay tuned for more information on this topic within the coming weeks.

One of the many things we have learned throughout the RPO Redesign is that this process will never be complete. Our office and its operations will continually evolve, as regulations, best practices, resources, and technologies change. The RPO staff is a dedicated, smart, and capable group of professionals and so we have every confidence in the continued success of the RPO Redesign.

RPO Staffing Changes:

One of our major success stories over the past year is that we conducted a thorough evaluation of RPO staffing needs, organization structure, and position descriptions and made a number of significant improvements. These changes will facilitate more streamlined support to researchers across the protocol lifecycle, facilitate cross training among the staff, and promote staff growth and development. To that end, we are pleased to announce the following:

- Donna Silver's position has changed from Assistant Director to Assistant Director for Administrative Operations;
- Melanie Locher has been promoted to Assistant Director for Education and Monitoring;
- Nancy Heller, Gale Weld, and Abbey Peterson continue in their redesigned Research Review Analyst positions;
- Sarah Wright was promoted to and joins the Research Review Analyst team;
- Karin Crain and Sheila Beaulieu are our Research Review Assistants; and
- Caleb Cousins, Business Systems Analyst, and Lynn Tracy, IT Professional, continue in their positions.

News from the RPO Director (continued)

Leadership Changes:

CHRMS

After 20 years of dedicated service to the IRB, Deborah Rubin, MD, is stepping down as Chair of CHRMS. We are grateful for her leadership and the many contributions she made to the protection of our research participants during her tenure. We are very pleased to announce that, effective July 1st, the new members of the CHRMS leadership team joining IRB Executive Chair Alan Homans, MD, are David Kaminsky, MD, as IRB Chair and Alexandra Potter, PhD, as Associate Chair. David and Alexi are long-time, experienced IRB members and David has served as the Associate Chair of CHRMS for many years. We know they will both be great in their new roles and we are so fortunate that Alan has agreed to stay on in his committee leadership role.

CHRBSS

There will also be a change in the position of Associate Chair of CHRBSS, effective July 1, as Sara Barry, MPH, has taken an exciting new position outside of the University. We thank Sara for her outstanding contributions. We are grateful that Dr. Theodore Marcy will continue providing superb oversight of CHRBSS while we finalize additional leadership plans.

RPO

As many of you know, I will be retiring from UVM on June 30th. The national search for the next RPO director is well underway, so stay tuned for the forthcoming announcement. I am confident that a well-qualified person will be identified and that the entire RPO enterprise will continue doing excellent work in support of the welfare and safety of human and animal participants in research, the researchers, and the environment. I am grateful to have spent the past 25 years in this rewarding position and for the great fortune of working with so many outstanding staff, review committee members, committee leadership, researchers, faculty, administrators, and especially all of the extraordinary RPO staff members, both present and past. In case I don't have another chance to say this, it's been a privilege and I thank you all.

UVM Researcher Credentialing Reminder for FY17

Spring has arrived and with it an appropriate time to remind you about the UVM Researcher Credentialing Policy. This policy is in place to ensure that research staff will have the appropriate orientation, competency, and oversight before participating in research activities and is a regulatory requirement.

Please communicate with your UVM research faculty and staff that current UVM Medical Center ID research badges will expire **June 30, 2016**.

Information regarding UVM Researcher Credentialing can be found on the Office of Clinical Trials Research website.

For questions regarding the UVM Researcher Credentialing process please contact the Office of Clinical Trials Research at 656-8990 or clinicaltrials@med.uvm.edu.

RPO Form Updates:

- Health Record Review Protocol (new)
- Continuing Review for Health Record Review (new)
- Qualitative Protocol Form (revised)

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