



**HUMAN SUBJECTS RESEARCH NEWSLETTER**  
**COMMITTEES ON HUMAN RESEARCH**  
SERVING THE UNIVERSITY OF VERMONT  
AND THE UNIVERSITY OF VERMONT MEDICAL CENTER  
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**RPO Redesign Update: Who's My Analyst?**

As mentioned in our Spring 2016 newsletter, the RPO has been undergoing a redesign effort involving several initiatives to help reduce researcher burden and increase efficiency. Currently, we have analysts who specialize in types of reviews. For instance, one analyst works with continuing reviews while another works on initial submissions and yet another processes all amendments. This process is something that has evolved over the years as staff were added.

However, as part of the redesign effort, we have determined that assigning one analyst to handle all aspects of review for a single protocol versus assigning multiple analysts to handle different pieces of the review for a single protocol will be more efficient. To that end, we have assigned each analyst protocols based upon the protocol's department. We feel oversight by a single analyst will provide consistent service to researchers and allow the analysts to become proficient with all review types.

This change will occur as of March 1. We have created a [tool](#), located on our website, for coordinators and PIs to identify which analyst you will be working with going forward. We are very excited about this change and hope you find that it makes a difference in your day-to-day interactions with RPO.

**InfoEd: Update on Electronic Submission**

We are also very excited about the progress we have made within the last six months in preparing for roll out of the electronic protocol submission software, InfoEd.

1. August – December - The pilot phase was successfully completed. The 30 protocol contacts who participated in the pilot are submitting everything electronically for their respective PIs going forward.
2. November - In preparation for rollout, view access was provided to all researchers.
3. December/January - The chairs of our Committees are conducting electronic reviews of these same submissions.
4. January - The Committee meetings are now paperless.
5. February - Another 35-40 contacts (research coordinators/nurses) who are responsible for multiple protocols have been contacted to schedule group training. These protocol contacts are in the following departments: Cancer Center, Pulmonary, Surgery and Psychiatry.
6. February - Finalization of an InfoEd Resource webpage. This will include [FAQs](#), an ongoing weekly training schedule, and training videos.
7. March 1 – Open training to the remainder of community.
8. July 1 - Deadline date by which all researchers will be required to submit electronically.

**Single IRB for Multi-Site Research**

The Department of Health and Human Services, National Institutes of Health issued policy in July 2016 that requires by September 2017 that all institutions that receive NIH funding rely on a single IRB for cooperative research. Currently, the choice to have cooperative research reviewed by a single IRB is voluntary with the exception of reliance on the National Cancer Institute Central IRB (NCI CIRB) for cooperative group adult and pediatric research. We are using our experience with the NCI CIRB to prepare for this new NIH requirement. We will update you with any relevant news regarding this change. For a more detailed description of the new requirement, please follow this link to the official NIH policy <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-094.html>



## **Important Notice about NetIDs for Non-UVM Staff**

A UVM NetID and password is needed to log-in to required CITI training courses and to log into InfoEd to view or submit protocol materials. All UVM employees are issued a UVM NetID upon hire but there are many UVM (non-UVM) research key personnel who do not have a UVM NetID. A UVM NetID can be issued to UVM personnel for the purposes of human subject training registration and access to the InfoEd system through a special process. See the [FAQs](#) on our webpage about obtaining a UVM NetID and password.

We track approximately 2800 people through our training program of which 900 are UVM. During a recent audit, we found that many UVM people appear to be inactive and some UVM key personnel, after having been assigned a UVM NetID, neglected to follow through with their training and were never added to a protocol. To keep our database clean, we are placing a limit of 30 days after UVM NetID assignment to allow time for people to complete their training and be added to a protocol. We will also be deactivating UVM NetIDs for any persons who appear to be inactive. A UVM NetID can always be reactivated if necessary.

As with any password, you must reset the password that is associated with your UVM NetID on an annual basis. UVM does send a notice of impending expiration, however, this notice goes to a [uvm.edu](mailto:uvm.edu) address which most of you are probably not checking. To avoid password expiration should have your new UVM email forwarded to your preferred email address. For more information about email forwarding, visit the [TECHTE@M](#) site.

If you experience problems with logging into either CITI or InfoEd, it is likely that your password has expired. Please go to [uvm.edu/account](http://uvm.edu/account) for directions on how to reset your password. If you are still experiencing problems, contact [irb@uvm.edu](mailto:irb@uvm.edu) or call 656-5040.

## **Research Standard Operating Procedures**

The University of Vermont Medical Center and UVM College of Medicine have updated and implemented standard operating procedures related to the conduct of research. These procedures are available by logging in [here](#).

- Research 1 – *Clinical Research process at The University of Vermont Medical Center Inc.* – Updated SOP
- Research 2 – *Pre-FDA or FDA Inspection of Clinical Trials Preparation and Conduct* – New SOP
- Research 3 - *Informed Consent/HIPAA Authorization and Confidentiality Requirements at The University of Vermont Medical Center Inc.* – New SOP
- Research 4 - *Research Subject Enrollment Requirements at The University of Vermont Medical Center Inc.* – New SOP
- Research 5 – *Credentialing and On Boarding Procedures for UVM Clinical Research Employees* – Updated SOP

## **Research Manual Update**

### **Appendices Added:**

- Q. Noncompliance Policy and Procedures
- R. Electronic Signatures Policy
- S. Research Tissue Acquisition Policy

### **Other changes include:**

1. References to separate HIPAA authorizations (when applicable) were removed as HIPAA language is now being embedded into consent forms.
2. References to the old human subjects training tutorial were removed and replaced with “UVM and UVM Medical Center approved training” and links provided to resources and [FAQs](#)
3. The term “blood collection” replaced “blood drawing”.

## Changes to the Common Rule

The “Common Rule” established in 1991, was the first set of regulations developed to ensure compliance with the principles of the Belmont Report. The ethical principles of Respect of Persons, Beneficence and Justice became the basic ethical framework by which subsequent regulations were designed to ensure protection of human subjects in research. In September 2015, a Notice of Proposed Rulemaking (NPRM) published by the Department of Health and Human Services (DHHS) and other regulatory agencies, outlined proposed changes and revisions meant to strengthen and modernize the Common Rule regulations to better protect human subject participants in the ever-changing research environment. Another goal of these changes is to reduce administrative and regulatory burden.

On January 19<sup>th</sup>, 2017 the final rule was published in the Federal Register. However, as part of the new administration’s regulatory freeze, this final rule has been postponed for 60 days to allow for review. Whether the removal of proposed changes to non-identified biospecimens and resulting reduction in proposed costs will make this less of a target for elimination is unknown.

The final rule is effective January 19, 2018 with the exception of cooperative research (mandated single IRB review) for which the compliance date is January 20, 2020. The final rule differs from the NPRM in important ways. Visit the Federal Register to see a summary of differences as well as the full version of the Final Rule:

<https://www.federalregister.gov/documents/2017/01/19/2017-01058/federal-policy-for-the-protection-of-human-subjects>

The final rule makes the following significant changes:

- Establishes new requirements regarding the information that must be given to prospective research subjects as part of the informed consent process.
- Allows the use of broad consent (i.e., seeking prospective consent to unspecified future research) from a subject for storage, maintenance, and secondary research use of identifiable private information and identifiable biospecimens. Broad consent will be an optional alternative that an investigator may choose instead of, for example, conducting the research on nonidentified information and nonidentified biospecimens, having an institutional review board (IRB) waive the requirement for informed consent, or obtaining consent for a specific study.
- Establishes new exempt categories of research based on their risk profile. Under some of the new categories, exempt research would be required to undergo limited IRB review to ensure that there are adequate privacy safeguards for identifiable private information and identifiable biospecimens.
- Further relating to the use of single IRBs, the new rule creates the requirement for US based institutions engaged in cooperative research to use a single IRB for that portion of the research that takes place within the US, with certain exceptions. This requirement becomes effective 3 years after publication of the final rule.
- Removes the requirement to conduct continuing review of ongoing research for studies that undergo expedited review and for studies that originally underwent full review that have completed study interventions and are merely analyzing study data or involve only observational follow up in conjunction with standard clinical care.

Please do not begin to initiate any of these changes. We will wait for the regulatory freeze to pass before we begin our work to revise current procedures. Please stay tuned for updates.