Dear Researchers and Research Staff engaged in Human Subject’s Research,

In alignment with the recent National institutes of Health (NIH) issued policy, Policy on Good Clinical Practice Training for NIH Awardees Involved in NIH Funded Clinical Trials; NOT-OD-16-148, which states that NIH-funded investigators and staff are required to be trained in Good Clinical Practice, we will be requiring that all investigators and staff engaged in Human Subject’s research at UVM and the UVM Medical Center complete Good Clinical Practice training effective July 1, 2017.

This training requirement applies to all Investigators and staff who are involved in the conduct, oversight or management of clinical trials involving Human Subjects irrespective of fund source supporting the research activity. Researchers and their staff must be trained in Good Clinical Practice (GCP), consistent with principles of the International Conference on Harmonization (ICH) E6(R2).

Completion of GCP training will demonstrate that individuals have attained the fundamental knowledge of clinical trial quality standards for designing, conducting, recording and reporting trials that involve human research participants. GCP training should be refreshed at least every three years in order remain current with regulations, standards and guidelines. Recipients of GCP training are expected to retain documentation of their training.

The University of Vermont has contracted with the Collaborative Institutional Training Initiative (CITI) to provide online educational modules in the responsible conduct of research. GCP training is one of several free research training modules (including the UVM Protection of Human Subjects in Research Tutorial) available to our research community. These training resources can be accessed using the login and registration instructions below.

Additional information regarding GCP training, access to CITI training and FAQ’s can be found on the IRB website.
http://www.uvm.edu/irb/?Page=training_faqs.html

CITI Login and Registration Instructions
Instructions for participating in the CITI RCR training program follow.
To access the CITI online training courses:

1. Go to https://www.citiprogram.org/ Choose to "Log in via SSO" (single sign on) and scroll down to click on the link for the University of Vermont. Login with your UVM NetID and password.

2. Go through the registration process and choose the Good Clinical Practice Course, US FDA
3. The course allows users to save their work and come back to it later. It will take several hours to complete.

Courses that meet our institutional GCP Training requirement are:

**U.S. FDA Focus**
- GCP for Clinical Trials with Investigational Drugs and Medical Devices
- GCP FDA Refresher (The refresher should be taken every 3 years subsequent to the completion of the course above)

**ICH Focus**
- GCP for Clinical Trials with Investigational Drugs and Biologics
- GCP ICH Refresher (The refresher should be taken every 3 years subsequent to the completion of the course above)

As a Clinical Researcher, you are required to ensure that you and your research team are compliant with this institutional requirement.

The deadline for compliance with this requirement is July 1, 2017. The deadline for NIH Funded researchers and research staff was January 1, 2017.

After July 1, 2017, IRB approvals of new research will be held until all key personnel have complied with the requirement of having completed GCP training.

If you have questions or concerns regard this requirement or your responsibility as the PI for clinical research please contact the Office of Clinical Trials Research either by phone 656-8990 or email.

Thank you for your prompt attention to this requirement and upcoming deadline.

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