The University of Vermont

THE University of Vermont MEDICAL CENTER

HUMAN SUBJECTS RESEARCH NEWSLETTER
COMMITTEES ON HUMAN RESEARCH
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NIH Notice Regarding Clinical Trial Protocol Template

The National Institutes of Health (NIH) and Food and Drug Administration (FDA) have released a clinical trial protocol template with instructional and example text for NIH-funded investigators to use when writing protocols for phase 2 and 3 clinical trials that require Investigational New Drug application (IND) or Investigational Device Exemption (IDE) applications. In March 2016 a draft template was released for public comment generating nearly 200 comments from 60 respondents. All comments were carefully considered and many were incorporated into the final template. The agencies' goal is to encourage and make it easier for investigators to prepare clinical trial protocols that are organized consistently and that contain all of the information necessary for the review of the protocol. The template follows the International Conference on Harmonisation (ICH) E6 (R2) Good Clinical Practice and is available as a word document.

The NIH also released a secure web-based e-Protocol Writing Tool that allows investigators to generate a new protocol using the NIH-FDA Phase 2 and 3 IND/IDE Clinical Trial Protocol Template. The e-Protocol Writing Tool fosters protocol writing collaboration by allowing multiple writers and reviewers to participate in the protocol development process. The e-Protocol Writing Tool allows the author to assign writers and collaborators and the tool assists the author with tracking progress and document version control.

The NIH expects to expand the development of the e-Protocol Writing Tool by adding instructional text and sample text for other types of studies, such as a behavioral and Phase 1 trials. Future releases of this e-Protocol Writing Tool will have improvements and enhanced tool functionality.

Electronic Submissions Update

- Just a reminder that as of **July 1**, RPO will no longer accept paper submission. All submissions will need to be submitted through the InfoEd system. Training resources are available here for those who opted out of in-class training. If you have questions about the submission process please call the main line at 6-5040 or Lynn Tracy at 6-1333. If you have been submitting electronically and want to provide feedback, feel free to email us at irb@uvm.edu.
- Effective immediately, clean versions of consent forms are no longer required if you are submitting electronically. We ask that consent forms be submitted with Tracked Changes using Microsoft Word only.

Single IRB Update

NIH released a notice on June 16, 2017 indicating that they are extending the effective date for the policy on the use of a Single IRB. This new policy was set to take effect in September 2017 but has been moved to January 25, 2018.

Open Notes in MyHealth Online

Beginning June 15, the UVM Medical Center began sharing outpatient office visit notes written by health care providers with patients on MyHealth Online. Making visit notes easily available to patients supports efforts to be transparent and to provide patient- and family-centered care.

Researchers need to be aware that this new function may have unintended consequences for their research. Concerns include the potential for unblinding a research subject, the potential for creating misunderstandings for participants who read research notes (i.e. jargon or reference to specific protocol issues) and/or confidentiality issues for participants who are minors under the age of 12 years. (e.g. research related pregnancy testing results). Adolescent proxy access to My Health Online (typically for parents) is automatically withdrawn at age 12 (though 18) as there are a number of legal ramifications regarding that age range.

Open Notes does allow for researcher/research staff to choose not to share a note. This can be achieved by clicking the "share with patient" button to turn off the sharing and the note will not go to the patient/ subject's MyHealth Open Notes.

In some clinical research situations it may be necessary for the clinician to write two separate notes. One note is the clinical note and the second would be a separate Research Note that is a restricted note type that can only be seen by the research team.

These are things that researchers will need to be thinking about for current ongoing studies and for new research activities going forward.

For more information regarding Open Note and research, contact PRISM support for technical questions (prismsupport@uvmhealth.org) or Jim Wallace, MD (James.Wallace@uvmhealth.org) for other questions or concerns related to Open Notes.

UVM Researcher Credentialing Reminder for FY18

We are taking this opportunity 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 their current UVM Medical Center ID research badges expire on **June 30, 2017**.

Information research the research credentialing process is on the Office of Clinical Trials Research website, Credentialing Process.

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

Training Updates

Good Clinical Practice

Effective July 1, 2017, all investigators and staff engaged in Human Subject's research at UVM and the UVM Medical Center that fits the definition of a Clinical Trial will be required to complete Good Clinical Practice (GCP) training. Please see the Notice to Researchers dated 6/8/17. Additional information regarding GCP training, access to CITI training and FAQ's can be found on the IRB website here.

Certification Webpage

If "[No NetID Associated]" appears beside your name in the CITI Tutorial completion dropdown, it is likely that you did not log in through UVM when signing into CITI. For instructions on how to associate your NetID with your CITI training, CLICK HERE. Associating your NetID will help to ensure that you do not receive unnecessary reminders to complete the training.

RPO Staffing News

It's hard to believe, but the time has come. Nancy Heller is retiring! Her final day with us is July 31st. Nancy has been working for the Research Protections Office for 33 years. She was initially one of a 3- person team that helped to develop much of what each of us has come to know today as the IRB office. We will miss her wisdom and experience, but most of all, we will miss her friendship and the thoughtful way she has encouraged each of us over the years. Please join us in congratulating her!

As of June 1, Karen Crain, Research Review Assistant, was promoted to Research Analyst. This is a particularly exciting time for the IRB office and we feel very fortunate to have Karen step into this role. Please join us in congratulating Karen.

Research Manual Updates

Section 5- Addition of Good Clinical Practices training requirement for personnel working on Clinical Trial studies
Section 8.A.5. - updated information on sharing data with outside institutions
Section 8.A.6. - updated data that can be collected for a Health Record Review to include pathology slides or radiographic reviews
Section 10.B.3. - updated section on delegating informed consent tasks to key personnel
New Attachment T: Guidance for Researchers Using Deception or Incomplete Disclosure in Research

Miscellaneous Updates and Reminders

- When submitting documents electronically through InfoEd, it is required that you put the date at the end of the document name that you are submitting. The required format is mm/dd/yy.
- When submitting an amendment form, please remember to also submit a Tracked Changes version of your protocol with the proposed changes.
- Amendments should not be submitted for protocols not yet approved. Please wait until the protocol has been approved before amending.
- When preparing a submission of any type, please visit our forms library to obtain the latest version of the form you need. Our forms are updated frequently to capture information needed as processes change.
- We are revamping our website! It is not ready yet but changes are forthcoming and will include new pages pertaining to electronic submissions and other initiatives.