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 44, SUMMER 2016

Announcement about Research Flag Update in the Electronic Medical Record (PRISM)

Dear Colleagues,

Effective September 8, 2016, our organizations will begin populating the research protocol title in the Research Flag in PRISM.

The research status of patients who participate in research studies will continue to be displayed as "active" or "inactive" in the banner of their electronic medical record. By clicking on the Research flag hyperlink "active" or "inactive" in the patient banner, clinicians and researchers will open a window that includes information related to the study.

The new information visible beginning September 8 includes:

- the protocol title (unless a waiver has been approved)
- the NCT# and a hyperlink to clinical trials.gov (if the study is registered there)

Researchers who think it would be inappropriate to include the full protocol title in PRISM within the research flag can request a waiver from the Research Protections Office (RPO)/IRB when a new protocol is submitted. This is done via a new section in the common protocol cover form; requests will be considered during the RPO/IRB review process.

Researchers requesting a waiver for ongoing projects – and projects submitted but awaiting approval – will need to submit the "*Request to Waive the Requirement to Include the Full Study Title in PRISM* " form to the RPO/IRB.

For more information regarding the waiver process, please see the UVM Research Protections Office News .

For questions related to the waiver request please contact either

UVM Research Protections Office
(802) 656-5040 or IRB@uvm.edu

or

The Office of Clinical Trials Research
802-656-8990 or clinicaltrials@med.uvm.edu

Sincerely,

Gordon L. Jensen, M.D., Ph.D.
Senior Associate Dean for Research

Claude Deschamps, M.D.
President & CEO UVM Medical Group

Research Manual Update

Throughout the manual any references to a separate HIPAA authorization form have been removed as the HIPAA language must now be included within the consent document.

7.E. Projects Where the Only Procedure Involves Chart Review
This is a new section explaining the review categories and providing guidance on chart review projects.

8.A.6. Health Records Review Protocol
New protocol submission form for chart reviews.

Appendix P. Requirement to include a full Protocol Title in the Electronic Medical Record (PRISM)

Required Consent Template Changes

The IRB, in conjunction with the UVMMC Privacy Specialist, have been meeting on a regular basis to discuss compliance issues with HIPAA regulations. It has been determined that we could reduce researcher burden while improving compliance if we were to include the HIPAA authorization language within the consent form. The IRB Committees as well as legal counsel from both institutions have been consulted and are in agreement with this change in consent procedure.

The HIPAA required language has been reduced to what is minimally required and is now included in our consent template. There will no longer be a separate HIPAA Authorization form.

As of August 31, 2016, all new protocols where HIPAA is applicable, will be required to use this new consent template. Ongoing protocols that are still accruing participants, will be required to revise their consent forms at time of amendment or continuing review whichever comes first. Please note, if this change has not been completed by the time of the protocol's next continuing review, it will be required at that time as a contingency for continued approval.

We took this opportunity to include other minor changes to the consent template as well. We no longer require that you list the number of local subjects and we no longer require injury language from the sponsor's perspective. Neither of these are required elements and they provide no additional protections for the subject.