The University of Vermont

THE University of Vermont MEDICAL CENTER

HUMAN SUBJECTS RESEARCH NEWSLETTER
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Consent Form Development

HIPAA

Since September 1st the IRB has been requiring that HIPAA authorization language be incorporated into consent forms where HIPAA is applicable. This should be done for all ongoing protocols that are still accruing participants at the time of your next amendment or your next continuing review. The new process was developed to reduce researcher burden while improving compliance.

In an effort to clarify some confusion surrounding this new process, here is some information that will help you:

- 2 new templates can be found on our Consent and HIPAA Guidance page. One template should be used if you intend to review patients' PHI from UVMMC and the other should be used if you intend to review patients' PHI from LUSE Center at UVM.
- The language from the applicable template should simply be copied and pasted into your consent form and changes should only be made to the sections in red.
- It is important to remember that although this template language will be different from your last approved HIPAA authorization form, this new language has been approved by the IRB and legal counsel and it is required.

Once your amendment or continuing review has been approved, you will receive the newest version of your consent form, which will be stamped by our office and must be used going forward. Your previous consent form and separate HIPAA authorization form are no longer relevant and should therefore not be used. When submitting your new combined consent form for review to the IRB, please remember to submit a copy with tracked changes as well as a clean copy.

For those of you planning on submitting a new protocol where HIPAA is applicable, please use our consent template which includes the required HIPAA language that has been reduced to what is minimally required.

Injury and Compensation Language

A common mistakes we are seeing in consent forms are inclusion of injury language when it is not applicable. Just a reminder that injury language only needs to be added to protocols that are more than minimal risk and therefore can be removed for expedited protocols in the majority of cases. Additionally, compensation language does not need to be included if you are not offering participant compensation.

Sponsor Injury Language

As of September 1st we began asking that Sponsor injury language NOT be included in consent forms as it is often redundant and/or contradicts our locally required language. Our institution has agreed to provide medical care and/or appropriate treatment to subjects in the event they are injured due to participation in a study, regardless of funding. If we have a clinical trial agreement with a sponsor, our institution will then seek reimbursement from that sponsor per the agreement or the subject's insurer when applicable. Since the subject's costs will be covered, discussing the contractual details between UVM and the sponsor within the consent is unnecessary.

RPO Form Updates:

Request for Modification/Amendment to Approved Protocol (Revised)

Blood Draw Protocol Form is now Blood Collection Form (name revision)

Consent Form Template for Behavioral/Social Study (revised)

Please note that the Not Research Review Form is for Quality Assurance and Improvement/Program Evaluation and Public Health Projects.

To ensure you always have the latest version of a form, please upload forms directly from the forms library located on our website.

InfoEd: Electronic Submissions Update

Over the summer, RPO staff have been working with a pilot group of research coordinators to develop and test procedures necessary to support electronic protocol submission from the perspective of both the submitting researcher as well as RPO staff. We've successfully trained 34 individuals how to navigate InfoEd and submit electronic documents to our office using this system. We have received several different submission types from our pilot group including initial applications, amendments, continuing reviews, key personnel, safety, as well as researcher responses.

InfoEd has recently run a script that allows all PIs and key personnel view access. You will only be able to view protocol records in which you are listed as a PI or key personnel. The protocol records are limited to submission and approval dates at this time. You will not find protocol documents nor signed approvals at this time. We are working on scanning and loading each record with necessary protocol submission materials. Even though the records are incomplete at this time, you are welcome to sign in and start getting a feel for the system. To do so, sign in here using your UVM Net ID and password. We recommend that you bookmark this page for easy access. You are also welcome to view more information and instructions on our resource materials page here. Please remember **you do not have permission to submit anything electronically at this time.** Unless you have been part of our pilot group, your access has been strictly limited to view only. Stay tuned for further information on our progress and how it affects you.

We want to thank the pilot team and their departments for all their help!

Reminder

A friendly reminder that UAPs should be reported promptly to the IRB within 7 days. If all information is not available within 7 days, an initial report should be submitted with follow-up information as it becomes available.

Having trouble figuring out which form to submit?

We understand that it can be difficult to figure out which form(s) to fill out for your particular research project. RPO staff can help you navigate through the website and forms library when you have questions. Please call our office at 656-5040 and we'll point you in the right direction!