HUMAN SUBJECTS RESEARCH NEWSLETTER
COMMITTEES ON HUMAN RESEARCH
SERVING THE UNIVERSITY OF VERMONT
AND THE UNIVERSITY OF VERMONT MEDICAL CENTER
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IRB PROCEDURAL CHANGES:

1. CHANGE TO COMPENSATION FOR INJURY LANGUAGE

Effective immediately, new template language regarding research-related injuries has been adopted by the University of Vermont and the University of Vermont Medical Center. The consent forms for **all research protocols that are more than minimal risk involving physical interventions** must contain the new compensation language, **verbatim**.

See the FAQ's on our website for information regarding implementation of this required consent form language and the forms page for the consent form template.

2. NEW EXEMPTION CATEGORY POSSIBLE FOR STUDIES WITHOUT ANY FEDERAL FUNDING

In keeping with an internal operations review of the Research Protections Office, we have sought ways to streamline some of our less risky projects. We have reviewed the work of a national humans subjects research coalition looking at a more flexible approach to increasingly burdensome federal requirements, by finding simpler ways of reviewing studies, while maintaining compliance.

Our first initiative is to add a new exemption category for certain studies that have no federal funding and are not more than minimal risk. We have this ability to utilize this flexibility for non-federally supported research in accordance with the terms in our Federalwide Assurance for the Protection of Human Subjects. This flexibility is limited to studies with no federal funding that will involve no greater than minimal risk**.**

We will refer to this new category as "**Non-Federal Exemption #7**" and it will cover "research involving collection or study of **existing** data, documents, records, pathological specimens or diagnostic specimens, where this information is personally identifiable or coded." Currently this type of research is reviewed under the expedited review process and undergoes continuing review each year. This type of research falls into the minimal risk category. The only risk is a breach of any private information about an individual, we have determined that as long as the data are protected appropriately, there is no risk to the participant and no need for ongoing review of the activity.

As we are reviewing new submissions, we will keep in mind this new exemption criteria. If we determine that Exemption #7 fits the research activities, then we will certify the project as exempt and notify you. There will be no need for additional continuing reviews. We will also be re-evaluating the continuing reviews as they are submitted. If we find that the initial scope of activities fits this new exemption, we will administratively change the determination to exempt and notify you. You will no longer be required to submit continuing review reports.

This first flexibility initiative will greatly reduce burden for both the investigator and the IRB staff. Be on the lookout for the next initiative!

Research Engagement Determinations: Is UVM or UVM Medical Center engaged?

An institution is considered engaged in human research when employees or agents for the purposes of the nonexempt research project, obtains: (1) data about the subjects of the research through intervention or interaction with them; (2) identifiable private information about the subjects of the research; or (3) the informed consent of human subjects for the research. An institution is also considered engaged when the institution receives a direct federal award to conduct human subject research, even when all activities involving human subjects are carried out by a subcontractor.

Researchers may utilize the new Engagement Determination checklist located on our forms page to assist them with this determination. It is not a requirement that this determination be made by the IRB, however we can review and acknowledge your determination.

See Appendix J in our Research Manual for additional guidance.

Submission Requirement Reminders

Our forms page tells you how many copies of each form that is required. These submissions are forwarded to the Committee reviewers, so we want to make sure that what they need to review is clear to them.

Please collate the paperwork in the following way:

- Staple the protocol cover forms to the consent forms.
- Staple or clip the protocol
- Staple or clip the Investigational Drug or Device Brochure

Remember if you have determined that your submission falls under expedited review, the full meeting deadline and the multiple copies of materials does not apply. For expedited review submit one copy.

Partial Waiver for Recruitment Clarification

The RPO staff has noticed that there is some confusion on the appropriate use of this form.

This form should only be submitted if you intend to review patient's protected health information for the purposes of research when you do not have a current clinical relationship with the patient.

The requirement does not apply to health care providers or their agents. An agent is defined as an individual who is under the direct supervision and control of the provider engaged in the recruitment activity or under the direct supervision and control of a member of the provider's immediate practice group or coverage group. **Research staff are considered agents.**

Therefore, a partial waiver request is not necessary for research staff who review medical information to identify a patient for potential inclusion in a trial.

Fee Policy Revision

The IRB Fee policy has been recently revised to clarify which protocols are charged IRB fees as well as which institution is responsible for the budget and contract negotiations with those sponsors.

For **industry-initiated** projects, the University of Vermont Medical Center Office of Clinical Trials Research (OCTR) works with sponsors to include the IRB fees in project budgets during the proposal and award negotiation processes.

For **investigator-initiated, industry sponsored** projects, OCTR works with UVM Sponsored Project Administration (SPA) to include the IRB fees in project budgets. OCTR identifies IRB fees and protocol start up fees as separate line items in a budget.

The Institutional Affiliation Agreement clearly outlines these responsibilities, therefore researchers are not able to choose the office they work with on these sponsored projects. Please see Attachment C of our Research Manual for the revised policy. If you are still unsure whether your research is billable or who should be managing the negotiations please don't hesitate to contact our office.

Staffing Announcement

Please welcome Jesse Macomber, Research Administrator to our IRB team. Jesse joins us from Boston University School of Medicine where she was a research coordinator and from Pfizer where she was an Associate Scientist. She is a wonderful addition to our team.

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