HUMAN SUBJECTS RESEARCH NEWSLETTER
COMMITTEES ON HUMAN RESEARCH
SERVING THE UNIVERSITY OF VERMONT
AND FLETCHER ALLEN HEALTH CARE
ISSUE 28, WINTER 2009

Change to Procedures for Committee Review of Resubmissions/Revised Grant Applications

The RPO and the Pre-Award Services unit of the Office of Sponsored Programs are working closely to meet our obligations for regulatory review of sponsored research projects. Specifically, regulations require that the IACUC or IRB verification of approval to a funding agency constitute approval of the information submitted in the application/proposal, or include notification of any significant changes required by the Committee. We are also required, as a condition for NIH funding, to ensure that recombinant DNA research comply with the *NIH Guidelines*.

We have encountered many challenges in our efforts to match each grant application to a specific protocol. This has been particularly challenging for revised, resubmitted applications. In an effort to reduce the amount of paperwork required to match these protocols – both for OSP staff and for investigators – we have developed a new process that will **no longer require** a new protocol submission for a grant resubmission provided it is substantively similar to a previously approved protocol. We will require only a protocol amendment to add the additional grant application and when applicable, a description of any associated minor changes to the protocol file. Although this mostly pertains to NIH grant applications, this may also apply to other funding sources.

The new process for submission of protocols to RPO Committees that correspond to resubmission of grant applications is as follows.

Each new grant application and/or renewal to continue (competing renewals) will continue to require a new protocol for review.

Supplements and resubmissions will now require only completion of an amendment to the previously approved protocol if they are substantively similar to the original submission. We have modified each of our amendment forms to provide review of the resubmitted grant and describe any associated minor changes to the grant and protocol. **Thus, for supplements and grant resubmissions for substantively similar projects, PIs will no longer need to submit a full protocol and new cover form for review – only an amendment!**

These changes are outlined in the chart below.

Old NIH Term	New Grants.gov Term	Old Committee Requirement	New Committee Requirement
New	New	New protocol	New protocol
Competing Continuation	Renewal	New protocol	New protocol
Competing Supplement	Revision	New protocol	Amendment
Revision or Amended Application	Resubmission	New protocol	Amendment (if substantively similar)
Progress Report	Continuation	Nothing Required	Nothing Required

Updating the Information Provided to a Research Subject Utilizing the Consent Form Addendum

Over the course of a subject's participation in a research trial it is necessary to keep the research subject informed of any changes in the research, in particular, any changes to the risk/benefit profile which may influence their continued participation. There are two different ways to handle this exchange of information.

Utilizing an informed consent addendum is one way to exchange new information. The consent addendum method requires the subject to sign consent to continue participation.

The consent addendum includes only the new information. Since changes can range from being as simple as a phone number correction to a major change in the risks, we have found that this method more effectively presents just the new information which helps to reduce subject confusion. The subjects are requested to sign the consent addendum in much the same way as the original consent document. Signature indicates their willingness to continue participation in the study given the new information. The subject is provided a copy of the fully signed consent addendum and the original addendum is placed with the originally signed consent document. If there are multiple consent addendums the same process is used each time.

There is an addendum template located on our submission page under templates. Addendum consents require IRB review and approval and must have an IRB stamp with an expiration date to be valid.

The other way to accomplish this exchange is to revise the entire consent form.

Note: The IRB's prefer that a consent addendum be used instead of requesting that the subject sign a full revised consent form again as this often causes confusion for the research subject. If sponsors are requesting that a full consent be signed each time an amendment is made, the sponsor must provide in writing to the IRB justification for why an addendum is not sufficient.

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SPONSOR DOCUMENTATION - WHAT DO THEY WANT?

The IRB has a template assurance document that is used to indicate approval of your protocol. This assurance (approval) covers not only the protocol but all materials that were part of the initial submission (e.g., consent, flyers, questionnaires, diaries, etc). There is a section at the end of our cover form that allows you to document what was part of the initial submission.

Sponsors, however, continue to request separate documentation from the IRB of approval of these "other" materials.

We would prefer not to have to create additional or different documentation for every sponsor for this purpose. To that end, please ask the sponsor prior to submission what they require documentation for and note that specifically as part of your submission materials. This will allow us to create the assurance to include a list of the materials they need approval documentation for.

Thank you for your assistance with this process.

PRIMARY CONTACTS

The IRB requires a contact person be named on the initial Protocol Cover Form and each subsequent review.

The contact person that you list can be contacted with any number of questions (e.g., form corrections, missing information, invoicing, contract status). When you choose the contact for each protocol it is important that this person have the resources available to them to respond to IRB inquires. It is also very important that this person's information as presented on the form is correct each time it is submitted. If this is not correct your research may be delayed awaiting a response.

MEETING SCHEDULE 2009

MEDICAL SCIENCES	
MEETING DATE	**SUBMISSION DEADLINES**
March 18	March 4
April 15	April 1
BEHAVIORAL SCIENCES	
March 11	February 25
April 08	March 25