HUMAN SUBJECTS RESEARCH NEWSLETTER
COMMITTEES ON HUMAN RESEARCH
SERVING THE UNIVERSITY OF VERMONT
AND FLETCHER ALLEN HEALTH CARE
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CHANGES TO TRAINING GRANT INTERNAL REVIEW PROCESS

In the past, the RPO Committees (IACUC, IBC, IRBs) have given a single certification of approval for institutional training grants that were awarded to UVM through a process we called "administrative review." This process was based on the requirement of certain federal sponsor for a single certification that all the individual research protocols named in the institutional training grant application had been reviewed and approved by the appropriate committee. Over the years, we have found that this certification is no longer required.

The research that trainees are involved in changes over the life of a project and any approval is only a "snapshot" in time. What is important to the funding agency is the institution provides assurance that all projects that a trainee will work on have been appropriately reviewed and approved. This assurance does not need to be in the form of a single IRB or IACUC certification of approval.

Because this administrative review activity is no longer necessary we are phasing out single protocols associated with institutional training grants. We will notify individual investigators that they will no longer be required to complete and submit continuing review paperwork and the files will be closed.

Principal investigators of training grants, however, are still required to provide the funding agency with a list of the projects and approval dates that trainees are working on with their annual progress report. The Research Protections Office can assist you with obtaining protocol approval information if you submit a list of protocols as follows for our completion:

CHRMS CHRBS IACUC IBC Numbers	PI	Protocol Title	Committee Approval Date (completed by RPO)

Please call (656-5040) or email (rpo@uvm.edu) the Research Protections Office if you have any questions about this change.

DSMPs vs DSMBs: Battle of the Acronyms

Did you know there is a difference between a "DSMP" and a "DSMB"? A data and safety monitoring plan (DSMP) is a general term meaning a proposal to protect participant safety and data. DSMPs can contain a variety of measures to address data quality and confidentiality, safety monitoring (of adverse events, new information, risk/benefit ratio), adverse event reporting plans, and (when appropriate) the inclusion of a data and safety monitoring board (DSMB). A DSMB is a set of individuals whose task is to evaluate study design and data in order to monitor the safety of the subjects and determine if a study needs to stop. DSMB members should be independent from the direct management of the research and not have conflicts of interest. Boards are generally made up of experts knowledgeable in the specific field, in clinical research, and/or in biostatistics. Whether a study needs a DSMB is based on a variety of factors— study risk, study population, design (double-blinded, etc.) size, and complexity.

It is important to note that all studies require a DSMP, but only some kinds of studies require a DSMB (board). (From Mount Sinai Medical Center Program for the Protection of Human Subjects E-Newsletter.)

Meeting Schedule 2008

Medical Sciences	
Meeting Date	**Submission Deadlines**
10/15	10/01
11/19	11/05
12/17	12/03
Behavioral Sciences	
10/08	09/24
11/12	10/29
12/10	11/26

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Case Studies & the IRB

The IRB has defined a case study as a retrospective analysis of one, two or three clinical cases. Publishing retrospective case studies does not constitute research, and therefore, does not require prior IRB review and approval. However, investigators need to keep in mind that if there are any individual identifiers associated with the protected health information to which HIPAA applies, patients may need to provide authorization for use of their data. You may use the FAHC Authorization template for this non-research purpose but its' use does not require IRB review.

If your "Case Study" is prospective and includes a hypothesis, methods/procedures, analysis and/or an outcome, you're probably conducting research. In these cases you would need to obtain prior IRB approval.

If you have any questions about whether your case study requires IRB review, contact the staff at the RPO office.

IRB Invoicing

We are receiving requests from research coordinators to modify our invoices to meet the sponsors' needs. We are willing to modify and reissue invoices, however we need to be provided with enough information to apply the requested changes to the appropriate protocol invoice. The PI name and sponsor name is not enough.

If the sponsor requests a new invoice, please provide the following:

- CHRMS or CHRBS number,
- PI name,
- protocol title,
- identify whether the invoice was for initial or a continuing review, and
- provide the correct contact person name and their email address.

This information enables us to find the appropriate invoice, make the changes and reissue in a timely fashion.