



HUMAN SUBJECTS RESEARCH NEWSLETTER COMMITTEES ON HUMAN RESEARCH

SERVING THE UNIVERSITY OF VERMONT
AND FLETCHER ALLEN HEALTH CARE
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HAPPY NEW YEAR

We will continue to use this medium to get important information and feedback to you, the users. Feel free to review our past newsletters for quick updates at

[HTTP://WWW.UVM.EDU/~IRB/?PAGE=EDUCATION/NEWSLETTER.HTM](http://www.uvm.edu/~irb/?PAGE=EDUCATION/NEWSLETTER.HTM).

Upon reflection over the last year we want to take this opportunity to review some submission pointers.

- Always use the most current version of the form by going to our forms webpage each time you need to submit anything.
- Complete all questions on the forms. Do not leave fields blank. If it doesn't apply put in NA. If you have a question, please contact our office. We would rather field your calls then receive incomplete or inaccurate information. The calls provide an opportunity for us to obtain feedback on the way our forms are functioning e.g. are we asking the question in the right way?
- Pay attention to timelines. If we send you a continuing review form that means your protocol is about to expire. Work on getting that in to us as soon as possible so your work will not be interrupted.
- Request that your sponsors submit their contracts to OCTR as early as possible to avoid delays in the release of your protocol approval.

CONSENT WAIVERS

The definition of waiver is: the act of intentionally relinquishing or abandoning a known right, claim, or privilege; *also*: the legal instrument evidencing such an act.

There are two types of waiver as follows:

- Waiver of Informed Consent
- Waiver of Documentation of Consent

Waiver of Informed Consent is just that, subjects are not given the opportunity to provide written or verbal consent. These subjects would be included in the research without their knowledge. It is very infrequent that a Waiver of Informed Consent is approved and the criteria to obtain such a waiver are very strict. The risk to the subject would have to be minimal. An example might be retrospective chart reviews when no identifiable information is recorded.

Waiver of Documentation of Consent is different in that subjects provide their informed consent, just not in written form. Verbal or implied consent are utilized in these situations. Again criteria for a Waiver of Documentation would be research that is either very minimal risk or the only risk would be the consent document itself tying the subject to the research thus creating a potential for breach of confidentiality. An example would be research that involves only administration of a questionnaire. After explanation of the research project, the subject can choose to complete the questionnaire or not. Completion implies consent to participate.

Additional information can be found in our research manual and the Summer 2006 newsletter.

AMENDMENTS

We realize that many of you download our amendment form and use it repeatedly for a particular protocol and submit amendments as necessary over the life of the protocol. While this practice makes sense, it is leading to some errors in data that we need to bring your attention to. Notice below the highlighted area

COMMITTEES ON HUMAN RESEARCH
REQUEST FOR MODIFICATION/AMENDMENT TO APPROVED PROTOCOL

Study modifications may not be instituted until you have received written approval from the Committee. Form completion instructions are on the web site. If this is a General Clinical Research Center and/or Vermont Cancer Center study you must submit to their respective committees for review as well.

1. CHRMS <input type="checkbox"/> CHRBS <input type="checkbox"/> #:	Principal Investigator (PI):
Protocol/Project Title:	
Sponsor's	
2. Sponsor Study #:	Amendment Number:
	Date of Protocol Amendment:
	Date of Consent Version (if applicable):
3. Modifications and Justifications	

We are finding that these fields are not being updated with each new amendment. This error requires some back and forth with the person submitting it to identify the correct information. This wastes valuable time on both ends.

Please, if you wish to download and use the form in this fashion, make sure that you are revising these two fields each time you are submitting a new amendment. Thank you.

**Please Note on our Forms Page that All
Three Initial Submission Forms Have Been
Revised.**

NEW IRB STAFF

Please welcome Linda Warner. Linda joined us this fall as an IRB Assistant Review Administrator and is pre-reviewing all new submissions to help prepare the paperwork for a smoother review. Don't be surprised if you get an email from her asking for clarifications or training completions.

This Newsletter is a publication of the Committees on Human Research at the University of Vermont and Fletcher Allen Health Care.

Editor: Donna.Silver@uvm.edu

Web Site: <http://www.uvm.edu/irb>

Newsletters archive:

<http://www.uvm.edu/~irb/?Page=education/newsletter.htm>

****IMPORTANT****

CLINICAL TRIALS REGISTRATION: WHAT YOU NEED TO KNOW!

There are two different clinical trial registry mandates:

- 1) International Committee of Medical Journal Editors (ICMJE)
 - Required as a **condition for publication** of trial results
 - Clinical research studies must be entered in a public registry before any subject enrollment
 - See definition of clinical trial in the link below
- 2) FDA
 - Enacted as **law with penalties**
 - See link below for types of trials requiring registration and timing of registration
 - Types of trials have recently expanded and number of data elements increased

**Where should a clinical trial be registered?
Who is responsible? What is the process for
registering a clinical trial? Who do I call if I
have questions?**

All of the questions listed above are answered in the document entitled:

"Clinical Trials Registration Information"
which can be found on the front page of our [website](#).

MEETING SCHEDULE 2008

MEDICAL SCIENCES	
MEETING DATE	SUBMISSION DEADLINES
02/20/08	02/06/08
03/19/08	03/05/08
04/16/08	04/02/08
05/21/08	05/07/08
BEHAVIORAL SCIENCES	
02/13/08	01/30/08
03/12/08	02/27/08
04/09/08	03/26/08
05/14/08	04/30/08