



HUMAN SUBJECTS RESEARCH NEWSLETTER COMMITTEES ON HUMAN RESEARCH

SERVING THE UNIVERSITY OF VERMONT
AND FLETCHER ALLEN HEALTH CARE
ISSUE 26, SPRING 2008



To NIH Funded Researchers/Authors:

NIH has released a new policy, entitled the NIH Public Access Policy. **This policy became effective April 7, 2008, and applies to articles arising from grants active from October 1, 2007.** Under this new federal law NIH requires that the final version of any peer reviewed journal article resulting from NIH-funded activities be submitted to the PubMed Central (PMC) repository where it will be made available to the public within 12 months after the article is published.

The new policy has three main compliance issues which UVM authors must address: **(1)** Copyright, **(2)** manuscript submission to PMC, and **(3)** citing PMC ID numbers. Failure to comply with the policy may jeopardize your eligibility for future funding.

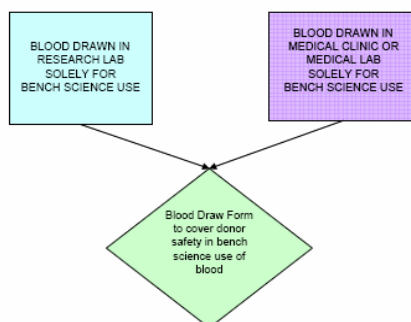
For more information on this new requirement, go to the [Office of Sponsored Programs Website](#).

NEW BLOOD DRAWING PROTOCOL

All blood drawn for research purposes must be done with an IRB approved research protocol. Until now, investigators have been submitting the Common Protocol Cover form and creating a protocol for submission. If the only procedure involves the collection of blood, researchers may now use the new "Blood Drawing Protocol..." form in lieu of the Common Protocol Cover and a protocol. Please refer to our [website](#) for this form, a sample consent and guidance on handling blood.

BLOOD DRAWING PROTOCOLS FOR BLOOD/CELL USE IN BENCH SCIENCE PROJECTS (NON-CLINICAL, NON-TREATMENT)

FOR USE ONLY WHEN **NO** OTHER HUMAN SUBJECT PROCEDURES ARE INVOLVED



NOTES:

1. If any other human subjects procedures are to be used, do **NOT** USE THIS FORM!!
You should complete a Common Protocol Cover Sheet and any other applicable IRB form.
2. The use of the blood in the laboratory may require Institutional Biosafety Committee (IBC) approval. This form only covers the collection of the blood.

CHANGES TO RESEARCH SUBJECT PAYMENTS UVM

Research subjects who are eligible for reimbursement from the research study are required to provide personal information such as name, address and social security number. This information along with the study name is forwarded to [Procurement Services](#).

The practice to date has been to collect this same information each time they were due for a payment. This practice has been identified as risky to the subjects and therefore is being revised. At the first visit the all the information noted above will be collected. Going forward, the subject name, address and only the last four digits of the social security number will be collected. This change in practice will reduce the risk to subjects while still enabling payment.

FAHC

The process for paying research subjects is virtually the same as above. The only difference is that FAHC assigns a unique ID upon the first payment visit and uses that ID going forward to reimburse subjects.

In both cases all correspondence should be sealed in an envelope and marked confidential.

CONTINUED APPROVAL POLICY FOR INACTIVE PROTOCOLS: (approved 10/17/07)

In order to resolve the issue of indefinitely reviewing and re-approving protocols annually for which work has not ever been started, the IRB voted to approve the following policy:

If the work on a research protocol has not yet begun after a three-year period, the protocol will be closed. A new protocol must be submitted for review at the point in time when activity is anticipated to begin. Exceptions may be made if the funding period exceeds three years and the human subjects' protocol is not scheduled to begin until after that time period. You must indicate that that is the case on your continuing review form.

This policy does not apply to protocols that have been and plan to remain open to accrual but have just not had any enrollment to date, such as many of the oncology group protocols that are approved for rare tumors. For that situation, the category "active - work in progress" should be checked on the continuing review form.

The majority of protocols that we have been reviewing and re-approving for many successive years actually never get started. If the work was to begin many years after submission, the original forms and protocol would likely be outdated and it would be beneficial for the protection of human subjects to give the project a new review.

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>

CLOSING PROTOCOLS

Before closing a protocol

- enrollment must be complete,
- all subjects must have completed study interventions with all data collected, and
- the study data analysis (at least locally but sometimes nationally) must be complete.

If the above-criteria are met for non-funded studies, the study can be closed with an amendment form. Make sure that you include a final report as requested on the form.

If the above-criteria are met for billable studies, in addition to the above, make sure that any outstanding invoices have been paid. We cannot close out the study until any outstanding payments are received.

We have been finding that some researchers are closing their studies prematurely using the amendment form. This happens primarily in studies that are industry-sponsored. Sponsors typically require that studies remain open with the IRB until they have completed their close-out site visit with the researcher, in some cases longer if study data is still being collected at other sites.

When a study is closed prematurely, depending upon when the error is discovered, the IRB may need to conduct a continuing review to begin the cycle of review again. This would generate an additional continuing review invoice. To avoid the extra cost and work, you should check with the sponsor before submitting an amendment to close the study.

MEETING SCHEDULE 2008

MEDICAL SCIENCES	
MEETING DATE	SUBMISSION DEADLINES
6/18/08	6/4/08
7/16/08	7/2/08
8/20/08	8/6/08
BEHAVIORAL SCIENCES	
6/11/08	5/28/08
*7/9/08	6/28/08
*8/13/08	7/30/08
* The summer meetings will be held only if necessary. Check with the Committee office.	