



HUMAN SUBJECTS RESEARCH NEWSLETTER COMMITTEES ON HUMAN RESEARCH

SERVING THE UNIVERSITY OF VERMONT
AND FLETCHER ALLEN HEALTH CARE
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IRB Fee Changes to Industry Sponsored Research Effective July 1, 2009

Two major IRB fee changes will be implemented on July 1, 2009.

First, after review of the current IRB fee schedule for industry-sponsored research, the IRB review fees will increase as follows:

Initial Review: \$2000 to \$2500 per review

Continuing Review Fee: \$1000 to \$1500 per review

These are very challenging economic times. It has been two years since we have adjusted our fee schedule, and like most enterprises, our costs have been rising. Although is a national trend towards charging incremental IRB fees for additional IRB services, such as the review of **each** amendment, consent form change, advertisement, final report, serious adverse event, and Drug/Device Brochure Update, we believe that by raising the current review fees our expenses for all of these services will be covered and that payment of our current simple fee structure will be less burdensome for all involved than processing invoices for each of these individual services.

The Office of Clinical Trials Research (OCTR) will include this fee increase in contracts that are currently under negotiation. For previously approved contracts, PIs should contact OCTR to assist in any renegotiation that is required. **This change in the fee schedule will apply to all new industry-sponsored protocols to be reviewed after July 1, 2009 and all ongoing trials that will undergo continuing review by the IRB after July 1, 2009.**

The second major change is that FAHC will be taking over the IRB fee invoicing function through their Financial Edge accounting software. The IRB fees will be paid from the researchers' clinical trial accounts at the time the sponsor is invoiced. Protocol approvals will no longer be withheld pending receipt of sponsors' payment of these fees.

Change to Adverse Event/Unanticipated Problems Reporting Policy and Procedures

The IRB has made a change to the current policy regarding reporting of adverse events in order to allow for an increased level of reporting in clinical trials that are deemed to be higher risk. The current requirement is for reporting all **local adverse events** whether serious or not serious, that are unexpected **AND** possibly, probably, or definitely related to study participation. The new change would be the addition of the following:

The IRB may categorize a protocol as "higher risk" and require the Investigator to report **all** local adverse events promptly to the IRB, **regardless of whether the event is related or expected.**

The IRB has determined that a higher level of reporting may be desirable in certain situations. Examples of clinical trials for which the IRB may institute more stringent reporting are: local, investigator-initiated early phase (Phase I, Phase I/II) study; local, investigator-initiated trial in extremely vulnerable populations, e.g., very sick patients, subjects unable to consent for themselves, prisoners.

When the IRB finds a clinical trial to fall into this "higher risk" category, the investigator will be required to promptly submit all adverse events. The IRB made this decision based on the opinion that adverse events in "higher risk" studies, such as early phase trials, by their very nature cannot be initially determined with absolute certainty to be unrelated, and the determination of whether they are expected may need a higher level of reporting to determine if the event is occurring at a higher than anticipated rate. Thus all events must be promptly reported on an ongoing basis.

The IRB will usually make this determination of "higher risk" at the time of initial review and will clearly communicate this requirement at the time of approval. However, the IRB may also make this determination at any later point in time, either in conjunction with a continuing review, an amendment, or as a result of an adverse event report.

Biological Specimens/Data Repositories – Review is Required

The use and control of human tissue and medical charts for research is governed and restricted by federal and state laws and local regulations to ensure human protection measures are adequate. In the past tissue registries, tissue banks, pathology archives, research waste materials, hospital and clinic charts, and other databases have often been accessible to medical researchers. Often this “tissue” material was acquired from human subjects (living persons and fetuses) for non-research purposes such as diagnosis, medical therapy, public health control, quality assurance and transfusion/transplantation therapy. Researchers were often permitted access to these materials without adequate human protection mechanisms in place. More recently, human protection standards on use of tissue material have become more stringent and less trivial based on newly identified issues such as medical/legal privacy acts, HIV status, genetic confidentiality issues, religious and ethical beliefs, fetal restrictions, and other issues. The days of free access to personal data and tissues by researchers without subject consent have passed.

Operation of a specimen/data repository is now subject to oversight by the committee. The committee will review and approve a protocol specifying the conditions under which sample collection occurs and then all subsequent requests to access the specimens or data for research purposes. This is done to ensure adequate provisions to protect the privacy of subjects and maintain the confidentiality of data. See update to research manual for [full policy](#).

A specific submission form “Biological Specimens/Data Repository Protocol” has been developed for this research activity as it greatly differs from the standard ‘clinical trial’. Please use this form for submission of any banks or repositories going forward. We have identified currently approved repository protocols so that we may present investigators at time of continuing review a different continuing review form that is more specific to a repository. If you have any questions about this new review requirement or ongoing requirements in regards to banks, please contact our office for further information.

[FDA Public Health Advisory 3/5/09 Risk of Burns During MRI Scans from Transdermal Drug Patches with Metallic Backings](#)

“The FDA has been made aware of information about certain transdermal patches (medicated patches applied to the skin) that contain aluminum or other metals in the backing of the patches. Patches that contain metal can overheat during an MRI scan and cause skin burns in the immediate area of the patch.

Transdermal patches slowly deliver medicines through the skin. Some patches contain metal in the layer of the patch that is not in contact with the skin (the backing). The metal in the backing of these patches may not be visible. The labeling for most of the medicated patches that contain metal in the backing provides a warning to patients about the risk of burns if the patch is not removed before an MRI scan. However, not all transdermal patches that contain metal have this warning for patients in the labeling.

FDA is in the process of reviewing the labeling and composition of all medicated patches to ensure that those made with materials containing metal provide a warning about the risk of burns to patients who wear the patches during an MRI scan.

Until this review is complete, FDA recommends that healthcare professionals referring patients to have an MRI scan identify those patients who are wearing a patch before the patients have the MRI scan. The healthcare professional should advise these patients about the procedures for removing and disposing of the patch before the MRI scan, and replacing the patch after the MRI scan. MRI facilities should follow published safe practice recommendations concerning patients who are wearing patches.”

Given this new advisory, the IRB has modified its current “[Standards and Language for Studies Involving MRI](#)” policy to include this new information. Please make sure that you as the researcher are inquiring about transdermal patches prior to subjects undergoing MRIs for research purposes. Research subjects need to be made aware of this new risk and the study consents need to be modified to include this new risk. This can be accomplished via an amendment form with reference to this FDA advisory.

Challenge Grant & Supplement Submissions **American Recovery and Reinvestment Act (ARRA) and the IRB**

As most of you know, on Tuesday, February 17, 2009, President Obama signed the American Recovery & Reinvestment Act of 2009 (ARRA), the economic stimulus, into law. Under this act NIH, NSF and other science agencies are receiving substantial funding in support of ARRA's mission to have a short-term impact on job creation and a long-term effect on investments of value and transparency. The NIH will receive \$10.4 billion to be spent by September 30, 2010 and NSF will receive \$3 billion.

For more information regarding ARRA proposals, see the Office of Sponsored Programs' website at: http://www.uvm.edu/osp/?Page=Research_ARRA.html

ARRA and the IRB:

How will this impact the IRB? We know there are over 50 challenge grant applications submitted, some of which include the use of human subjects. For those projects requiring full committee review, there will definitely be time pressure to obtain IRB approvals. Investigator's with fundable scores should be in contact early with OSP's Pre-Award Services as well as the IRB so that we can work together to stay on top of deadlines.

In addition to the challenge grants, there have been many Supplement Submissions. There are two types of supplement submissions:

- 1) Administrative Supplements (same InfoEd number as currently approved grant)
- 2) Competing Revisions (new InfoEd number assigned)

If the protocol for which you will be receiving this supplemental funding involves human subjects, you should submit an amendment to the existing protocol. We have revised our Amendment Form to account for this type of funding change along with questions that will provide additional information regarding these Supplement Submissions. In addition to the amendment form, you will be required to provide the IRB with a copy of the actual supplement submission. Again, we will work together to address any required timelines.

MEETING SCHEDULE 2009

MEDICAL SCIENCES	
MEETING DATE	SUBMISSION DEADLINES
APRIL 15	APRIL 1
May20	May 6
JUNE17	JUNE 3
BEHAVIORAL SCIENCES	
APRIL 8	MARCH 25
May 13	April 29
JUNE 10	MAY 27

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