

IRB Newsletter

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Thomas Jefferson University
Division of Human Subjects Protection
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http://www.jefferson.edu/human_research/irb/
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FDA INSPECTION:

An inspection of four clinical trials was conducted by the FDA in March 2014. IRB files were examined to determine whether the Jefferson DHSP/IRBs followed all applicable regulations and that our files contained all relevant documents for initial approval, continuing review, and amendments. The inspector had no significant concerns and that FDA found that human subjects enrolled in our device trials are protected from undue hazard or risk.

An FDA visit always provides an IRB with the opportunity to benchmark the quality of its human research protection program (HRPP), so we are obviously very pleased by the positive outcome of this audit and take it as an affirmation of our standard practices.

USE OF INDEPENDENT IRBS: In the clinical trials arena, commercial sponsors often will go to an independent IRB first to approve a study at multiple sites, and then will approach select academic medical centers later and after enrollment has already begun. This creates a highly pressured, inequitable, and sometimes money-losing situation for those academic investigators chosen to be involved, as they are always rushing to catch up with enrollment, and often can enroll only a few subjects before study-wide enrollment closes.

In light of this situation, the DHSP in conjunction with Doreen Kornrumpf of the Office of University Counsel has signed Master Service Agreements with two independent, commercial IRBs: Western IRB (WIRB) and Quorum Review IRB. Our intention is to make select industry-sponsored phase 2, 3, and 4 trials available to Jefferson Investigators earlier in the regulatory review process so our investigators have an equal chance to enroll for these trials.

An additional benefit of this process is that approved Jefferson investigators will be added with their expertise and experience as trialists to the independent IRB's roster that is periodically circulated to sponsor-clients.

Applications from Jefferson PIs to participate in trials overseen by Quorum or WIRB will be made through the OHR Division of Clinical Trials Support. We are looking towards having application forms and SOPs available on the IRB forms page by September 1, 2014.

We will keep you updated on this exciting initiative!

NEW WEBPAGE

A new webpage has been created on the IRB website to educate researchers about the IRB submission process. The webpage is entitled **How To Submit To The IRB**, and the address is: http://www.jefferson.edu/university/human_research/irb/HowToSubmitToTheIRB.html

The webpage provides a brief overview of the dual electronic submission process and provides useful links to training documents.

HOW TO SUBMIT A NEW STUDY:

Following is a brief overview of the electronic IRB submission process. For a more detailed explanation of how to use JeffTrial and the Portal, please consult the applicable training manuals on the new webpage described above.

Once a New Study is ready for submission, it will need to be electronically uploaded into 1) Jeff Trial and 2) DHSP Portal and 3) a set of paper copies will need to be submitted to DHSP

1. Jeff Trial:

- ✚ Go to the Division of Human Subjects Protection (IRB) webpage at: http://www.jefferson.edu/university/human_research/irb.html. In the left side menu click on JeffTrial and log on using your campus key and password. If you do not yet have access to JeffTrial, go to the DHSP website, click on JeffTrial and view the instructional video. Once completed, send your campus key in an e-mail to Kyle.Conner@jefferson.edu and he will provide access for you.
- ✚ Please be sure to note the JeffTrial Protocol number in the Details tab of your JeffTrial study record before using the Portal.

2. Portal:

- ✚ Once your study is in JeffTrial, go back to the DHSP website. On the left side menu click "IRB Submission Portal". Note that there are now two options: Faculty Portal and Student Portal. If you are a student doing research required by your curriculum, please use the Student Portal. All other research should be submitted using the Faculty Portal.
- ✚ Enter your campus key and password and select "New Study" from the drop down menu under "Create an IRB Application". You will then need to enter the Jeff-Trial Protocol number from above. To add documents, use the drop down menu next to "Type of File" and use the Browse function to find the file, and click "Add file to submission". Continue until all files are added.
- ✚ Once all files are uploaded, click "Save as A Finalized Submission". You will receive periodic emails from OHR on the status of your submission.

- ✚ If you need to revise the Final submission, you can pick “Manage Your Submissions” from the main menu and click “Please change status back to draft” with an explanation.

3. DHSP Paper Copy:

- ✚ Provide all of the uploaded forms in paper (one copy for expedited and exempt transactions; 6 copies for full transactions) to the DHSP.
- ✚ Include all supplemental materials (e.g., advertising, recruitment letters, questionnaires, etc.).
- ✚ For commercially sponsored studies, submit one copy each of the Investigator Brochure and Protocol (may be submitted as a CD).
- ✚ If study is supported by a grant, provide one copy of the grant proposal (omitting financial information and facilities sections).
- ✚ If study is an investigator initiated treatment trial (IITT), submit one copy of the protocol.
- ✚ If study is FDA regulated, submit a copy of the IND or IDE letter.
- ✚ If the study involves a drug or device that is not investigational, include one copy of the package insert or device brochure.

Signatures on forms: Please try to ensure that the final versions of forms uploaded to the Portal have all appropriate signatures. If a signature can't be obtained in time for submission, attach a brief explanatory memo after the last signature page (maternity leave, out-of-country, etc.).



Before e-submissions!

Reporting Unanticipated Problems Involving Risk to Subjects or Others: When using eazUP, please note that the eazUP reporting form has changed. At item #5, the form asks if the UAP involved risk. Now, if there is “no increased risk”, you may stop at that point, print the form, get appropriate signatures and keep the form in your study file. At the time of Continuing Review, provide these UAP reports plus any that did involve risk along with the other required paperwork. If you keep the UAPs in a folder, you can up-load the entire folder to the Portal rather than up-loading individual reports.

Forms: As always, please check the DHSP forms page in order to use the most current forms for your submissions.

Compliance Corner: There have been no non-compliance issues since the last newsletter.

TJU DHSP in the news: The lead article in the August 2014 issue of *IRB Advisor*, vol. 14, No.8: “IRBs Grappling with Tissue Requests from Biotech Firms” was based largely on an interview with Bruce and Kyle. They presented the Jefferson position that our faculty should have some scholarly activity associated with the use of tissue from Jefferson patients and that we would not provide tissue for money except under contractual agreement defining the involvement of our faculty in the research. If you want to read the article, e-mail Bruce.Smith@jefferson.edu and he will forward a copy to you.

Kudos to the Associate Director, DHSP!

Kyle Conner, Associate Director, DHSP, won this year’s Special Recognition Award from the Jefferson School of Population Health! The award was presented by Dr. Caroline Golab, Associate Dean for Academic and Student Affairs, at JSHP’s Student Night. Kyle was recognized for his efforts educating JSHP students on the IRB process. Dr. Golab introduced Kyle by citing his avocation as a poet and then delighted the audience with a clever limerick of her own!

Thanks to Christine Hubert (Urology) and Pranoti Pradhan (Neurology) for contributing to the step-by-step directions for submitting a new study.

**This and past issues of the IRB Newsletter can be accessed from the DHSP web page.
The link is in the IRB Reference Documents Box.**

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