TRB Newsletter

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Thomas Jefferson University Office of Human Research 1020 Locust Street, Room M34 Philadelphia, PA 19107

http://www.jefferson.edu/university/human_research.html

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Periodically, the Office of Human Research (OHR) sends out announcements concerning updates to IRB policies and processes. These can be very useful in staying up-to-date on the process for making IRB submissions. The announcements will also inform you of new IRB policies and changes to existing ones. If you would like to receive these announcements, you can add your name to the distribution list. To do this, please go to the Office of Research Administration (ORA) web page http://www.jefferson.edu/university/research_administration.html. On the top, right hand side, where it says, "Join Listserves for," click on "Clinical". You will be taken to a page where you can add your name to the distribution list. Please note that by adding your name, you will also receive other research related emails from other departments.

AAHRPP Site Visit

The Thomas Jefferson University IRB is accredited by the Association for the Accreditation of Human Research Protection Programs (<u>AAHRPP</u>). This is a rigorous process to ensure we meet the highest standards of research oversight. We are in the process of re-accreditation. Our Step 1 and Step 2 applications have been accepted, and a site visit is planned for March 14-16, 2016. We look forward to introducing our team to the site visitors.

Commercial IRBs

The TJU IRB has formal master agreements with <u>WIRB and Quorum</u> IRBs. Such agreements allow for more rapid initiation of clinical trials at Jefferson, while still ensuring the safety of research participants. Effective immediately, TJU will also accept the review of other commercial IRBs (such as Chesapeake, Shulman, and others), so long as the IRB in question has <u>AAHRPP</u> accreditation. The mechanism is an individual IRB Authorization Agreement (IAA) on a per study basis. The forms are available on the <u>forms page</u> at the OHR website.

Abington Integration

Representatives from the TJU IRB office met with Susan Nolte and Chris Christenson of the Abington IRB as part of the integration of our institutions. The meeting was extremely positive. We discussed how we would think about harmonization of our activities. For now, we can establish reciprocity of review easily using an IRB Authorization Agreement. We will continue to move forward with the integration of research activities over the coming months.

Staff Updates

We are pleased to welcome Heather Krupinski as Quality Improvement Coordinator. Heather works with Patrick Herbison in our quality assurance group in standardizing our polices and with quality improvement audits.

Tracey Smith has left TJU to take on a new post at the Temple University IRB. She assumes an advanced role in her new position. Tracey was a true Jeffersonian with 14 years of service. We all will miss her good nature, judgment and professionalism. We certainly are sad to see her go, but are happy for her personal growth and development that will come with this new challenge.

Below is the current list of the OHR staff:

Name	Phone	Title	Responsibility
	Number		
Kathleen Avender	503-9820	Administrative Assistant to Director	Oversees required Human Subjects Training (CITI)
Latesh Boyd	503-4299	Administrative Coordinator	Data entry
Elaine Braddock	503-4847	Continuing Review Administrator	Manage administrative function for review and approval of continuing reviews
Kyle Conner	503-8966	Associate Director OHR	Primary resource to the Jefferson research community
Viola Dallas	503-3849	IRB Administrative Secretary (Chambers)	Prepare and maintain Board Meeting minutes; Manage new submissions
Patrick Herbison	955-4239	Research Compliant Manager	Oversee quality assurance and audit functions of OHR
Walter Kraft	503-0203	Director, OHR	Director of OHR
Heather Krupinski	503-6528	Quality Assurance/Improvement Specialist	Perform QA/QI audits
Patricia Oden	503-9817	Amendment Coordinator	Ensures appropriate and timely handling of submissions for protocol amendments
Jennifer Polizzi	503-4187	IRB Administrative Secretary (Chung)	Prepare and maintain Board Meeting minutes; Manage new submissions
Roseann Talarico	503-4743	Associate Director of Operations	Directs day-to-day operations in OHR
Jacquie Wright	503-9816	IRB Administrative Coordinator (Weinstein)	Prepare and maintain Board Meeting minutes; Manage new submissions

Key Personnel

The definition of key personnel is defined in the TJU Policy G 601. While research specific activities typically should be performed by key personal, certain standard clinical activities may be conducted by non-key personnel. A helpful <u>additional guidance</u> has been posted on the <u>Frequently Used Documents</u> section of our website to assist with the determination.

Policy Updates

In an effort to keep the research community informed of new and revised Office of Human Research (OHR) policies and forms, summaries of recent changes are available on the OHR website. Other important IRB announcements are also available on our site. Use the following link to access these announcements: http://www.jefferson.edu/university/human_research/irb-announcements.html. Please remember to always access the most current policies and forms on the OHR Website. Note: When using this link, if prompted for user name and password, click cancel and the website should load.

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

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