

JRB 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
Vol. 18 Issue 2: June 2016

AAHRPP Site Visit

The Thomas Jefferson University IRB had our 5 year re-accreditation visit by the Association for the Accreditation of Human Research Protection Programs ([AAHRPP](http://www.aaahrpp.org)) on March 14-16, 2016. We thank everyone who participated in the process and are pleased to announce very positive feedback from the site visit. The feedback we received from AAHRPP includes comments on our community outreach evaluation method, evaluation of IRB members, how we record our meeting minutes, and document voting. The TJU IRB has already put these suggestions into practice and we anticipate formal approval of our accreditation at the AAHRPP council meeting in early June.

New Frequency of Meetings

Due to the increased use of central IRBs, we are altering the frequency of IRB meetings.

Thursday of the Month	Chair/Vice Chair	Time
1 st	Chung/Hickok	1-3 PM
2 nd	Weinstein/Hooper	3-5 PM
3 rd	Chambers/Chaballa	3-5 PM
4 th	Weinstein/Hooper	3-5 PM
5 th (when applicable)	Chambers/Chaballa	3-5 PM

Resubmissions will be accepted and reviewed at any of the meetings. The turn-around time for submissions will not be affected.

Working with Commercial IRBs

TJU IRB continues to expand the external IRBs with whom we work. Currently, we have master service agreements with Western IRB (WIRB) and Quorum Review IRB. We can execute IRB authorization agreements (IAA) with other AAHRPP-accredited IRBs as needed to facilitate research on campus on a case by case basis. Please reach out to Kyle Conner or Walter Kraft with questions.

Community IRB Members Needed!

We are looking for volunteer IRB members who are not affiliated with Jefferson. The IRB needs diversity of expertise and viewpoints, and in this regard the voice of the community is particularly important for the review of research at Jefferson. Please refer on anyone who is looking to support our IRB missions.

Updates to eSAEy and eazUP Reporting Systems

You now have the ability to run an electronic report of all the serious adverse events (SAEs) or unanticipated problems (UAPs) for a given study. This can be done in the eSAEy and eazUP systems. We hope that these reports will be helpful when submitting continuing reviews and at other times when a list of this nature is called for. Please see the 5/31/16 [IRB Announcement](#) for more information.

As you know, SAEs and UAPs must be reported to the IRB in the required timeframe per [OHR Policy GA 120](#). The reporting timeframe starts when any member of the study team becomes aware of the event. To better capture the start time, that field in the eSAEy and eazUP reports has been changed to 'Date PI/Study Team became Aware'. The stop time is when the PI or Co-I signs and approves the report. Please continue to report all SAEs and UAPs in the required timeframes.

Roe Talarico is Retiring

After 35 years of dedication and hard work, Roseann Talarico has decided to retire. Roseann started her career at Jefferson in the Controller's Office, Sponsored Programs Accounting and then worked her way into the Dean's Office as Budget Officer for Grants and Contracts. That position was eventually moved over to the Office of Research Administration where Roseann took on many titles including Acting Director. Roseann eventually moved over to the newly created Office of Clinical Trials which then was folded into the Office of Human Research where she served as Associate Director of Clinical Trials Support for the past 11 years. Roseann will be spending summers at the Jersey Shore with her husband and winters in sunny Florida. Please join us in wishing her luck in future endeavors.

Staff Updates

We are pleased to welcome Kimberly Bell to the staff as a full time. Kim is studying social work and when schools starts in Sept. will work three days a week. Many of you already know Kim and understand what a valuable addition she has been to the team.

Below is the current list of the OHR staff:

Name	Phone Number	Title	Responsibility
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
Kimberly Bell	503-3849	Data Coordinator	Manage IRB submissions and meeting agendas
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 Improvement Coordinator	Assists with the quality assurance and audit functions of OHR
Patricia Oden	503-9817	Amendment Coordinator	Ensures appropriate and timely handling of submissions for protocol amendments
Jennifer Polizzi	503-4187	IRB Administrative Secretary	Prepare and maintain Board Meeting minutes; Manage new submissions
Roseann Talarico	503-4743	Associate Director of Operations	Directs day-to-day operations in OHR
Jacque Wright	503-9816	IRB Administrative Coordinator	Prepare and maintain Board Meeting minutes; Manage new submissions

Please direct your questions to the specific staff, but for general questions Kim Bell is a good place to start.

Policy Updates

Please remember to always access the most current policies and forms on the OHR Website.

Use the following link to access these announcements:

http://www.jefferson.edu/university/human_research/irb-announcements.html.

When using this link, if prompted for user name and password, click cancel and the website should load.

Coming down the pike...

Portal 2.0

We will in the next few months begin the roll out of Portal 2.0. This is an update of the current submission system. Improved functionality will be automation of data input for certain OHR forms, cross checking with conflict of interest, and fully electronic signatures.

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](#).

Published by:
Office of Human Research
Thomas Jefferson University

Editors: Walter Kraft, Kyle Conner, and Patrick Herbison
Assistant Editor: Kathleen Avender