ORIC NEWSLINE

The Office of Research Integrity & Compliance Newsletter **Summer 2016**

Director:
Daniel R. Vasgird, PhD
drvasgird@mail.wvu.edu

Assistant Director:
Deyanira Santiago
dsantiago@mail.wvu.edu

866 Chestnut Ridge Rd.
Suite 211
Morgantown, WV 26506-6845
P: 304-293-7073

Our mission is to foster a culture of integrity and compliance within the University, directed at ensuring that participants in the West Virginia University research enterprise internalize and pursue the goal of self-directed responsible conduct of research. We operate as facilitators, educators, and a resource center for the WVU research community.

Accreditation Site Visits

Both the WVU Human Research Protections Program (HRPP) and the IACUC hosted site auditors throughout the month of March in hopes of gaining accreditation from their respective organizations.

- The *AAALAC* site visit was done on March 20-21, 2016. The AAALAC council has met in mid-May to vote on the review of our program that was submitted by the site visitors that were here. Notification of that vote is expected at the end of June or mid-July.
- The *AAHRPP* site visit was conducted from March 29-30, 2016. The AAHRRPP council will meet in mid-June to vote on the review conducted over the course of the site visit. Notification of the vote is expected at the end of July or mid-August.

New This Issue:

Encouraging Collaboration

IRBchoice. WVU is a participant in the IRBchoice program, an expansion from the previous IRB reliance models. In this program WVU and other sites involved in the program can share protocols much like the previous IRBshare program. Within IRBchoice, WVU can serve as the lead IRB or the local IRB. This new system allows optimal flexibility for investigators in IRB reliance when conducting multi-site studies.

Updating IAAs. The Office of Research Integrity and Compliance SOPs, Section 3.18, has been updated regarding Interinstitutional Authorization Agreement (IAA) procedures if WVU is the relying institution. The IAA form is submitted to the ORIC via email, accompanied by a copy of the lead site's IRB approval letter, a short summary of the study, and the approved informed consent document.

Research at Affiliate Sites. According to a recent agreement, Camden Clark Medical Center's research protocols will now be submitted to the WVU ORIC. In the past, multiple overlapping research protocols have been conducted at each institution. This agreement affords one Human Research Protection Program responsibility for all of those IRB reviews, allowing for a more unified approach and consistency in research compliance. The transfer of protocols into the WVU+kc system is currently underway and will soon be finalized.

Re-zoning the Citi

Recently, the Biomedical Research Alliance of New York (BRANY) acquired the CITI Program from the University of Miami. BRANY is committed to maintaining and improving upon the high standards that CITI has set over the past 16 years. As such, the WVU IRB & IACUC will continue to require that the respective research ethics trainings for human and animal subject research are completed using this tool.

IRB Investigator Resources

One goal of the HRPP is to continually improve upon the guidance we offer the WVU research community. Over the next several months, we will be revising and updating the guidance documents found on our website to better help investigators and students organize and develop their research. Check the ORIC-IRB website to see what's new!

ORIC Welcomes New Staff

The ORIC administrative team welcomes Johnathan Herczyk, MPH, as a Human Subject Research IRB Administrator. A graduate of West Virginia University's School of Public Health, John focused on Epidemiology and worked as a graduate research assistant at the WVU Injury Control Research Center. He will be working on expedited protocol reviews and collaborating with Sarah Stutler on IAA's and Responsible Conduct of Research.

Also joining the ORIC staff is Laura Davisson, MD, MPH, FACP as the WVU IRB Quality Coordinator. Dr. Davisson is an associate professor in the WVU School of Medicine's section on General Internal Medicine and Geriatrics. As the IRB Quality Coordinator, Dr. Davisson will be responsible for quality assurance and improvement monitoring of protocols. She will educate faculty, staff, and/or students involved with human subjects research on best practices. Dr. Davisson will join Ms. Lilo Ast on the Quality Improvement Program (QIP) site visits, in order to gain information and inform the IRB of any improvement opportunities for protocols.

IRB Contact Information

Lilo Ast, M.A.
Senior Program Coordinator
lilo.ast@mail.wvu.edu
(304)293-7555

Sarah Stutler, MBA, CCRP
IRB Coordinator
sarah.stutler@mail.wvu.edu
(304)293-1119

Johnathan Herczyk, MPH
IRB Administrator
jmherczyk@mail.wvu.edu
(304)293-5971

Afton Wagner
IRB Administrator
afton.wagner@mail.wvu.edu
(304)293-5923

Compassion Fatigue

Compassion fatigue is defined as "a state experienced by those helping people or animals in distress; it is an extreme state of tension and preoccupation with the suffering of those being helped to the degree that it can create a secondary traumatic stress for the helper." This condition is becoming more common in the realm of animal research. Compassion fatigue can effect anyone involved with caring for the animals, making it important to learn ways to identify and methods to treat this issue.

Studies have shown that animal caregivers play host to a high level of compassion fatigue. Every day workers struggle to function in care giving environments that constantly present heart wrenching, emotional challenges. Compassion fatigue symptoms are normal displays of chronic stress resulting from the care giving work. There are many symptoms of individual workers and organizational symptoms that might suggest the presence of compassion fatigue. These symptoms, along with ways to address and deal with compassion fatigue, can be found at www.compassionfatigue.org.

Supervisors should recognize compassion fatigue as a problem that can negatively impact somebody's performance and productivity. Co-workers and collaborators should consider the feelings of others when witnessing animals suffer or perish. Staying flexible when working with someone with compassion fatigue is essential to their self-treatment and may help maintain a level of productivity at the same time.

A New Interim Attending Veterinarian

Robert Faith, DVM, Ph.D has been appointed Interim Attending Veterinarian by Dr. Fred King until a new, permanent Attending Veterinarian has been acquired. Dr. Faith has previous experience as the Interim Director for Animal Resources at both the University of Texas and West Virginia University. He also served a term as the Associate Dean for Veterinary Medicine and Director of the Biomedical Resource Center at the Medical College of Wisconsin. Dr. Faith will be on campus every other week while remaining in constant contact with the IACUC staff, veterinary technicians, and the Clinical Veterinarian, Matt Kessler, should you need any assistance.

IACUC Contact Information

Melinda Hollander
Animal Care & Use Officer
Melinda.Hollander@mail.wvu.edu
(304)293-9368

Izabella Fonesca Barbosa
Administrative Assistant
izfonsecabarbosa@mail.wvu.edu
(304)293-1050

Revised Documents for Protocols

The IACUC staff has updated important documents that investigators must use for protocol submissions. Please, always download the forms found on the ORIC-IACUC website whenever starting to create a protocol or submit a protocol renewal to ensure that the most updated versions are being used.

IRB & IACUC Protocol FAQs

The Office of Research Integrity & Compliance is dedicated to continuing to improve upon the standards already in place, in order to accelerate the review process for both IRB and IACUC protocol submissions. Below are the most recent updates to the methods in which protocols are submitted for review.

IRB Protocols

IRB Questionnaire Revisions:

The IRB staff has been working to update and reorganize the Questionnaires required for protocols. All changes to the sections have been made. If any additional assistance is needed, please contact the ORIC.

Protocols Affected:

All protocols created before the changes were finalized are affected by this update to the Questionnaire. This includes NHSR, exempt, expedited, and full board protocols as well as amendments and renewals to an existing protocol.

Updating Your Protocol:

Unless you are submitting a brand new protocol, we recommend that the first thing you do before making any changes to a protocol is to update the sections of the Questionnaire. In order to identify the sections that need updated, navigate to the Questionnaire page and click the Expand All button.

All of the sections that need updated will have the message "Questionnaire Update Status: Update Required." Update all of these sections and save the protocol, prior to entering any new data.

For questions related to issues with the updates, please call the ITS Help Desk at (304) 293-4444 or the ORIC at (304) 293-7073.

IACUC Protocols

IACUC Protocol Amendments:

1. Download the current version of the document 'Main Protocol Form' from the ORIC-IACUC website. Complete the form with all of the changes to the original protocol highlight in the document.
2. In the body of the submission email, or as a separate document, include a brief summary of the amendment and justification for the amendment request.
3. All protocol forms must be submitted as a Microsoft Word document. The submitted forms should include the highlighted changes to the original protocol.

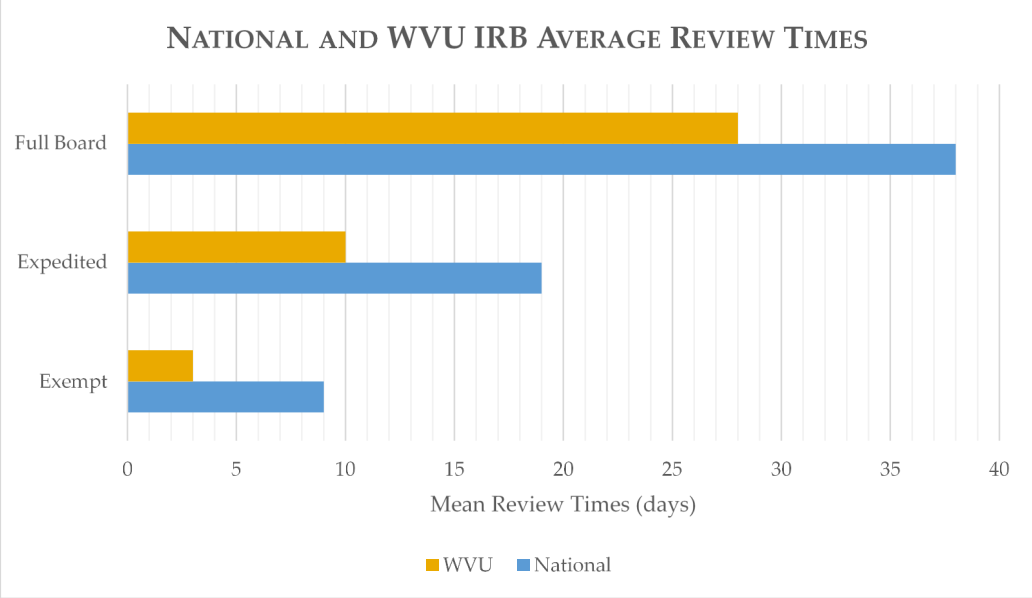
IACUC protocol amendments may be submitted by either the Principal Investigator or the Co-Investigator/Study Staff. Anyone submitting an amendment should also include the PI on the submission email.

Adding Personnel:

1. Complete the 'Add Personnel Form' found on the ORIC-IACUC website.
2. Add the required information (name, department, email address, and a list of procedures they will be conducting) into Section 3 & 4 of the protocol. Please also include a narrative of the qualifications and experience each new team member has with the target species and procedures. Highlight the additional information
3. Submit the protocol as an amendment.

You will receive an email notification from the IACUC office indicating that the personnel have been added to the protocol.

IRB Review Statistics



The WVU IRB continues to surpass the national average review times for all types of protocols, as shown in the figure to the right. **The national average for a full board review is 38 days, whereas the WVU IRB's average is 28 days. Likewise, the average review time , at WVU, for exempt and expedited protocols is 3 and 10 days respectively. These times are well below the national averages for these protocol types; 9 days for exempt and 19 days for expedited.** These times were taken from the first quarter of this year. More national HRRP performance measurements can be found at the Association for the Accreditation of Human Research Protections Programs website. The majority of IRB submissions during the were expedited (51%), followed closely by exempt protocols (45%). Non-Human Subjects Research (NHSR) submissions (8%) and full board protocols (7%) were less common.

IACUC Review Statistics

Both initial and continuing review protocols submitted to the IACUC have an average review time of 30 days. The average time for the WVU IACUC to complete the review of an amendment is 19 days. These times account for the time of submission to the time of approval.

Responsible Conduct of Research

A central focus of the ORIC is to foster the responsible conduct of research and support West Virginia University's faculty, staff, and students in all research endeavors. Training and educational material regarding the Responsible Conduct of Research (RCR) is available on the ORIC website. In person consultations and education is also available to anyone who requests.

Recently, Dr. Daniel Vasgird has been doing Grand Rounds talks in the various departments of the WVU School of Medicine. The primary objective in these talks is to inform medical staff and researchers about current scientific integrity standards, both nationally and internationally.

Annual AAMC Forum on Conflict of Interest (FOCI) Academe Conference

The Forum on Conflict of Interest in Academe offers educational opportunities related to conflict of interest issues; provides a national forum for discussion of the development and application of conflict of interest standards related to research, medical education, and clinical decision-making; and serves as a resource for institutions, policymakers, the media, and the public.

The overarching theme of this years' annual FOCI Academe Conference was that of the major shift in research funding opportunities in the past few years (from predominantly government-sponsored to predominantly industry-sponsored) and how that might affect the assessment and management of conflicts of interest, with a secondary focus on the nationwide academic push toward entrepreneurialism. The panel discussions transitioned into some contentious interactive debate as COI in research specialists and administrators were asked to critically evaluate the themes expressed in a series of articles published this past year in the NEJM and JAMA and begin to consider alternative approaches to the status quo in the conflicts arena. The articles included Lisa Rosenbaum's widely panned 3-part series on physician-industry ties and a related editorial by the NEJM's editor-in-chief, Jeffrey Drazen, both of which suggest that criticisms of physician-industry financial ties are overblown. The following are several questions that we examined:

- Have the conflict of interest rules and management strategies strayed too far from their intended purpose and stifled principled partnerships with industry?
- Have we allowed an emotional response to the appearance of conflict to eliminate the need for an empirical basis for presuming financial relationships with industry result in bias?
- How do we determine whether the presence or absence of particular interactions with industry are either harmful or beneficial to patients?

Conflict of interest is an ever-evolving aspect of research compliance that continues to spark lively debate among academic research institutions and policymakers around the world. We are very pleased to maintain our membership with the AAMC FOCI Academe and take part in these invaluable conversations. Through that critical examination of current practices and with the insights of 150 peer institutions in the U.S., we are able to develop and improve the policies that help our research community to move forward.

COI in Headlines

Doctors' Magical Thinking About Conflicts of Interest

When the Food and Drug Administration creates an advisory committee to help it decide whether to approve drugs, it often asks academic physicians to serve on the committee as external experts. This is supposed to help the committee render judgments that are unbiased and scientific. A study published today by Genevieve Pham-Kanter in The Milbank Quarterly brings that assumption into question. Read More

Maryland Gets a New View of Conflicts of Interest

Nearly $230,000 refunded; COI training mandated. An investigative committee at the University of Maryland (UMD) in College Park has recommended mandatory education on conflicts of interest for research faculty and advised an IRB to revisit its expedited review and informed consent waiver policies. Read More.

COI Contact Information

Joy Edwards
COI Officer
joy.edwards@mail.wvu.edu
(304) 293-5475

Disclosure of Interest in Research Form

Each member of the West Virginia University research community must file a form annually.

Do you have a current form on file?

Verify that your form is current by contacting Joy Edwards.

New Look, Same System

As of June 2016, the WVU+kc system has been re-organized to better help investigators and study coordinators create, locate, and submit their protocols for IRB review. This dashboard upgrade adds 4 new sections to the program: a menu bar, news feed, last activity, and associated activity lists.

Menu Bar

The first new feature in the June update simplifies navigation of the system. Under the IRB menu, the options to create a protocol or search for a protocol are centralized. Likewise, the Quicklinks menu provides access to important IRB forms, COI forms, and CITI training.

News Feed

This new feature will act as a message board. It will show users notifications that need to be taken on protocols that have been submitted to the IRB; whether a protocol needs reviewed, revised, or approved for submission. These notifications act as links directly to the protocol that needs an action taken.

Last Activity

Recent activities performed in the WVU+kc system will be shown in the upper right portion of the dashboard now. This will make it easier to return to a particular protocol that you may be working on, or go straight to other recently visited functions.

Associated Activity Lists

The bottom half of the dashboard contains varying lists; these lists can then be filtered to show active protocols on which the user is listed. Be sure to select the IRB option in the blue box on the bottom left side of the screen. This filters the lists to the right of this box. You can then select whether you wish to see either not submitted protocols, protocols that have been submitted for review, all active protocols in the WVU+kc system, amendments or renewals and so forth. This feature is intended to help users find all of their work in one, centralized location.

The Information Technology Services team has composed a FAQs page, found on the TeamDynamix website, to help investigators navigate the new WVU+kc dashboard. **If you require additional help, please contact the ITS Help Desk at (304) 293-4444 or the ORIC at (304) 293-7073.**