ORIC NEWSLINE

FALL/WINTER 2015

WEST VIRGINIA UNIVERSITY

OFFICE OF RESEARCH INTEGRITY AND COMPLIANCE

It is our mission 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.

Daniel R. Vasgird, PhD, ***Director***
DRVASGIRD@mail.wvu.edu

Deyanira Santiago, ***Assistant Director***
DISANTIAGO@mail.wvu.edu

886 Chestnut Ridge Rd. Suite 211
Morgantown, WV 26506-6845

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WELCOMING A NEW IRB ADMINISTRATOR

We would like to announce the addition of **Sarah Stutler** to our office as the new IRB Administrator.

Sarah is from Clarksburg, WV. She received her Masters of Business Administration from Salem International University. Previously, she worked the WVU Clinical Trials Research Unit as the Lead Regulatory Associate. Sarah enjoys spending time with her two children, Amayah and Ryker.

Sarah will be handling all Expedited protocols and will be responsible for the Responsible Conduct of Research Program for the ORIC. You can contact Sarah by phone at 304-293-1119 or by email at sarah.stutler@mail.wvu.edu

SEMINAR: "IRB REVIEW OF PHASE 1 CLINICAL TRIALS"

As part of the WVU Clinical and Translational Science (CTSI) Seminar Lecture Series, Ada Sue Selwitz visited the Health Science Campus of West Virginia University on August 26, 2015 to give a seminar about the IRB Review of Phase 1 Clinical Trials.

Ms. Selwitz is the director at the Office of Research Integrity and the co-director of the Regulatory Support and Research Integrity at the Center for Clinical and Translational Science at the University of Kentucky.

The seminar was held in the Health Science Center and broadcast to WVU-Charleston and the WV School of Osteopathic Medicine. It was attended by IRB members, the ORIC staff, and the WVU CTRU staff.

PARTNERING FOR BETTER HEALTH

WVCTSI West Virginia Clinical and Translational Science Institute

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

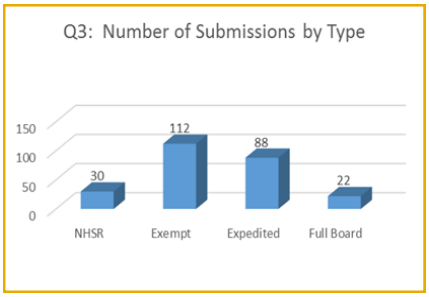
Sarah Stutler, MBA, CCRP
IRB Coordinator
sarah.stutler@mail.wvu.edu
(304)293-1119

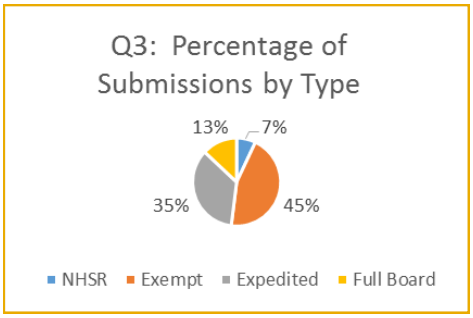
Afton Wagner
IRB Administrator
afton.wagner@mail.wvu.edu
(304)293-5923

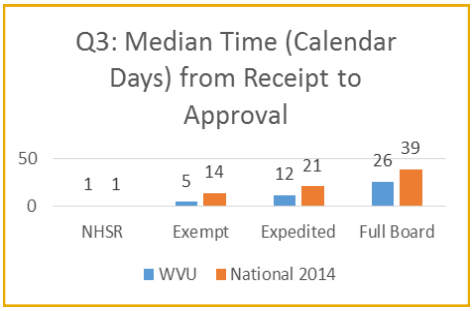
HUMAN SUBJECTS RESEARCH AND THE IRB

THIRD QUARTER 2015 (JULY THRU SEPTEMBER) ACTIVITY REPORT

For the months of July, August, and September 2015, the IRB staff received 30 new not human subject research (NHSR) submissions, 112 exemptions, 88 expedited submissions, and 22 full board submissions. This brings the total number of active protocols in the KC submission system to 2,397 as of June 30th, 2015.







Overall, the type of review that accounted for the largest percentage of submissions in Quarter 3 were exempt reviews. Exempt reviews accounted for 45 percent of the total while expedited reviews accounted for 35 percent of the total. Full board reviews accounted for 13 percent of the total, which is higher than the standard 5 percent rate. The median approval time in calendar days for exemptions and expedited protocols were 5 days and 12 days, respectively. According to the 2014 year-end Association for the Accreditation of Human Research Protection Programs (AHRPP) nation-wide metrics, exempt acknowledgements average about 14 calendar days and expedited approvals average 21 calendar days.

Full board reviews require the most time and averaged 26 days during the third quarter. Once again, this was significantly faster than the national standard review time of 39 calendar days for full board review.

WRITING AND EDITING SUPPORT AVAILABLE TO WVCTSI MEMBERS

Brandi Talkington, PhD, research coordinator, **provides support to WVCTSI member investigators**, including NIH manuscript compliance guidance, IRB and protocol submission support, and writing and presentation development. She has specific experience in supporting investigators for whom English is a second language. Those **WVCTSI members** seeking assistance with IRB submissions and writing and/or editing abstracts, manuscripts, or PowerPoint or poster presentations should contact Brandi at bnsnyder@hsc.wvu.edu or 304-581-1959. Her office is located in WVCTSI's administrative offices in suite 2244 of the WVU Health Sciences Center.

HUMAN SUBJECTS RESEARCH AND THE IRB

PROTOCOL GUIDANCE FOR RESEARCHERS

One of our goals at the Office and Research Integrity and Compliance (ORIC) is to provide guidance and facilitate open lines of communication for the members of the WVU Research Community. In doing so, we have developed comprehensive guidance documents for each level of review to assist researchers in creating and managing protocols in the WVU+kc system.

These guidance documents have been developed to assist with protocols at all levels of review, including: full board protocols, amendments, renewals, and additional attachments needed for a successful submission. You may find the guidance documents on our website under the IRB Checklists and Guidance Section.

RECENT CHANGES TO IRB STANDARD OPERATING PROCEDURES

The IRB chairs have approved recent changes to the standard operating procedures for the IRB. The following sections of the SOPs (found here) were updated in September.

Section 3.10.2 involving the Continuing Review process. Continuing reviews must be submitted and approved prior to the expiration date of the protocol. By federal regulation, no extension to that date can be granted. To assist investigators, renewal notices will be sent out three months, two months, and one month in advance of the expiration date.

Section 3.12.1 involving the administrative closure of protocols that were never submitted for review. The purpose of this change is to eliminate any protocols that were created in the electronic system more than six months prior to the date of the search and that have never been submitted for review. A notification will be sent to the investigator to prompt further action six months after the protocol creation date or it will be eliminated.

UPDATES TO THE WVU+KC SYSTEM

- Automatic emails will be sent to notify PI when a draft protocol has not been submitted. Protocols that have not been submitted after 180 days will be deleted.
- Email notification to WVU Pharmacy when drugs are being stored as part of the study.
- Attachment Version Indicator – When a document is merged into a protocol through an Amendment or Renewal, the version of the amendment or renewal used will show. If a document is merged in amendment A002, this will update next to the document name.
- Submit Button – To address user concerns about the uniformity and number of buttons available, the submit button has been emphasized.
- The Protocol Summary page has been added.
- A resubmission will now be shown as such in the information header at the top of the protocol.
- The PI will now be displayed in the header at the top of the protocol.
- Review completion data will now be tracked and viewable in the Summary and History section on the protocol actions page.
- The system will display a warning when changing protocol types after an initial save - letting users know that the questionnaire may change and require new/different information to be entered.
- The Funding Source section on the Protocol tab has been re-added, allowing users to link their awards to their protocol.
- When changing a PI as part of an amendment, the workflow will now require approval by the new PI and Unit Administrator.
- Notifications sent that allude to correspondence within the WVU+kc system, will now have a link that will take you to a page to download/view said correspondence.
- Validations and reminders have been added to ensure users remember to click the add button when uploading attachments.
- Users will now be able to add their own non-WVU personnel without submitting a ticket to the ITS help desk.
- Questionnaire text boxes have had their character limit raised from 2,000 to 3,000.
- 'WVU MyID Search' has been renamed 'WVU Employee/ Student Search' on the Personnel tab.
- A link to the WVU+kc Person Lookup has been added to the Quicklinks section.
- Character count added below text boxes.
- Approval message added for unit approvers outlining what their approval signifies.
- CITI training field on Personnel page shows most recent training, not the entire history of trainings.

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

WE ARE LISTENING TO YOU!

There have been several ways that WVU could reduce self-imposed regulatory burden regarding the animal program (i.e., PIs, IACUC staff, IACUC members, veterinary staff, and the IO). Upper administration at WVU implemented a mandate on the IACUC to decrease administrative burden on PIs to the extent possible.

Following these events, a subcommittee of the IACUC and IACUC staff reviewed all IACUC processes and made recommendations about ways to reduce unnecessary administrative burden with regard to processes involving the IACUC. This change will decreases administrative requirements for PIs, IACUC staff and IACUC members.

IACUC Contact Information

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

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

ANIMAL RESEARCH AND THE IACUC

ANNUAL REVIEWS OF IACUC PROTOCOLS

The Animal Welfare Regulations require that protocols involving USDA-regulated species (9CFR §1.1) receive an annual review. The Office of Laboratory Animal Welfare, the oversight body of NIH for animal research, requires "…continuing review of each previously approved, ongoing activity…at appropriate intervals as determined by the IACUC, including a complete review at least once every 3 years…". After reexamining the procedure of the IACUC to require an annual review for ALL protocols regardless of the animal species being used, it was decided that only protocols involving USDA-regulated species would require a specifically scheduled annual review.

SEMI-ANNUAL LABORATORY INSPECTIONS

The practice of the IACUC scheduling inspections for every laboratory where an animal procedure is being done regardless of the species and/or procedure was reevaluated and changed to more specifically align with the regulations.

The committee acknowledges that it is still important that they have an understanding of and grasp on all space where animals go throughout the WVU campus for procedures. Therefore, the post-approval monitoring (PAM) program, currently lead by Dr. Stanley Yokota, will be made a bit more robust to facilitate visits to more laboratories.

SEARCHES FOR ALTERNATIVES TO PAINFUL OR DISTRESSFUL PROCEDURES

WVU IACUC has decided to modify this requirement to pertain to only protocols involving USDA-regulated species undergoing category D or E procedures. Therefore, those protocols that involve conducting category D or E procedures on non-USDA-regulated species are still required to consider alternatives, but they will no longer be required to document conducting a database search.

REVIEW OF IACUC PROTOCOLS AND AMENDMENTS

In the past, the WVU IACUC required that all protocols involving category D or E procedures be reviewed via FCR. However, the WVU IACUC has decided to refine this procedure and require only those protocols involving unalleviated pain or distress (i.e., category E) procedures to be reviewed by FCR. All other protocols, category B, C or D, protocols can go through the designated member review determination process. Nevertheless, it must be noted here that any IACUC member can request that ANY protocol be reviewed via the FCR process for any reason.

It is the job of the IACUC to ensure compliance while facilitating research using animals. It is understood that regulatory burden is time consuming and pulling PIs away from what they were hired to do…and what they love to do. Please know that the IACUC is sensitive to that fact and has implemented the changes described above in an attempt to alleviate unnecessary requirements for all involved. This will be a dynamic process where the IACUC and IACUC staff will continue to evaluate processes to identify ways that can benefit all individuals, especially the PIs, involved in the animal care and use program.

COI IN THE NEWS

Reconnecting the Dots — Reinterpreting Industry–Physician Relations

Physician–industry interactions are common and diverse, ranging from the $10 bagel sandwich to the $1 million research grant. Although most observers agree that we must mitigate the risk of bias introduced by these relationships, the benefits wrought by interactions between physician-scientists and industry at the basic or translational research level are equally clear. Read More

U of Connecticut investigated for conflict of interest in buying from faculty start-up

The University of Connecticut (UConn) and some of its faculty are being investigated for allowing a no-bid contract for $250,000 worth of equipment purchased from a start-up company the faculty have a stake in. Read More

Targeted by crusading congressman, scientist speaks out on conflicts, climate, and controversy

Conflicts of interest and disclosure of funding sources have been topics du jour lately in science policy circles. Read More

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

CONFLICT OF INTEREST IN RESEARCH (COI)

Financial conflict of interest in research involves situations in which a researcher has a significant financial interest that may compromise, or have the appearance of compromising, professional judgment in the design, conduct, or reporting of research. A significant financial interest could include personal compensation from industry, equity interest or a management role in a company, or royalties generated from intellectual property rights.

FINANCIAL CONFLICTS OF INTEREST ARE COMMON IN A MODERN RESEARCH UNIVERSITY, AND TO SOME EXTENT, THEY ARE INEVITABLE.

Academic researchers and industry have a long history of collaborating, and these collaborations can provide mutual benefit by contributing to a university's research mission and helping to focus the research directions of industry. Industry/researcher collaboration is accomplished by personal consultation and/or sponsored research.

Also, universities are responsible for stimulating economic development and transferring discoveries to the private sector. Universities commercialize their technologies by licensing discoveries to established companies or to companies started by academic inventors.

All of these situations can create opportunities for researchers to receive financial rewards related to their research. With the opportunities comes risks that the direction of research will be affected, the objectivity of the data will be compromised, and the interpretation of research results will be skewed.

AS A RESEARCHER, YOU MIGHT NOT CONSIDER THAT YOUR FINANCIAL INTEREST WOULD POSE THESE RISKS, BUT IT CAN CREATE THAT PERCEPTION. THIS PERCEPTION OF BIAS CAN BE AS DAMAGING TO THE RESEARCHER AND THE INSTITUTION AS ACTUAL BIAS.

At WVU, we seek to minimize the adverse affects of conflict of interest in research and to advise faculty and staff on how to mitigate, manage, or if necessary, eliminate those conflicts. We are committed to complying with federal regulations and University policies related to disclosure, review and management of financial interests.

Each member of the West Virginia University research community must file an annual Disclosure of Interest in Research Form. **Do you have a current form on file?** To verify that your form is current contact Joy Edwards

COI EDUCATION AND TRAINING OUTREACH AVAILABLE

The WVU ORIC is pleased to offer individual as well as group COI training sessions, available at your convenience. Department visits and brief training summaries can be an invaluable resource for faculty and researchers to gain better insight from the COI Officer. We are here to help you, so please contact us for assistance. To schedule a training session or for other COI information, please contact Joy Edwards, by email or phone (304)293-5475

RESPONSIBLE CONDUCT OF RESEARCH (RCR)

WHY IS RCR SO IMPORTANT?

The objective of the Responsible Conduct of Research program is to provide graduate students, postdoctoral scholars, faculty, staff and NSF funded undergraduate students with information, training, and tools to address the increasingly complex issues that they will confront during their careers. The RCR program may be used to satisfy NIH and NSF training grant requirements for responsible and ethical conduct of research training programs.

RCR Program topics include:

- Animal Subjects Research
- Collaborative Research including Collaborations with Industry
- Conflict of Interest
- Contemporary Ethical Issues in Biomedical Research
- Data Acquisition and Laboratory Tools; Management, Sharing, and Ownership
- Export Controls
- Human Subjects Research
- Intellectual Property
- Mentor/Mentee Responsibilities and Relationships
- Peer Review
- Research Misconduct
- Responsible Authorship and Publication

WHO IS REQUIRED TO COMPLETE RCR TRAINING?

Consistent with federal mandates from the NIH (2010) and NSF (2009), UM's Responsible Conduct of Research (RCR) policy extends to all trainees who are involved in research. "Trainees" include undergraduates, graduate students, and post-docs. It also includes faculty supported by grants that explicitly include an RCR training requirement.

Persons are considered "involved in research" if they participate substantively in the design, conduct, or reporting of research. A person who is funded on a research grant is considered to be a substantive participant in research unless demonstrated otherwise.

REGULATORY UPDATES

The USDA National Institute for Food and Agriculture (NIFA) requires that all program directors, faculty, undergraduate students, graduate students, postdoctoral researchers, and any staff participating in a research project, directly supported by NIFA or as a sub-award from another entity, receive appropriate training and oversight in the responsible and ethical conduct of research (RCR) and that documentation of the completion of such training be maintained and available to NIFA.

Non-compliance can result in audit findings that can have negative impacts on individual projects – including termination – and result in institutional penalties influencing all WVU NIFA projects. Please note that, unlike RCR requirements for NIH and NSF projects where the RCR requirement extends only to post-docs and graduate students, the NIFA requirement extends to all individuals who will be working on a NIFA supported project.

For more information on WVU's compliance with this requirement, please click on the following link:http://oric.research.wvu.edu/services/responsible-conduct/usda-nifa or contact the Office of Research of Integrity and Compliance at 304-293-7073.

Sarah Stutler, MBA, CCRP
RCR Coordinator
sarah.stutler@mail.wvu.edu

For more information, please visit our Policy and Requirements page.