

Newsline

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General News

Please Welcome Our New IACUC Administrator

We would like to announce the addition of Izabella Fonseca Barbosa to our office as the new IACUC Administrator.

Izabella is from Brazil and moved to Morgantown seven months ago. She has a bachelor's degree in Trilingual Secretarial Science from the Federal University of Viçosa and a specialization course in Marketing Management from IBMEC. In Brazil, she worked for Mercedes-Benz and Noble Drilling.

You can contact Izabella by phone at 304-293-1050 or by email at izfonsecabarbosa@mail.wvu.edu.

General ORIC Contacts

Daniel Vagird, PhD Director, ORIC (304) 293-6094	Deyanira Santiago, MBA, RLATg Assistant Director, ORIC (304) 293-5791
Tracye Tennant Administrative Secretary (304) 293-7073	

Human Subjects Research & the IRB

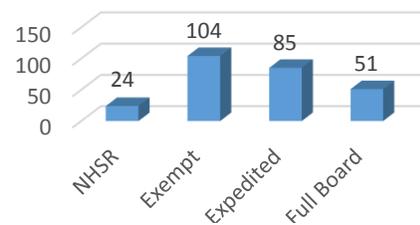
Quarter Four 2014 (October thru December) Activity Report

For the months of October, November, and December 2014, the IRB staff received 24 new not human subject research (NHSR) submissions, 104 exemptions, 85 expedited submissions, and 51 full board submissions. This brings the total number of active protocols in the KC submission system to 1,741 as of December 31st, 2014 (note that this excludes any protocols still active in the BRAAN2 system).

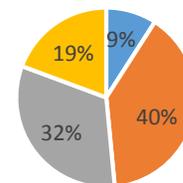
Overall, the type of review that accounted for the largest percentage of submissions in Quarter 4 was again exempt review. Exempt reviews accounted for 40 percent of the total while expedited reviews accounted for 32 percent of the total. Full board reviews accounted for 19 percent of the total, which is higher than the standard 5 percent rate.

The median approval time in calendar days for exemptions and expedited protocols were 9 days and 20 days, respectively. According to the 2013 year-end Association for the Accreditation of Human Research Protection Programs (AHRPP) nation-wide metrics, exempt acknowledgements took 17 calendar days and expedited approvals took 30 calendar days. The review type that normally requires the most review time was full board, which stood at 25 days during the third quarter. Once again, this was significantly faster than the national standard review time of 52 calendar days for full board review.

Q4: Number of Submissions by Type

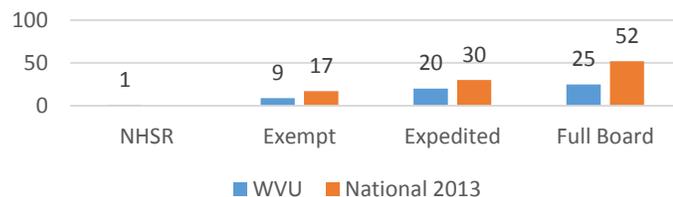


Q4: Percentage of Submissions by Type



■ NHSR ■ Exempt ■ Expedited ■ Full Board

Q4: Median Time (Calendar Days) from Receipt to Approval



Recent Changes to IRB Standard Operating Procedures (SOPs)

The IRB staff and chairs have approved recent changes to the standard operating procedures (SOPs) for the IRB. The following sections of the SOPs (found at <http://oric.research.wvu.edu/r/download/207495>) were updated in February:

- Section 3.3.4 involving procedures for exempt determination. Grant applications are no longer required to be attached to new protocols, including exempt, expedited, and full board protocols.
- Section 3.16 involving procedures for using a central IRB. The use of the Chesapeake IRB as an external IRB for multi-site studies prompted greater detail being added to this section.

- Section 5.13.1 involving re-consent. More details is given for when re-consent is needed and how to go about obtaining it.
- Section 17.12 involving case studies and case series research. Any research that uses a case study design involving only 1-3 (inclusive) subjects may now be seen as not human subjects research (NHSR).

BRAAN Unavailable After March 31st

Our office would like to remind you that, if you have a protocol in BRAAN (the previous electronic system) that has not been moved to KC after March 31st of this year, then the protocol will no longer be accessible. This means that you can no longer perform any actions on the protocol in BRAAN after that date. If you would like to continue being able to make changes to your BRAAN protocol, you should migrate the protocol to KC before March 31st. You can find instructions on how to migrate your protocol at <http://oric.research.wvu.edu/r/download/165110>.

KC Training and IRB Workshops Schedule for Spring Semester

The following is a listing of scheduled dates and times for all upcoming training and workshops being offered for the Spring Semester 2015. Unless otherwise noted, all training will take place in the [Chestnut Ridge Research Building](#), Room 209. You can click on any of the below entries to register via the WVU Calendar. Please note that registration is limited for all events.

[March 23rd 1:30 – 3:00 | KC IRB Submission System Training](#)

[March 26th 1:30 – 2:30 | IRB Workshop: Surveys, Interviews, Focus Groups, and Medical Chart Reviews](#)

[April 6th 11:00 – 12:00 | IRB Workshop: Surveys, Interviews, Focus Groups, and Medical Chart Reviews](#)

[April 13th 1:30 – 3:00 | KC IRB Submission System Training](#)

[April 15th 11:00 – 12:00 | IRB Workshop: Surveys, Interviews, Focus Groups, and Medical Chart Reviews](#)

[April 24th 1:30 – 2:30 | IRB Workshop: Surveys, Interviews, Focus Groups, and Medical Chart Reviews](#)

[May 4th 1:30 – 3:00 | KC IRB Submission System Training](#)

KC Updated on February 22nd

As of February 22nd, the following updates have been made to the KC system for IRB protocols:

- Using wildcard searching (* or %) is no longer necessary for lead unit field. Enter name of department, or part of the department name, and all associated results will display.
- *Copy* protocol action will copy all questionnaire answers for protocols using the new questionnaire implemented after the August 2014 upgrade.
- Completed CITI training courses will display on the Personnel page for each person who has been associated with a protocol. Please note: The most recent date of completion for CITI training will now be available in the personnel tab. This is an opportunity for you to confirm that all personnel's CITI training is up-to-date prior to submission.
- Permissions are editable at all times for all protocol types (i.e., no amendment required).
- Amendment/renewal approval letters indicate the board of review in the body of the letter.
- Review type of protocol is included in the email subject line that goes to a reviewer when assigned to review a protocol.
- If an amendment/renewal has already been created, the option to create another one will not be available until the current amendment/renewal has been approved.

Protocol Hints and Tips Available



The IRB staff has noticed that many of the same issues frequently being reported are stemming from the protocol creation process. As a result, we have created a very brief series of helpful hints and tips that may be used during the protocol creation process in KC. You can find the protocol hints and tips at <http://oric.research.wvu.edu/r/download/188398>. If you continue to have any problems during protocol creation, please contact Afton Wagner at Afton.Wagner@mail.wvu.edu / 304-293-5923 or Jonathan Young at Jonathan.Young@mail.wvu.edu / 304-293-1119.

Human Research & IRB Contacts

Lilo Ast, MA Sr. Program Coordinator (304) 293-7555	Barbara White HRPP Administrator (304) 293-5971
Jonathan C. Young, PhD, CIP Sr. HRPP Administrator (304) 293-1119	Afton Wagner HRPP Administrator (304) 293-5923

Animal Research & the IACUC

Implementation of a Post-Approval Monitoring Program – the “What’s” and the “Why’s”

Continuing oversight by the Institutional Animal Care and Use Committee (IACUC) of activities involving animals is required by federal laws, regulations and policies (the Guide, p. 33-34).

- Continuing IACUC oversight of animal activities is required and monitoring animal care and use is required by the PHS Policy – OLAW FAQ, Institutional Responsibilities (G6)
- The IACUC is responsible for the appropriate monitoring of animal use activity at the research facility – Animal Welfare Regulations [2.31(d)(5)]
- There must be a system for ensuring that animal procedures conform with the approved protocol or study plan – Association for Assessment and Accreditation of Laboratory Animal Care, International (AAALAC), FAQ C5

Post-approval monitoring (PAM) consists of all types of protocol monitoring after the IACUC’s initial protocol approval and can use a variety of mechanisms to facilitate regulatory compliance. Current monitoring includes semi-annual inspections of animal holding facilities, semi-annual laboratory inspections of procedural areas, investigations regarding animal welfare concerns, and annual reviews of IACUC protocols. However, adequate monitoring of approved animal activities is identified as one of the top institutional problems by regulatory and accrediting bodies. In response to the need for better understanding, oversight and assurance of compliance – in view of institutional obligations, vulnerabilities and liabilities – and in acknowledgement of the limitations of IACUC members and staff, WVU has implemented a more robust PAM program. Effective post-approval monitoring can make substantial contributions to the improvement of the animal care program, including but not limited to: quality of animal care; communication with investigators; compliance with protocols, policies and regulations; refinements and improvement of experiments, while providing better assurance for the institution.

The activities of the PAM program will complement and expand the current efforts of the IACUC to provide more complete monitoring of IACUC-approved animal activities. The goal of the PAM program is to provide the IACUC with the requisite information to assure proper oversight of activities with animals – assure compliance and protection of both animals and investigators – and to improve the animal care program. PAM is used to review animal use and the performance of procedures on animal care protocols, the practice of animal husbandry, and programmatic effectiveness. In the execution of these tasks, the PAM program can greatly enhance communication with animal users and provide education and advice.

Each investigator should expect to participate in the PAM review process in addition to the semi-annual laboratory inspections that currently occur. PAM visits could be announced or unannounced, encompassing all protocols/laboratories.

To assist with PAM, a new Quality Coordinator position has been established to serve as an agent of the IACUC. In addition to his teaching and administrative responsibilities, Dr. Stanley Yokota will be developing and leading this new post-approval monitoring program for WVU. Dr. Yokota will be a true asset to the animal care program in this role as he has served on the IACUC for seventeen years and served as chair for thirteen years. Dr. Yokota is an Associate Professor in the Physiology Department and is well known in the community of animal users. His wealth of experience and breadth of knowledge will greatly benefit the animal care program at WVU.

For more information about this new PAM program, feel free to contact Mindy Hollander 304-591-9368 or Melinda.Hollander@mail.wvu.edu.

New Policies

- Reuse of Research Animals
- Use of Pigeons in Behavioral Studies
- Forced Swim Test
- Unexpected Outcomes

Revised Policies and SOPs – make sure to re-read those that apply to your work:

- Use of non-pharmaceutical compounds
- Tail clipping
- Toe clipping
- Pain/Distress
- Use of Hazardous Chemicals
- Decapitation and cervical dislocation
- Fish and Aquatics SOP
- Mouse Anesthesia/Analgesia

And as always, please remember to always go to <http://oric.research.wvu.edu/animal/protocolsub> and use the forms posted here. This ensures that you are using the most up-to-date version of that form.

Animal Research & IACUC Contacts

[Melinda Hollander, MS, CPIA](#)

Animal Care and Use Officer

(304) 293-9368

[Izabella Fonseca Barbosa](#)

Animal Care and Use Administrator

(304) 293-1050

Conflict of Interest in Research

WVU Joins the Association of American Medical Colleges (AAMC) Forum on Conflicts of Interest (FOCI) Academe!

The Association of American Medical Colleges (AAMC) developed the Forum on Conflicts of Interest (FOCI) Academe to provide a forum for the leadership in the biomedical arena who oversee and manage conflicts of interest to promote the highest ethical and professional standards in the conduct of their institutions as they carry out their missions of patient care, research, education, business, and service. There are over 400 members from over 95 institutions.

Aside from providing us with incredible resources and feedback The FOCI Academe spearheaded the COI Metrics Project. In 2011, 73 institutions registered to participate in the Metrics project, designed to collect information readily available to participating AAMC member medical schools and teaching hospitals to measure the impact, cost, and outputs of implementing and administering the NIH Rule. It has proven to be a unique opportunity to gain perspective on the effect and effectiveness of the rule using annual aggregate data about conflict of interest programs and review processes, disclosures made by investigators to institutions, and financial conflicts of interest identified and reported to federal funding agencies. The information has also been provided to the NIH for their own retrospective review of the effect and regulatory burden of the new rule.



The findings have been pretty fascinating thus far. The results from the first surveys can be found at the following link:

<https://www.aamc.org/download/363236/data/firstresults.pdf>

Federal Demonstration Partnership (FDP) Institutional Clearinghouse

We are excited to announce that WVU is now a participating institution in the FDP Institutional Clearinghouse. This site provides a central location for educational institutions and other entities to document that they are in compliance with the PHS Financial Conflict of Interest (FCOI) rules and regulations. It is highly recommended that institutions join the clearing house as a step toward a standardized locale for institutions to find assurance that sub-recipient institutions follow the new PHS standards. For more information and to see a list of participating institutions, visit

http://sites.nationalacademies.org/PGA/fdp/PGA_070596.



WVU Electronic Disclosure of Interest in Research Form

Each member of the WVU research community must submit a Disclosure of Interest in Research (DOIR) Form annually to the Office of Research Integrity and Compliance (ORIC). This requirement must be fulfilled before your protocol can be processed through the IRB and before funds will be released by the Office of Sponsored Programs.

Please use the following link to access our new electronic DOIR

form: <http://oric.research.wvu.edu/conint/disclosure-of-interest-in-research>

For any questions or suggestions concerning conflict of interest in research please visit our website at: <http://oric.research.wvu.edu/conint> or contact Joy Edwards.

Conflict of Interest in Research Contacts

Joy Edwards COIR Officer (304) 293-5475	
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Responsible Conduct of Research

Policy Reminder

Please remember that all applicable students, fellows, and trainees on applicable protocols must adhere to the WVU Responsible Conduct of Research (RCR) [policies and guidelines](#). The ORIC encourages all faculty and staff to educate their students on the RCR [core areas](#) and principles. [Education and training](#) is available for faculty, staff, and students to facilitate adherence to these very important policies and guidelines, both in-person and online.

Responsible Conduct of Research Contacts

Daniel Vagird, PhD Director, ORIC (304) 293-6094	Jonathan C. Young, PhD, CIP HRPP Administrator (304) 293-1119
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