

Newsline

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General News

Please Welcome Our New Staff!

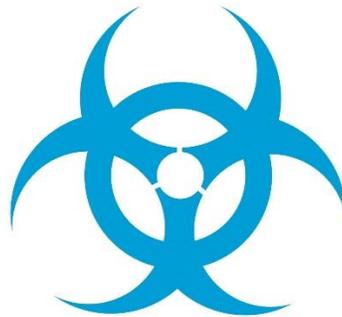
The ORIC would like to welcome two new staff members. [Tracye Tennant](#) has taken over the administrative secretary responsibilities for the ORIC) and [Amber Harbarger](#) is our new animal compliance administrative associate.

Tracye has been with the University for 12 years and comes to us from The Center for Service and Learning. She has nearly completed the Regents B.A. program here at WVU and plans on graduating in 2016 with her son. In her spare time she enjoys traveling and spending time with her family.

Amber received her AA degree in Office Business Administration from Westmoreland County Community College and is also a certified a phlebotomist. Amber has worked at WVU for 7 years and resides in Greensboro, PA where she enjoys spending time with her family, being outdoors, and learning new things.

Transfer of Biosafety Functions

In addition, you should also know that the position of the WVU Biosafety Officer and accompanying oversight responsibilities have been transferred to [Environmental Health & Safety](#). If you have any questions pertaining to biological safety at WVU, please contact John Hando at John.Hando@mail.wvu.edu or 304-293-5799.



General ORIC Contacts

[Daniel Vasgird, PhD](#)

Director, ORIC
(304) 293-6094

[Tracye Tennant](#)

Administrative Secretary
(304) 293-7073

Human Subjects Research & the IRB

Recent Changes to IRB Standard Operating Procedures (SOPs)

In recent months, the IRB SOPs have been changed in regards to the inclusion of suicide ideation measures or procedures in human research protocols. If you plan to conduct a study involving suicide ideation, please read the SOP located in section 17.11 of the [WVU IRB SOPs](#).

IRB Quarterly Report

The quarterly report for the first quarter of calendar year 2014 is now available for IRB submissions. According to the report, which includes submissions from January thru March of 2014 inclusive, there were 118 exempt, 175 expedited, and 50 full board submissions. In total, there were 343 new IRB protocol submissions during the first quarter.

The approval time for exempt submissions was approximately 9 calendar days, while the same statistic was 23 calendar days and 27.00 calendar days for expedited and full board submissions, respectively. In comparison to the last Association for the Accreditation of Human Research Protection Programs ([AAHRPP](#)) report available for the 2012 calendar year, WVU's times were faster than the national scores. Nationally, exempt acknowledgements took about 17 calendar days, expedited approvals took 30 calendar days, and full board approvals took 45 calendar days.

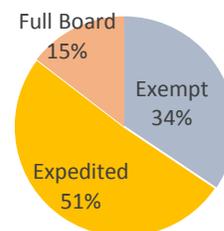
IRB Protocol Aggregators will Now Receive Email Notifications

The IRB staff and ROIT have collaborated to make a new change in the KC system. Previously, only the principal investigator (PI) would receive email notifications for transactions (e.g., revisions requests, approvals, etc.) occurring in the system. However, now anyone who is listed as an aggregator (editor) on the Permissions tab of the protocol will receive email notifications. This should help ease the gap in communication about a protocol's status that may arise from only notifying the PI and no one else on the research team.

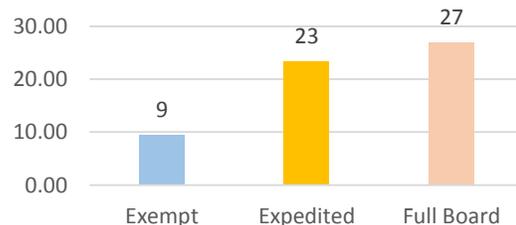
Q1: Number of Submissions by Type



Q1: Percentage of Submissions by Type



Q1: Time (in calendar days) from Receipt to Approval





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. We have tested this FAQ device with a significant number of active researchers and the results indicate that approximately 90% of protocol creation problems can be answered with this tool. 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.

Amendments No Longer Required for NHSR or Exempt Submissions

In an effort to improve the IRB process for researchers, the ORIC has recently determined that amendments that do not increase risk for participants for not human subject research (**NHSR**) or IRB **exempt** studies will no longer be required. Please note that amendments for **expedited** and **full board** reviews are still required. If you suspect that a change to your study may increase the risk to participants, then please do submit an amendment regardless of the type of review.

Two examples of changes on NHSR or exempt protocols that would not require an amendment would be if you are adding a new research team member or if you are changing question order on an anonymous, online survey. If you have questions or need help with the amendment process, please contact Jonathan Young at Jonathan.Young@mail.wvu.edu or 304-293-1119.

Human Research & IRB Contacts

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

Animal Research & the IACUC

IACUC Policies Unmasked

There are a number of IACUC policies that have been implemented to help animal users

1. prepare animal care and use protocols,
2. conduct various procedures correctly, and
3. stay in compliance.

However, there are a few important points that animal users need to know with regards to these policies.

First, animal users need to know where to find these policies. The most obvious place is the hyperlinks to the specific policies in section 10 of the animal care and use protocol. They are also listed at <http://oric.research.wvu.edu/animal/guidelines>.

Second, all animal users should know that it is now standard for all new or significantly altered IACUC policies to be posted for a 10-day public comment period. The IACUC has found that this is important to engage the animal users to ensure that the policies can be implemented as written and to create transparency with the animal users.

Third, animal users need to be aware that the policies are reviewed at least once every three years and the policy list is updated frequently so it is important to know what policies are required for your animal care and use protocol and whether those policies have been updated. Remember that any new policy or any policy that incurs significant changes is first posted for public comment and then is posted once the IACUC has approved any changes. The IACUC office will typically send out a notice when a policy or policy change is approved so keep an eye out for policies that affect you. But when in doubt, know that the policy posted at <http://oric.research.wvu.edu/animal/guidelines> is the most up to date version.



Finally, and probably most important, animal users must remember that if a policy pertains to their work, they should READ that policy and make sure to follow it! If for some reason, a certain policy cannot be followed, this needs to be indicated in section 10 of the animal care and use protocol and a justification needs to be provided. An animal user may only opt out of following a policy that is relevant to their research if they receive IACUC approval.

So remember...know where the IACUC policies are and FOLLOW THEM!! And when in doubt, call the IACUC office and ask. We are always here to help!

Animal Research & IACUC Contacts

[Melinda Hollander, MS, CPIA](#)
Animal Care and Use Officer
(304) 293-9368

[Amber Harbarger](#)
Administrative Associate
(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 Vasegird, PhD Director, ORIC (304) 293-6094	Jonathan C. Young, PhD, CIP HRPP Administrator (304) 293-1119
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