Welcome Additions to the ORIC Staff

Mary Neely joined the ORIC in November of last year as our Office Manager. Mary has been with WVU since 2012 when she started as the part-time Human Resources generalist for the Research Office. She provides an advanced level of operational and administrative support to the office, to include budgeting, accounting, human resources, customer service and is our primary point of contact.

The Human Research Protection Program (HRPP) welcomes two new administrative staff members. Gretchen McMasters, MBA, CHRC, CIP, CIM, LSSBB is the new Director of the Human Research Protection Program for WVU. As an eleven-year veteran in IRB operations, she joins us from Northern Arizona Healthcare where she oversaw IRB operations for the regional medical center.

The Institutional Animal Care & Use Committee (IACUC) welcomes Amanda Knutsen as its new Post Approval Monitoring Administrator. More information about Amanda’s new role in the office can be found on page 4.

Finally, a new student worker will be helping throughout the summer. Anna Gunter is a WVU sophomore majoring in Biochemistry with plans to attend medical school. She will be a welcome addition with her knowledge of computer applications, customer service experience, and her scientific background.

New This Issue:

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**Delay in Common Rule Revisions**

On January 17, 2018, the U.S. Dept. of Health and Human Services (HHS), along with 15 other federal agencies, announced an **Interim Final Rule (IFR)** to delay the implementation of revisions to the **Federal Policy for the Protection of Human Subjects (Common Rule)** by 6 months.

The IFR delayed the effective and general compliance date to July 19, 2018 to allow institutions further time to make and implement necessary changes to be in compliance with the 2018 revisions. The IFR is on public display and can be accessed on the website for the **Office of the Federal Register**.

HHS is collaborating with other federal departments and agencies to develop a notice of proposed rule making to further delay the effective date of the 2018 revisions until January 2019. As of now, all institutions must continue to follow the pre-2018 Common Rule until July 19, 2018. For more information regarding the Revised Common Rule and its implementation, please visit the **Office for Human Research Protections** website.

**Website Reorganization**

Over the past year, the team has updated the ORIC website making it easier to navigate and locate information. To find sections pertaining to the IRB, go to the “Services” section at the top of the screen and follow the menus to the section labeled “Human Subjects.”

The website isn’t the only information updated. Numerous **Guidance Documents** and **Form Templates** provided to the WVU Research Community have been changed and combined. These are available for everyone in the WVU Research community to reference and use for their own activities.

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**HRPP Administration Contacts**

**Gretchen McMasters**  
HRPP Director  
gretchen.mcmasters@mail.wvu.edu

**Sarah Stutler**  
Senior IRB Program Coordinator  
sarah.stutler@mail.wvu.edu

**Johnathan Herczyk**  
IRB Administrator  
johnathan.herczyk@mail.wvu.edu

**Lilo Ast**  
Temp. IRB Administrator  
lilo.ast@mail.wvu.edu

**General Contact—Mary Neely**  
IRB@mail.wvu.edu

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**IRB Training Sessions:** Staff are available to conduct trainings on a range of topics, from general IRB submissions to particular protocol types and the review process. If interested in scheduling one-on-one or department training sessions, please contact the ORIC either at 304-293-7073 or IRB@mail.wvu.edu.

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**TeamDynamix Guides for KC Users**

The Information Technology Services team publishes detailed articles and guides on common issues that users have while using the WVU+kc IRB system. The **Knowledge Base** created by ITS is not solely limited to WVU+kc, but has numerous resources for other University systems.

Reference information for WVU+kc can be found under the **Research Articles** section. Links to articles for troubleshooting **IRB module issues** can be found here.
IACUC Policy & Procedure Updates

There have been several policy and SOP updates, including one new SOP for the innovative Inhalation Facility! Please see below for a list of updated links to the documents found on the ORIC website:

<table>
<thead>
<tr>
<th>Updated Policies</th>
<th>Updated</th>
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</thead>
<tbody>
<tr>
<td>Tumor Development Endpoints for Euthanasia in Rodents Policy</td>
<td>November 2017</td>
</tr>
<tr>
<td>Care of Rodents Undergoing Survival Surgery</td>
<td>November 2017</td>
</tr>
<tr>
<td>Non-Pharmaceutical Grade Substances Used in Animals</td>
<td>September 2017</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Important Notes</th>
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</thead>
<tbody>
<tr>
<td>The Chronic Animal Monitoring Facility (CAMF) is no longer a Core Facility, therefore, the SOPs for the “Chronic Instrumentation” (mice &amp; rats) are no longer in use. If you have any questions regarding the use of the equipment, please contact Office of Laboratory Animal Resources (OLAR).</td>
</tr>
<tr>
<td>The Instructions for the submission of protocols and amendments are in the process of being updated to reflect the recent changes made to the protocol forms, as well as providing better guidance on the submission process. The instructions should be posted to the website early this summer.</td>
</tr>
</tbody>
</table>

Updated Standard Operating Procedures

<table>
<thead>
<tr>
<th>SOP Title</th>
<th>Updated</th>
</tr>
</thead>
<tbody>
<tr>
<td>Animal Models and Imaging Facility (AMIF)</td>
<td>August 2017</td>
</tr>
<tr>
<td>Rodent Behavior Core (RBC)</td>
<td>August 2017</td>
</tr>
<tr>
<td>Inhalation Facility</td>
<td>New as of February 2018</td>
</tr>
</tbody>
</table>

IACUC Administration Contacts

Deyanira Santiago
Director—Animal Welfare Program
disantiago@mail.wvu.edu

Izabella Fonesca Barbosa
Administrative Assistant
izfonsecabarrosa@mail.wvu.edu

Amanda Knutsen
PAM Coordinator
aknutsen@mail.wvu.edu

General IACUC Contact
(304)293-7073
acuc@mail.wvu.edu

IACUC Protocol & Grant Congruency

NIH Policy Statement 4.1.1.2 - “It is an institutional responsibility to ensure that the research described in the application is congruent with any corresponding protocols approved by the IACUC.” In accordance with the Public Health Service (PHS) Policy on the Humane Care and Use of Laboratory Animals, no monies will be released by the Office of Sponsored Program for awards involving the use of live animals for research and/or teaching until the Institutional Animal Care and Use Committee (IACUC) has reviewed and approved each component of the grant proposal that relates to the care and use of animals. In accordance with PHS and other granting agency policies, any and all experiments involving live animals contained within the grant must be approved by the IACUC prior to release of the grant monies. A general congruency review is performed during a pre-review of a new protocol, a three-year renewal, or any addition of funding via an amendment.
Post Approval Monitoring (PAM) Program at WVU

The Office of Research Integrity and Compliance (ORIC), in partnership with the Institutional Animal Care and Use Committee (IACUC), has redeveloped the Post Approval Monitoring (PAM) program to assist all research staff working with animals at WVU. The main purpose of the PAM program is to work with the research community to ensure quality animal work and the well-being of staff and subjects alike, in a supportive and collegial manner.

The PAM program is designed to:

1. Review approved IACUC protocol procedures. The review is meant to identify any protocol drift or any issues that may have come up since the protocol was approved. This is also an opportunity to see if any areas of the protocol could benefit from refinement.

2. Understand the training needs and records of the research staff and provide opportunities to ensure research staff is comfortable with their assigned responsibilities.

3. Provide support, education and training to all members of the research community. This could be in the form of answering questions, refining procedures or scheduling training for any member of the laboratory staff.

There are several types of PAM reviews, but one that is often overlooked is a preparatory visit. This is usually initiated by the PI or laboratory staff as they are setting up a new lab space or venturing into new procedures or techniques. If you have any questions or would like to schedule a Post Approval Monitoring visit, please contact Amanda Knutsen 304-293-5923 or email aknutsen@mail.wvu.edu

IACUC Protocol Form Updated

The Main IACUC Protocol Form was updated in December 2017. The most significant change was made to Section 9, which includes an updated chart for euthanasia methods. The IACUC Personnel Additions form, as well as Appendix C and Appendix K have also been recently updated. All protocol forms are available on the ORIC website.

Before submitting renewals or new protocols, be sure to check the website for the most recent versions.

A New PAM Coordinator Joins the IACUC Team

Amanda Nieman Knutsen joined the Office of Research Integrity and Compliance in January 2018 as a Post Approval Monitoring Administrator. She is a Registered Veterinary Technician (RVT) and has been with West Virginia University since 2005. As a Post Approval Monitoring Administrator, her responsibilities include meeting with Principal Investigators and staff approved to work with animals, observing the procedures they do and acting as a liaison between the research community and the IACUC.

If you have any questions or concerns, or if you would like to schedule a meeting with the new PAM administrator, please call 304-293-5923 or email aknutsen@mail.wvu.edu.
WVU IRB Exceeds National Average

The WVU IRB members and staff continue to work at improving the submission and review process for human subjects research protocols. The WVU IRB exceeded the averages reported by other academic institutions nationwide in 2017— for all protocol types as seen in the graph below.

Full Board protocols reviewed by the WVU IRB take an average of 27 days to be approved, surpassing the national time of 45 days. Expedited protocols reviewed by the WVU IRB (12 days) are approved an average of 8 days faster than the national average (20 days). Exempt submissions are also acknowledged twice as fast by the WVU IRB than the national average. While the WVU IRB is proud of this review record as it applies to process times, more improvements are on the horizon.

Be on the lookout!

The chart to the right compares the frequency of submissions from January—May of 2017 and 2018. Not only has the volume of submissions stayed relatively consistent but the variety of protocol types have been steady as well. Exemptions make up approximately 43%, expedited protocols are 52%, and full board protocols are 5% for the two quarters of the past two years.

IACUC Review Statistics

The WVU IACUC has an average approval time of 32 days over the past six months. Amendments take approximately 11 days to review, revise and approve. This value accounts for the time from the time of initial submission, time to address any revisions requested by the committee, and the time to review the protocol.
COI Submission Change

Late this summer, a time-saving Conflict of Interest (COI) module will be available in WVU+kc, replacing the current Wufoo form and dramatically reducing manual effort for both researchers and administrators. Easily accessible from the Kuali dashboard, this module will simplify and centralize the process of completing and managing COIs in one convenient, secure location. It will do so with an attractive new, user-friendly interface.

“This is going to revolutionize the process,” said Joy Edwards, Director, WVU Conflict of Interest in Research.

Because the new COI module will be integrated directly into WVU+kc, it auto-populates your information and reduces the risk of human error. No more repeatedly filling out things like contact and business data for different projects. And if you’ve previously submitted a COI via the Wufoo form, your information will be imported automatically into the new module.

Information Technology Services will provide periodic updates on this project. Documentation and training materials will be available for users, as well.

This module and the requirements related to it apply only to research, not other forms of conflict of interest across the University.

Please direct questions to Joy Edwards, 
Joy.Edwards@mail.wvu.edu.

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.