



The West Virginia University Office of Research Integrity & Compliance (ORIC)

ORIC is committed to helping faculty, staff, and students comply with all applicable federal, state, and institutional requirements and policies. Research integrity and compliance areas covered by this office include human research protections, animal welfare, biosafety, conflict of interest in research, export control and the responsible conduct of research. The ORIC Newsline online newsletter has the goal of keeping the WVU research community informed and up-to-date on policies and procedures, guidelines, educational programs, regulatory changes, and monitoring and accountability in these areas.

CONTENTS

Introduction	1
Human Research Protections	2
Responsible Conduct of Research	5
Animal Care and Use	6
Biological Safety	8
Conflict of Interest in Research	9
Other Announcements	10

<u>Daniel Vasgird, PhD</u>

Director, Office of Research Integrity and Compliance (304) 293-6094 DRVasgird@mail.wvu.edu

Kimberly Yoney

Administrative Secretary (304) 293-7073 Kimberly.Yoney@mail.wvu.edu



HUMAN PROTECTION

Lilo Ast, MA

Senior Program Coordinator (304) 293-7555 Lilo.Ast@mail.wvu.edu

Barbara White

Senior Administrative Assistant (304) 293-5971 Barb.White@mail.wvu.edu

Jonathan C. Young, MA

Office Administrator (304) 293-1119 Jonathan.Young@mail.wvu.edu

The ORIC will be conducting training for the new WVU+kc system on a regular, weekly basis.

Exemptions and NHSRs can now be submitted using the WVU+kc system.

Update on the New System, WVU+kc

The WVU+kc electronic research administration system will become available to faculty and staff on a rolling basis for the submission of **new exempt human research (IRB) protocols** (e.g., surveys, interviews, medical reviews, questionnaires). WVU+kc is being implemented to replace the BRAAN2 submission system and all exempt protocols will be required to be submitted through the new system in the near future.

Training is required to access WVU+kc and sessions will be offered by the Office of Research Integrity and Compliance (ORIC). Training sessions will be held on Mondays and Tuesdays from 1 to 3 p.m. in Room 209 of the Chestnut Ridge Research Building. **To sign up** for a training date, please click here. Search under Keyword (near the top right), and type in "wvu+kc," then press enter. You will want to click on the training date you prefer, then click *register* at the top right of the screen.

ORIC will provide PCs for the training sessions, but if you are a Mac user and would prefer to bring your own laptop to training, that is acceptable as long as it has wireless internet capabilities. If for some reason you cannot register with the WVU Calendar, please contact the ORIC by emailing Kimberly Yoney at Kimberly.Yoney@mail.wvu.edu. Due to limited seating at each session (a 15 person maximum), it is suggested that you register early to be able to attend the session you desire. When you arrive, parking passes for parking lot 85 will be posted on the front door of the building.

If you are working on a research team, at least one person from the team must attend a training session in order to provide guidance to the rest of the team on how to use the system. If you cannot attend training on one of the days listed, contact the ORIC in order to discuss other training options available.

The WVU+kc system will be available for the submission of new not human subject research (NHSR) submissions and new exempt protocols only. Higher level reviews that involve greater risk to the participants, such as expedited and full board protocols, should continue to be submitted through BRAAN2 until further notice.

If you are interested in learning more about the WVU+kc system, visit the project website at kuali.wvu.edu. Additional training documents are available online including short videos and downloadable handouts. For updates regarding future training dates and future protocol submission dates, sign up for the ORIC listserv or follow the WVU+kc project on Facebook, GHC listserv or follow the



HUMAN PROTECTION

Lilo Ast, MA

Senior Program Coordinator (304) 293-7555 Lilo.Ast@mail.wvu.edu

Barbara White

Senior Administrative Assistant (304) 293-5971 Barb.White@mail.wvu.edu

Jonathan C. Young, MA

Office Administrator (304) 293-1119 Jonathan. Young@mail.wvu.edu

Exemptions in the WVU+kc system will only be active for a maximum of 3 years.

Two key criteria must be met for medical records research to qualify as a category 4 exemption.

Three Year Expiration of Exemptions

Please note that, in the WVU+kc system, exemptions will expire after 3 years of activity. If you would like to continue your study past 3 years, you will need to submit another exemption. There will be no continuing review process for exemptions.

Changes for Medical Records Research

Research studies involving the collection of data from medical records may qualify as exempt from review under category 4 provided that the following two criteria are met:

- 1. The data must exist at the time of the exemption application. Studies wishing to collect data from the medical records of patients who have NOT YET BEEN SEEN clinically would not qualify for exemption.
- 2. The data must be recorded without codes or links to patient identifiers (i.e. the medical record number (MRN)). For example, researchers often obtain a list of MRNs patients with a specific condition being studied that they then use to locate medical records for the purposes of data collection. As long as no code or link is assigned to each patient that would allow linkage of the collected data and the specific medical record, this type of research may qualify for exemption. However, researchers wishing to assign such a link to enable revisiting of the medical record would need to apply for expedited approval. A HIPPA waiver application should be submitted for both review types (exempt an expedited), and a consent form waiver will need to be submitted for medical records research not qualifying as exempt category 4.

Human Research Protections

4



HUMAN PROTECTION

Lilo Ast, MA

Senior Program Coordinator (304) 293-7555 Lilo.Ast@mail.wvu.edu

Barbara White

Senior Administrative Assistant (304) 293-5971 Barb.White@mail.wvu.edu

Jonathan C. Young, MA

Office Administrator (304) 293-1119 Jonathan.Young@mail.wvu.edu

The post-approval guide is now available on the ORIC website.

New Post-Approval Guide Available

The ORIC has created a post-approval guide for use by researchers who have already had their research approved by the IRB. This guide covers several specific areas of interest for principal investigators and their research team, including:

- Principal Investigator (PI) Responsibilities and Delgation of Authority
- Recordkeeping
 - o Security/HIPAA
- Training Personnel
- Amendments
- Adverse Events, Protocol Deviations, and Violations
- Renewal/Continuation Submissions
- Informed Consent
- Study Closure and Document Retention

This guide is available at

http://oric.research.wvu.edu/r/download/141149.

Responsible Conduct of Research

More Information Available on our Website

Our website has recently been updated to include more extensive information about the Responsible Conduct of Research (RCR). A more robust explanation of the program is now available, including a streamlined section on Education & Training and policy requirements. Head over to http://oric.research.wvu.edu/rcr train to take a look.

Why is the Responsible Conduct of Research Important?

Over the last decade, research compliance and the responsible conduct of research have received increasing attention and responsive action from the scientific community. The broad forces behind that heightened consideration are the increasing potential rewards that can be garnered from innovation and the changing scale of research. The more specific driving factors are an increase in regulatory requirements, the influence of publicized compliance breakdowns at institutions of higher education, and heightened scrutiny from the media, advocacy groups and government. An added element is the idealistic desire of many scientists to attain a high ethical standard while practicing what many perceive as humanity's best hope for advancement to a more supportive and fulfilling existence, namely the scientific enterprise. The practical side of all this reflection and action can be summarized in a line from the recent National Academies publication Integrity in Scientific Research: "The public will support science only if it can trust the scientists and institutions that conduct research."

However, trust has to be thought of in its broadest sense and not just applicable to the individual research practitioner. Research institutions will only flourish when those who support them and ultimately make use of their product, i.e., the public, have high regard for their ways and means. Many academic institutions such as WVU have internalized this insight and have expanded their responsible conduct of research (RCR) training programs concomitantly to meet the needs of a more demanding and competitive era. The National Institutes of Health (NIH) have had an RCR education and training requirement in place for their training grants for nearly two decades, and WVU has offered courses to meet that requirement. The new initiatives are in response to recent federal requirements but are in keeping with the University's avowed commitment to academic integrity as specified in its Academic Integrity Committee Policy to be found at the following web address:

 $\frac{http://www.wvu.edu/\sim lawfac/mmcdiarmid/aic/Final\%20RIC\%20Policy\%}{20WVU\%205-9-11.pdf}$

For questions, concerns, and inquiries please contact Jonathan Young by email at Jonathan.Young@mail.wvu.edu or by phone at (304) 293-1119.



RESPONSIBLE CONDUCT

<u>Daniel Vasgird, PhD</u> Director, Office of Research Integrity and Compliance

(304) 293-6094 DRVasgird@mail.wvu.edu

Jonathan C. Young, MA
Office Administrator
(304) 293-1119
Jonathan.Young@mail.wvu.edu

The responsible conduct of research has gained increasing attention over the past decade.

NSF and NIH-funded studies should visit our website or contact our office to make sure compliance has been achieved.

ANIMAL CARE & USE

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

Robin Anderson Animal Care and Use Administrative Associate (304) 293-1050

Robin.Anderson@mail.wvu.edu

Important dates:

- IACUC meetings are the first Wednesday of every month
- Protocols and amendments are due on the 15th of each month

Important resources:

- The IACUC newsletters can be found at http://oric.research.wvu.ed u/animal/iacuc newsletter <a href="mailto:s
- The IACUC approved policies and those up for public comment can be found at http://oric.research.wvu.edu/animal/guidlines

Animal Care and Use

Some Important Points IACUC Reviewers Look for in an Animal Care and Use Protocol

In order to approve proposed use of animals for research or teaching or proposed changes in ongoing research projects or instruction involving animals, the IACUC must review those components related to the care and use of animals and ensure that the proposed activities are in accordance with Public Health Service Policy, Animal Welfare Regulations, and the applicable U.S. Government Principles.

The *Guide for the Care and Use of Laboratory Animals* gives very specific topics that should be considered in the preparation of an animal use protocol and its review by the IACUC. Listed below are some of the "must" statements that the committee is specifically looking for an answer to. The sections in the WVU Animal Care and Use Protocol form that these "must" statements pertain to are listed in italics.

1. LAY SUMMARY (section 7)

- a. There <u>must</u> be a clear rationale and purpose of the proposed use of animals.
- b. There <u>must</u> be a statement of benefit (i.e., benefit to society, benefit to animal health, benefit to the advancement of science).
- c. The IACUC is obliged to weigh the objectives of the study against potential animal welfare concerns.

2. EXPERIMENTAL DESIGN (section 8.A)

- a. There <u>must</u> be a clear and concise sequential description of the procedures involving the use of animals that is easily understood by all members of the committee.
- The above <u>must</u> be done for <u>each</u> group of animals in the study.
- c. A flow chart can often add clarity and use of one is strongly encouraged.

3. JUSTIFICATION OF NUMBERS (section 8.B)

- The number of animals used for each study <u>must</u> be justified.
- b. Whenever possible, the number of animals and the experimental group sizes should be justified statistically (e.g., provision of a power analysis).

4. CATEGORY "E" (Appendix G)

- a. Humane endpoints <u>must</u> be described and justified.
- b. There <u>must</u> be justification regarding why a less invasive or less painful procedure cannot be used to achieve the study objectives.



ANIMAL CARE & USE

Melinda Hollander

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

Robin Anderson

Animal Care and Use Administrative Associate (304) 293-1050 Robin.Anderson@mail.wvu.edu

Important dates:

- IACUC meetings are the first Wednesday of every month
- Protocols and amendments are due on the 15th of each month

Important resources:

- The IACUC newsletters can be found at http://oric.research.wvu.ed u/animal/iacuc newsletters
- The IACUC approved policies and those up for public comment can be found at http://oric.research.wvu.ed u/animal/guidlines

- 5. HUMANE ENDPOINTS (Appendix A, items 5 & 6; Appendix B, item 4; Appendix F, item 4)
 - a. The criteria and process for timely intervention, removal of animals from a study or euthanasia if painful or stressful outcomes are anticipated <u>must</u> be clearly stated.
- 6. MONITORING OF ANIMALS (Appendix A, items 4 & 5; Appendix B, item 3)
 - a. There <u>must</u> be a clear description of how often animals will be monitored after a potentially painful/distressful procedure.
 - b. There <u>must</u> be a clear statement regarding what personnel will be looking for to determine pain/distress in an animal during this monitoring.

7. EUTHANASIA (section 9)

- a. Even if the endpoint of the study is NOT death, a method of euthanasia <u>must</u> be indicated to account for the unlikely event that an animal needs to be euthanized.
- b. A secondary method of euthanasia to ensure death <u>must</u> be included.

8. PERSONNEL TRAINING AND QUALIFICATIONS (section 3 & 4)

- a. Personnel who will be involved with activities involving animals <u>must</u> be adequately trained with regard to the specific procedures they will be responsible for.
- b. Training and qualifications <u>must</u> be specific to the species being proposed.
- c. The roles and responsibilities for all personnel listed on the protocol, including the PI, <u>must</u> be included.

9. SURGICAL PROCEDURES (Appendix A)

- a. Appropriate anesthesia, analgesia, or sedation <u>must</u> be used at the appropriate doses for each species.
- b. A description of the specific surgical procedure <u>must</u> be included.
- c. Reference to the Rodent Surgery and Post-Operative Care WVU IACUC Policy <u>must</u> be included if the general surgical procedures described in that policy will be followed. If anything in that policy cannot be followed, justification and a clear description <u>must</u> be included.
- d. Post-procedural care and observation <u>must</u> be clearly stated with inclusion of postsurgical assessment forms.

Biological Safety

Biological Safety

The new West Virginia University Exposure Control Plan has been posted to our website. You can find the plan at

http://oric.research.wvu.edu/r/download/137908. Please note that this plan applies to non-hospital personnel only. When you download the policy, you can tailor it to the specific needs of your laboratory.

The WVU Sharps Policy is available at http://oric.research.wvu.edu/r/download/133854.

As part of the Bloodborne Pathogen (BBP) training, trainees will now also be required to sign a form indicating that they have or have not received the Hepatitis B vaccination.

The information regarding lab location and principal investigator or lab contact name is now being captures to develop a biosafety level 1 (BSL1) and biosafety level 2 (BSL2) database.



BIOLOGICAL SAFETY AND EXPORT CONTROL

Smitha Rayadurg, DVM, PhD, SM (NRCM), CBSP
Biosafety and Export Control Officer
(304) 293-7157
vrayadurg@mail.wvu.edu

Afton Wagner

Biosafety and Export Control Student Worker (304) 293-5791 Afton.Wagner@mail.wvu.edu

The WVU Exposure Control Plan (ECP) has been posted to the website.

The WVU Sharps Policy is now posted to the website.



CONFLICT OF INTEREST

Joy Edwards
Office Administrator
(304) 293-5475
Joy.Edwards@mail.wvu.edu

New University regulations regarding COIR went into effect on August 24^{th} , 2012.

Part of the new regulations requires COIR CITI training for all researchers.

For more information, please visit our website at http://oric.research.wvu.edu/c onint.

Changes in Regulations

As many of you may be aware, new requirements regarding conflicts of interest in research (COIR) funded by the Public Health Service were enacted into law last summer. Detailed information can be found at the DHHS website. These regulations will become effective on August 24, 2012. These are the first revisions to the regulations since 1995 and will require changes in the existing WVU guidelines and procedures regarding conflict of interest in research, including the introduction of newly required components, such as mandatory training and investigator reporting.

The Office of Research Integrity and Compliance (ORIC) has worked hard to try to minimize the burden the new regulations will place on our researchers. However, there will be some changes that will require advanced planning by our Pl's. The new regulations are extensive but the most important changes to the WVU Guidelines and procedures include these requirements:

- **Disclosure:** For **each** proposed research activity, regardless of funding source, all PI's and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of current or proposed research, (including collaborators, consultants, and students) **must** complete a Disclosure of Interest in Research (DOIR) Form before final approval can be given.
- Training: All investigators must complete the Collaborative Institutional Training Initiative (CITI) training modules on COIR before engaging in any research activity; training must be completed every four years thereafter. The course can be completed by going to http://www.citiprogram.org and following the instructions located at http://oric.research.wvu.edu/r/download/120167. The ORIC will check to insure completion of the training and testing. (Note: The CITI COIR course is different from the CITI IRB course and will require about 15 minutes to complete.)
- Travel: Investigators receiving PHS funding (including NIH) must disclose the occurrence of all reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available) related to their institutional responsibilities, within 30 days of such travel. This policy does not apply to travel that is reimbursed or sponsored by a federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

Other Announcements

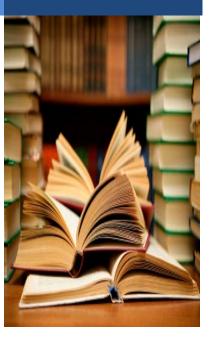
Schedule of Upcoming ORIC Presentations

To access the ORIC calendar of upcoming events and presentations, please click here. Search under Keyword (near the top right), and type in "research integrity," then press enter. You will want to click on the event you would like to find more information about. If the event requires registration, you will need to click *register* at the top right of the screen.

The ORIC, Now on Facebook

The ORIC now has a presence on Facebook at http://www.facebook.com/pages/West-Virginia-University-Office-of-Research-Integrity-Compliance-ORIC/299775123444843.

Please "like" the WVU ORIC Facebook page so you can receive regular and immediate updates on policies, WVU+kc, new developments, and more.



OTHER ANNOUNCEMENTS

Kimberly Yoney Administrative Secretary (304) 293-7073 Kimberly,Yoney@mail.wvu.edu