



ORIC newsline

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.

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Human Research Protections



HUMAN PROTECTION

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WVU+kc has been released for NHSR submissions only.

Summer is a great time to submit your IRB protocol.

Please do not hold submissions for the full release of WVU+kc.

Update on the New System, WVU+kc

As you may be aware, the Office of Research Integrity and Compliance (ORIC) has announced the first release of the WVU+kc electronic research administration system for the submission of IRB documents. The system is immediately available for the submission of **Not Human Subject Research (NHSR) documents only**. NHSR documents apply only to those projects that may need to be submitted to the **IRB** and may potentially involve human subjects and/or human-related data.

Training on the use of the new electronic system is required to gain access. Please note that this training is not the standard CITI ethics training; this is a separate, short training course (taking perhaps 10-15 minutes) designed exclusively for use of the new system. The training can be completed on your own through the online videos, through 1-on-1 remote training, or by scheduling a 1-on-1 session with the ORIC. Specific instructions for completing the training and requesting access can be found on the WVU+kc website at <http://kuali.wvu.edu/wp-content/uploads/ORG12-NHSR-Submission-Training.pdf>. Access to the system must be requested via an online form after reviewing all applicable training videos and downloadable handouts.

For more information about the WVU+kc system, visit the project website at <http://kuali.wvu.edu>. For updates regarding training and future protocol submission release dates, sign up for the [ORIC listserv](#) or follow the project on [Facebook](#), [G+](#), or [Twitter](#)."

For all other IRB submissions, to include exempt, expedited, and full board studies, please continue to submit using BRAAN 2 at <http://ecomp.wvu.edu>. Please do not hold your submissions for the full release of WVU+kc

Consider Summer IRB Submission

For any researcher that is planning to conduct a research project that will involve human research subjects, the summer season is an excellent time to [submit your project for IRB review](#).

The fall semester is always the busiest semester with new students and faculty arriving at the University. With this in mind, we encourage you to call our office at (304) 293-7073 if you need any guidance for your study or call (304) 293-1119 to begin the process of creating your protocol for approval for any future study.

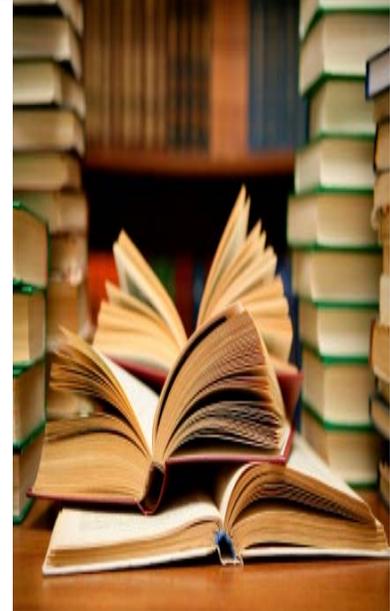
Adoption of New University-wide Policy

West Virginia University administration has adopted a new Responsible Conduct of Research (RCR) Education Policy for all new incoming graduate students, postdoctoral fellows, and faculty members. This new policy will go into effect on August 16, 2012. Therefore, all new graduate students, postdoctoral fellows, and faculty hires must take the CITI RCR course and receive a passing grade of 80% or better within 30 days of the beginning of their tenure at WVU.

The Office of Research Integrity and Compliance (ORIC) will publish a training list derived from the CITI website database of those who have taken the training. This list will be published daily on the ORIC website (<http://oric.research.wvu.edu>) in the "Training Lists" section. Each department (preferably utilizing a full-time staff person or office administrator) will then be responsible for ensuring that each incoming graduate student, postdoctoral fellow, and faculty member in the department has completed the most applicable RCR online courses via CITI by using the daily list.

Training checks should be done on all incoming faculty and graduate students at the beginning of each semester (Fall, Spring, and Summer). Furthermore, training checks should be done whenever a new faculty member or graduate student arrives at the University during any semester on any non-regular date. If any faculty member or graduate student remains out of compliance for more than 30 calendar days, then he or she must be reported as being in non-compliance to the ORIC. The ORIC will then take any necessary action. Audits will be conducted by the ORIC on random departments within the University every 30 days to ensure that departments are fulfilling their responsibility for conducting appropriate training checks.

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



RESPONSIBLE CONDUCT

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All new incoming graduate students, postdocs, and faculty must comply with the new policy starting on August 16th, 2012.

The ORIC will perform audits on a random department every 30 days to ensure compliance.



ANIMAL CARE & USE

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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.edu/animal/iacuc_newsletters
- The IACUC approved policies and those up for public comment can be found at <http://oric.research.wvu.edu/animal/guidelines>

Laboratory Inspections

Laboratory inspections and annual reviews are an important part of the continuing review process for Animal Care and Use protocols. However, because of new areas of emphasis in the 8th Edition of the Guide for the Care and Use of Laboratory Animals, the WVU Animal Care and Use Committee (IACUC) will be making some changes in these two areas.

The federal regulations state that all Animal Care and Use protocols must be reviewed on an annual basis for continuing approval. Therefore, beginning in June 2012, all Principal Investigators who have animal protocols will receive a form titled "Self Report Form and Protocol Renewal Application" which must be completed for each protocol and returned to the Animal Compliance and Training Officer. This form asks questions specific to the Animal Care and Use protocol and will be reviewed by one or more IACUC members. The purpose of this form is to determine if anything needs to change, be added, be removed, etc. If you would prefer to discuss the questions on the form with an IACUC member or the Animal Compliance and Training Officer in person, the phone number of the IACUC office is at the top of the form and a face to face meeting can be arranged. Please be sure to answer all of the questions on this form thoroughly to ensure an accurate review can be accomplished and that all protocol information is up to date.

The second change is with regards to laboratory inspections. Federal regulations require that the IACUC inspect all animal holding and procedure areas at least once every 6 months. Therefore, Animal Care and Use protocols that involve animals being moved from their general holding room (e.g., vivarium) to other areas (e.g., laboratories), for any reason, will require inspection of those procedure areas for continuing approval of the protocol. An IACUC member will contact you to set up these inspections a month or two before they are due to be completed. In addition to these laboratory inspections every 6 months, we will soon be starting a Post-Approval Monitoring (PAM) program. These PAM sessions will be a more in depth and thorough review of Animal Care and Use protocols and the procedure areas. They will also typically involve observation of one or more procedures listed in your protocol. This program is being established to satisfy the requirement that ensures all personnel listed on Animal Care and Use protocols are properly trained in the procedures that they are responsible for. Post-Approval Monitoring is designed to create an open dialog between animal users and various members of the Animal Care and Use staff (e.g., IACUC members, veterinary staff, compliance staff) to identify potential problems and establish a solution before problems become significant.

As always, please feel free to call anytime with any questions that you may have!



IACUC Policies, Standard Operating Procedures and Guidelines

Do you ever wonder what IACUC policies, SOPs or guidelines exist at WVU? Well, here is a list, which can also be found at <http://oric.research.wvu.edu/animal/guidlines> with hyperlinks to the exact policy or procedure!

IACUC Standard Operating Procedures

[Environmental Enrichment in Animals](#)
[Fish and Aquatics SOP/Guidelines](#)
[Procedures for Handling Streptozotocin](#)
[SOP for Usage of Radioactive Materials in Animals](#)
[Submission of ACUC Protocol Amendments](#)
[Use of BrdU and Other Thymidine Analogues SOP](#)

ANIMAL CARE & USE

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IACUC Policies

[Acclimation of New Arrivals](#)
[Breeding and Weaning of Rats and Mice at WVU](#)
[Calibration of Vaporizers](#)
[Euthanasia by Decapitation](#)
[Housing Two or More Rodent Species](#)
[Non-Pharmaceutical and Pharmaceutical Grade Compounds Used](#)
[Pain and Distress Policy](#)
[Peri-Operative Care of USDA Regulated Species](#)
[Policy for Tail Clipping](#)
[Policy for Toe Clipping](#)
[Rodent Surgery and Post-Operative Care at WVU](#)
[Rodent Tumor Policy](#)
[Use of Potentially Hazardous Chemicals in Vivarium Animals](#)

IACUC Guidelines

[AMIF Boilerplate Language for ACUC protocols](#)
[Guidelines for Mouse Anesthesia and Analgesia](#)
[Rat Anesthesia and Analgesia Guidelines](#)
[Review of Minor ACUC Protocol Modifications](#)
[Rodent Counting Guidance](#)

Biological Safety

The WVU OLAR Animal care personnel attended the training on the awareness of working in animal facility housing the Lab animals infected with the Respiratory Syncytial virus.

The WVU Exposure Control Plan (ECP) will be posted at the ORIC Biosafety website under the title of 'Bloodborne Pathogen Standard'. The ECP document is a part of the (Bloodborne Pathogen) BBP Training. The Lab Supervisors must make sure that the ECP in their labs is available to all their Lab employees.

The trainees completing the BBP Training will have to sign the Hepatitis B Vaccination acceptance or declination form which is also a part of the BBP training. The form will be posted online at the ORIC, Biosafety BBP website. The WVU Sharps Policy is about to be posted at the WVU ORIC Biosafety website. All lab personnel are required to refer to the WVU Sharps Policy regarding appropriate use & disposal of sharps.

The contact personnel are being assigned to oversee the Biohazard disposal at various colleges of the WVU Downtown campus as a part of the WVU Biohazard waste management program.

The CITI Biosafety training assignment list has been finalized. Completing the Biosafety training required by the WVU Institutional Biosafety Committee (IBC) is mandatory prior to receiving the IBC Approval letters for the approved IBC protocols. Also, submitting any information to the WVU Biosafety Officer as required by the WVU IBC is mandatory prior to receiving the IBC Approval letters for the approved IBC protocols.

The development of the required policies, guidelines & documents for the WVU Biosafety program is ongoing.

Export Control

The WVU ORIC is implementing a process in place to abide by the Export Control Regulations by The WVU Faculty & Staff who travel overseas. The WVU Faculty 7 Staff traveling overseas will be required to sign off on the WVU Academic travel information form & submit the form to the WVU Export Control Officer. If necessary, a second step requiring an in-depth review of the overseas travel will be conducted by the WVU Export Control Officer. The Academic Travel document has been modified & is undergoing review. The updated forms will be posted at the ORIC Export Control, Academic Travel website.

The I-129 questionnaire for deemed export verification has been modified. The 2 questionnaires have been merged into 1 questionnaire to make it convenient for the users. After the review process, the form will be posted at the WVU ORIC Export Control, I-129 Certification website. The CITI training on Export Control for WVU Staff & Faculty is being reviewed prior to its implementation.



BIOLOGICAL SAFETY AND EXPORT CONTROL

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The WVU Exposure Control Plan (ECP) will be posted on the website soon.

Completion of CITI biosafety training is now mandatory before receiving IBC approval letters.

The I-129 deemed export verification questionnaire has been modified.



CONFLICT OF INTEREST

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New University regulations regarding COIR go into effect on August 24th, 2012.

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

New 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 (<http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf>). These regulations will become effective on August 24, 2012. These are the first revisions to the regulations since 1995 and will require changes in our existing policies and procedures regarding conflict of interest in research, as well as the introduction of newly required components, such as mandatory training and reporting.

In order to comply with these new federal regulations, a number of changes and improvements to our COI system have been or are in the process of taking place. For example, the CITI COI training is currently being developed and a web-accessible travel reporting instrument is under construction. WVU policies on Conflict of interest in Research have been substantially updated, reviewed, and upon final approval, will go into effect in late August, 2012.

The new regulations are extensive but the most important changes to our policies and procedures include:

- The institution, not the faculty member, must determine whether a faculty member's outside interests overlap with/are related to their institutional responsibilities and if so, if they are related to their research/scholarship responsibilities (and specifically to PHS funded research). If that is the case the institution must determine whether a financial conflict of interest (FCOI) exists, rather than allowing the faculty member to make this determination.
- 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.
- All investigators must complete CITI training on COI before engaging in any PHS-funded research; training must be completed every four years thereafter.
- Almost all travel reimbursements must be reported.
- The threshold at which a personal financial relationship or interest is deemed significant will be decreased from \$10,000 in the current policy to \$5,000 in the 2012 revision. If that financial relationship or interest is related to a faculty member's institutional responsibilities and it is determined to have the potential to have a direct and significant effect on the research, or the research on the financial interest, then an FCOI (Financial Conflict of Interest) exists.



CONFLICT OF INTEREST

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- When a FCOI exists, institutions must assure the NIH that they have managed the FCOI related to a specific PHS funded project before an award can be accepted for that project and any monies spent. This assurance needs to be updated annually and as new FCOIs occur.
- The amount of information that must be reported to the NIH if a FCOI exists is significantly increased.
- Institutions must make readily accessible to the public, certain information concerning FCOIs that overlap with PHS funded awards.
- If noncompliance with regulations is found, a series of significant review procedures are required to take place.

We have 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 PI's. We will provide updated information on new WVU COIR requirements throughout the summer.

New University regulations regarding COIR go into effect on August 24th, 2012.

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

The Availability of the ORIC Responsibility Matrix

The ORIC website is now host to the ORIC responsibility matrix. The WVU research integrity and compliance matrix is a comprehensive easy-to-use source of information about the policies, education and training programs, forms, processes and leads on accessing ORIC services and can be located at <http://oric.research.wvu.edu/responsibility-matrix>.

This matrix was developed to facilitate the responsible conduct of research at WVU by providing its investigators with a single point of access for policy information, education & training programs, forms & submission processes, and more related to research integrity and compliance

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.

More News on WVU+kc

More information about the new WVU+kc electronic administration system can be found at <http://wvutoday.wvu.edu/n/2012/05/24/kill-the-paperwork-wvu-goes-online-with-simpler-electronic-system-to-facilitate-the-work-of-faculty-researchers>.



OTHER NOTIFICATIONS

The ORIC website now has a responsibility matrix for easy access.

The ORIC now has a presence on Facebook.

WVU news has released a piece on the new WVU+kc system.