



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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[Daniel Vasgird, PhD](#)

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 Research Protections



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

All new submissions and changes to existing approved research studies will soon need to go through the WVU+kc system.

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

Update on the New System, WVU+kc

The WVU+kc (KC) electronic research administration system will soon be replacing the BRAAN submission system entirely. Currently, all not human subject research (NHSR) and exempt submissions must be submitted via KC, including all amendments associated with already existing exempt submissions. Expedited and full board/quorum submissions may currently be submitted in either system. However, in the near future, we will be requiring all new submissions and changes (including amendments, renewals, deviations, etc.) to currently approved research be submitted in the KC system.

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 particular Mondays 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.

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](#), [G+](#), or [Twitter](#).

Upcoming Fee Increases for Particular Submissions

Beginning on April 1, 2013, fees for submission of industry-sponsored research involving human subjects will be increased for both initial submissions and renewals. In addition, a charge will be assessed for every amendment involving human subjects on industry-sponsored research. The new fees follow:

- \$2,500 for an initial review for industry-sponsored research involving human subjects;
- \$1,000 for a renewal for industry-sponsored research involving human subjects;
- \$500 for an amendment for industry-sponsored research involving human subjects.

Responsible Conduct of Research

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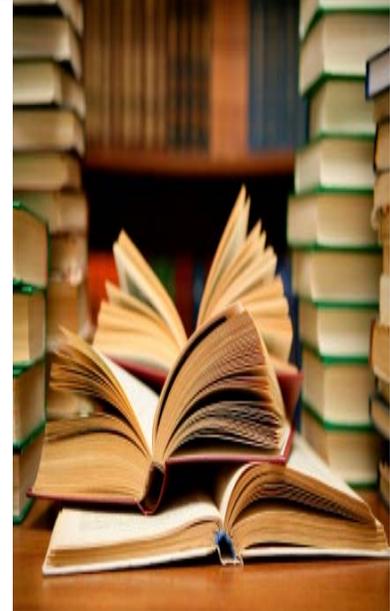
Why is the Responsible Conduct of Research Important?

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:

<http://www.wvu.edu/~lawfac/mmcidiarmid/aic/Final%20RIC%20Policy%20WVU%205-9-11.pdf>

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

[Daniel Vasgird, PhD](#)

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 and Use



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

Afton Wagner

Animal Care and Use
Student Worker
(304) 293-5791
Afton.Wagner@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 approved policies and those up for public comment can be found at <http://oric.research.wvu.edu/animal/guidlines>

Animal Care and Use Approved Protocol Formats

The IACUC office is sending the approved versions of animal care and use protocols to PIs along with approval letters upon approval of the protocol or amendments. Please note that this approved version is being sent out in a pdf format with a watermark on every page indicating the approval date. This is the version that must be kept in the laboratory where animal work is conducted and be made available to study personnel. However, the format that PIs send into the IACUC office are Word documents so please be sure to keep these files as you will need them if amendments are needed in the future. If our office makes changes for any reason to your protocol (e.g., correction of a typo, simple change in wording, etc.), we will also send you the Word document so you will have the current version in Word to be used for future amendments that may be needed.

Amendments to Animal Care and Use Protocols

ADDING PERSONNEL:

PIs adding personnel to protocols will now need to submit this change the same way amendments are submitted. The most current and approved version of your protocol must be used. Changes to personnel need to be added directly into the protocol and must be highlighted. When adding additional personnel, sections 3 and 4 of the new protocol form must be addressed. Once the personnel addition has been approved, you will receive an approval letter for that amendment AND an updated, approved protocol in a PDF format.

REMINDER:

To submit an amendment, you must make changes (additions or removals) in the most currently approved protocol form (even if it is the OLD animal care and use form). These changes must be highlighted in some way (different color font or actual highlighting) in the protocol form. In addition to making changes in the form, a brief statement must also be submitted which must include an explanation of the changes and why these changes are being requested. Amendment requests must be submitted to mhollander@mail.wvu.edu or ACUC@mail.wvu.edu.

Biological Safety

The documents used for submission to the Institutional Biosafety Committee will soon be changing to reflect updates in policies and guidelines and also to improve the submission process for researchers. Forms for current use during IBC submission can be found at <http://oric.research.wvu.edu/biosafety/bio-submit>.

Effective immediately, all approved IBC protocols will need to be renewed every three years. The renewal period has been implemented to allow better oversight of studies that are being conducted by WVU personnel.

Biological Safety Education and Training Updates

The biological safety officer will now be conducting both biosafety orientation training and in-person training related to biosafety and bloodborne pathogens.

The biosafety orientation is targeted toward biomedical research on all WVU campuses. The bloodborne pathogens training will be offered on a monthly basis on the third Friday of each month at 1 p.m. in room 209 of the Chestnut Ridge Research Building. For detailed directions to our office location, please visit <http://oric.research.wvu.edu/location>.



BIOLOGICAL SAFETY

[Smitha Rayadurg, DVM, PhD,](#)

[SM \(NRCM\), CBSP](#)

Biosafety Officer

(304) 293-7157

vrayadurg@mail.wvu.edu

[Nadine Brusca](#)

Biosafety

Administrative Secretary

(304) 293-0390

Nadine.Brusca@mail.wvu.edu

Protocol submission forms for IBC protocols will soon be changing.

In-person bloodborne pathogens training will be offered every third Friday at 1 p.m. in room 209 of the Chestnut Ridge Research Building.



CONFLICT OF INTEREST

[Joy Edwards](#)

Conflict of Interest Officer

(304) 293-5475

Joy.Edwards@mail.wvu.edu

New University regulations regarding COIR went into effect on August 24th, 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/conint>.

A Guide for Understanding the New COIR Requirements

An investigator is anyone responsible for the design, conduct, or reporting of research, regardless of their title or role on the project or the receipt of funding (this definition includes adjunct faculty, students, volunteers, subcontractors, consultants, collaborators, research coordinators, research assistants, and other research staff). For Conflict of Interest in Research Disclosure purposes, the PI is responsible for determining who they consider to be an “investigator” using the above definition. Each investigator must submit a completed Disclosure of Interest in Research (DOIR) Form with:

- (1) each new, continuation, or revised grant or contract application submitted to the Office of Sponsored Programs,
- (2) each new protocol involving animal or human subjects, and
- (3) whenever there is a new or previously unrecognized financial interest not reported on the initial disclosure

The form can be found on the ORIC website at

<http://oric.research.wvu.edu/conint>.

Also, each investigator will need to complete the **new** Conflict of Interest in Research CITI training. I have provided the instructions below, however they are also available on our website at

<http://oric.research.wvu.edu/conint/coir-education-and-training>.

To access the required COIR training, go to the CITI Website at

<https://www.citiprogram.org/>.

1. Choose “Add a course or update your learner groups for West Virginia University”
2. Answer Yes to Question 2, “Would you like to take the Conflicts of Interest course?”
3. Click on “Continue” at the bottom and complete the required modules.

Please let [Joy Edwards](#) know if she can assist you in any way.

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

