



# 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.

### CONTENTS

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Introduction	1
Human Research Protections	2
Responsible Conduct of Research	3
Animal Care and Use	4
Biological Safety	6
Export Control	6
Conflict of Interest in Research	7
Other Notifications	8

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## Human Research Protections



### *The Transition from BRAAN to Kualii-Coeus (KC)*

Our office has received numerous questions recently about the transition from BRAAN to KC. Primarily, researchers are asking if they should wait to submit their protocols via KC rather than BRAAN. Please do not wait to submit your IRB document since BRAAN will still operate in parallel with KC for at least one year after KC launches (tentatively scheduled for the Spring semester). This will allow you to maintain full access to your documents in BRAAN if you submit shortly before the launch of KC. In short, waiting for KC to launch in order to submit your IRB document will not provide any added benefits.

### *Training for KC*

#### **HUMAN PROTECTION**

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The new IRB submission system, Kualii Coeus (KC), is currently slated to be implemented in Spring 2012.

KC training programs will be implemented prior to the release of KC.

Research Office Information Technology (ROIT) will begin implementing several training programs prior to the release of the KC system. These training programs include Internet-based video training, a KC test-drive portal (<https://testdrive.kc.kuali.org/kc-ptd/portal.jsp>), one-on-one training, and group training sessions. Anyone planning to work with Kualii should familiarize themselves as much as possible with the system for their own benefit.

The WVU community is encouraged to follow the status of this project and provide feedback. Please 'Like' us on Facebook at WVU Kualii Coeus (KC) for weekly updates. Also we encourage the WVU IRB investigators to sign up for the WVU Office of Research Integrity and Compliance (ORIC) IRB listserv on the ORIC website at <http://oric.research.wvu.edu/>. For further information please contact us at [ResearchIT@mail.wvu.edu](mailto:ResearchIT@mail.wvu.edu) or 3-5967 in the Research Office Information Technology department.

## *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](mailto: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 16<sup>th</sup>, 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 15<sup>th</sup> of each month

#### Important resources:

- The IACUC newsletters can be found at [http://oric.research.wvu.edu/animal/iacuc\\_newsletters](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>

### *Pain, Distress, and Refinement in Animal Research*

The WVU IACUC is responsible for evaluating all procedures being done on animals for research, teaching or testing at WVU. One component of this evaluation is the potential for pain or distress during the course of the proposed study. If there is pain or distress that may occur during the study, the committee must perform a harm/benefit analysis that assesses the severity and duration of that pain. If pain or distress will occur that cannot be alleviated, scientific justification must be provided. It is up to the IACUC to determine the appropriateness of the scientific justification. For example, there should be more than the unsupported statement that analgesics might interfere with the purpose of the study. Finally, if pain is likely to occur, the protocol must describe criteria for early removal from the study.

#### *Pain and distress in animals*

Pain as an outcome of procedures that are carried out on animals must be minimized. It is the responsibility of the investigator to predict and prevent pain in their animal subjects whenever possible. If it is not known whether pain may occur, often a pilot study is required to gauge the potential for pain during the proposed procedures, and ways of alleviating any resulting pain must be planned.

#### *Refinement*

Refinement is the third of the “Three R’s” of alternatives and was first introduced in the 1959 book by William Russell and Rex Burch, *The Principles of Humane Experimental Technique*. Refinement is defined as “techniques that minimize any pain or distress the animals may experience” and covers anything that serves to reduce the animals’ pain and distress or to enhance their well-being.

#### *Examples of minimizing pain and distress*

- Giving an animal appropriate medication for pain;
- Using techniques that are less invasive to the animal;  
or
- Offering animals appropriate toys to play with.



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#### *Searching for alternatives to painful or distressful procedures*

Things to consider before beginning your search:

- Note the objectives and endpoints of the study;
- Note the drugs or compounds used in the procedures;
- Note the methods or procedures using animals that may cause pain or distress;
- Note potential alternative procedures that you know of; and
- Select the databases that are appropriate for the area of study, keeping in mind the type of protocol (research, teaching, testing, etc.).

Once you have considered these issues, develop a conceptual search strategy using the keywords and concepts that you noted above. Be sure that your search strategy is flexible, dependent both on the topic and on the database selected. If too many records are retrieved, additional relevant terms may make the results fewer and more useful; if too little is retrieved, fewer terms and a more conceptual approach may identify the relevant material. As a rule of thumb, a well done search should retrieve 10-50 hits.

#### *Summarizing the findings from your search*

Once you have completed your search for alternatives to painful or distressful procedures, an explanation must be provided detailing what alternative-related information you found. In this explanation, you must indicate how you are integrating those alternative methods, procedures, or models into your protocol, as well as why you are not using others. Please note that this information is relevant to sections 11.B.1 and 11.B.2 on the WVU IACUC Protocol Application for the Use of Animals.

## *Biological Safety*

Currently, the ORIC is developing a full WVU Biosafety Manual in order to better serve researchers who conduct studies using biological material. This manual is also being developed in the hope that federal, state, and University regulations be more fully and thoroughly understood.

Our office is also working on the development of the WVU Sharps Policy and the WVU Exposure Control Plan. Biosafety registration documents and the CITI Biosafety training requirements will also be undergoing changes.

The Biosafety website will soon be refurbished so that forms, guidance, and regulations are better organized for easier researcher access.

## *Export Control*

The Export Control website will soon be refurbished so that forms, guidance, and regulations are better organized for easier researcher access.



## **BIOLOGICAL SAFETY AND EXPORT CONTROL**

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The development of the WVU  
Biosafety Manual continues.

Both the Biosafety and Export  
Control websites are being  
reorganized.



## **CONFLICT OF INTEREST**

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New federal regulations regarding the disclosures made on the WVU Disclosure of Interest in Research (DOIR) Form and the WVU Supplemental Disclosure Form will go into effect in July 2012.

Conflict of Interest will become a working part of the Quali Coeus electronic system in late 2012.

Any University investigator/key personnel engaged in a research study, regardless of the source of funding, who wishes to be eligible to engage in a particular research program shall have an ongoing duty to complete and file annually (by June 30<sup>th</sup> of each year) the [WVU Disclosure of Interest in Research \(DOIR\) Form](#). This form was previously entitled “Conflict of Interest in Research Certification Form.” Federal regulations require the University to manage any potential conflicts of interest through an appropriate management process which is initiated and generally resolved through disclosure. If any questions arise as to who must complete and file a DOIR, or whether the DOIR is up to date please contact our office.

New federal regulations regarding the disclosures made on the WVU Disclosure of Interest in Research (DOIR) Form and the WVU Supplemental Disclosure Form will go into effect in July 2012. Currently amounts over \$10,000 earned through employment, consulting, or financial or significant relationships, including ownership, outside of an individual’s University activities need to be disclosed. With the new regulations, amounts earned over \$5,000 for payments for services and/or equity interests earned through employment, consulting, or financial or significant relationships, including ownership, outside of an individual’s University activities will need to be disclosed on the DOIR and Supplemental Forms. An equity interest of 5% or more will still need to be disclosed for interests in publicly traded entities. With the new regulations, any equity interest in non-publicly traded entities will also need to be disclosed. The ORIC would also like to announce that Conflict of Interest will become a working part of the Quali Coeus electronic system in late 2012.

If there are any questions regarding anyone who needs to complete and submit a DOIR Form, whether or not a DOIR is currently on file, or any other questions regarding the WVU Policy, please feel free to contact Joy Edwards (304-293-5475) or Dr. Daniel Vagird, ORIC Director (304-293-6094).

For more information, please visit  
<http://oric.research.wvu.edu/conint>.

### *The Availability of EthicsPoint Reporting*

We would like to remind the WVU community that the University has an anonymous system for reporting possible violations of the University's policies.

WVU has joined with EthicsPoint to establish a website to report possible violations at <https://secure.ethicspoint.com/domain/media/en/gui/14303/index.html>. There is also a toll-free hotline: 866-413-1955.

Reporting via the website can be done in one of three categories:

- Accounting and Financial Matters, which focuses on accounting or disclosure issues, fraud, theft or other financial issues
- Research, which covers issues related to compliance requirements of research grants
- Information Technology, which involves issues relating to misuse of technology resources and data privacy/integrity

WVU holds itself to the highest ethical standards and encourages employees, whenever possible, to discuss concerns with their supervisors or appropriate University personnel in such units as Internal Audit, Human Resources or the General Counsel's Office.

The University will not take retaliatory actions against employees or constituents who make good faith reports about potential misconduct. The EthicsPoint reporting system is a confidential alternative for reporting issues.



### **OTHER NOTIFICATIONS**

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EthicsPoint is available to all WVU affiliates.

Research concerns and violations is one of the three reporting capabilities of EthicsPoint.