Spring 2015

**Contact by Federal Agencies**
Have you been contacted by the FBI, Homeland Security or any other federal law enforcement agency? Many federal agencies are increasing their outreach to universities and we consider them our partners. If you are contacted by any federal law enforcement agency, please contact Kenya Faulkner in the Office of General Counsel at 513-556-3483. We want to ensure we are being consistent in following the university protocols and also that we are providing any information requested in a proper and timely manner. The Office of General Counsel will help you navigate the process and build the relationships with those agencies. If you have any questions, please feel free to reach out to them.

**Genome Data Sharing**
The National Institutes of Health (NIH) Genome Data Sharing (GDS) policy covers all genomes and NIH supported repositories.

The NIH GDS policy sets forth expectations that ensure the broad and responsible sharing of genomic research data. It applies to all NIH-funded research that generates large-scale genomic data regardless of species and also covers the subsequent use of these data. Large-scale data include genome-wide association studies (GWAS), single nucleotide polymorphisms (SNP) arrays, and genome sequence, transcriptomic, epigenomic and gene expression data.

► Get more examples of research projects that are subject to the policy. (PDF)
► Get more information on the NIH GDS policy.

**Protocol Updates/Additions**
Summer is fast approaching. Please ensure that summer students and other new personnel are trained and added to your protocol(s).

**Sustainability of Research**
The NIH has released a request for information on optimizing funding and “other strategies to improve the impact and sustainability of the NIH-funded biomedical research enterprise.” Comments are accepted through Sunday, May 17.

► Get details and respond.

As always, if you have a suggestion that will help us to help you, please contact us at research.compliance@uc.edu.

Jane Strasser, PhD
Director, UC Office of Research Integrity
Research Compliance Officer
Research Integrity Officer

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**EXPORT CONTROLS UPDATE**

**Website Updated/Travel Certificate Posted**
The regulations for export controls are complex and have potential criminal consequences. The [UC export controls website](http://example.com) has been updated to assist you in navigating the export control regulations.

There is also a new [International Travel Certificate](http://example.com) that you may complete and carry with you during your work travel. The certificate will be helpful with Customs in the U.S. and abroad, if they request further information regarding the items you are hand-carrying.

If you are traveling to comprehensively sanctioned countries (e.g. Iran, Cuba, etc.), please ensure compliance by contacting the UC Office of Export Controls at 513-556-1426 or [exportco@uc.edu](mailto:exportco@uc.edu).

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**ANIMAL CARE AND USE NEWS**

**IACUC Policy Update**
Institutional Animal Care and Use Committee (IACUC) policy “2” has been updated to include additional methods of identification and genotyping.

▶ [See Updated IACUC Policy 2](http://example.com).

**LAMS Security/Facility Access**
For security and personnel safety reasons, please ensure you do not "tailgate" when entering any Laboratory Animal Medical Services (LAMS) facility. It is critical that everyone swipe their badge before entering. If multiple people are entering at once, you do not need to wait for the door to close each time if someone has swiped ahead of you. Badge readers will recognize your badge even when the door is open so simply swipe your badge before entering. If you do not have badge access and therefore are not approved to work independently in a facility, you must be escorted and supervised at all times. Please contact a member of LAMS staff if you have questions regarding facility access.

▶ [Get LAMS contact information](http://example.com).

**Census, Cage Deactivation and Per Diems**
For all individuals handling cages/cage cards to be deactivated, it is imperative that you write the date on the cage card before placing it in the red deactivation box. If the date the cage was taken out of service is not written on the cage card and turned in for deactivation, LAMS continues to bill per diems for two scanning cycles before the barcodes in question are deactivated. If you forget to write the deactivation date on your cages or fail to turn them in, please contact LAMS immediately to avoid further charges being billed to your account.

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**BIOSAFETY INFORMATION**

**Biosafety Cabinet: Designed for a Single Operator**
When used correctly, biosafety cabinets (BSCs) protect workers from the inhalation of hazardous particles/microorganisms and prevent their spread into the laboratory. In addition, most BSC types create a sterile environment that protects the BSC contents.

There are a variety of BSC sizes available on the market. A larger BSC is normally used to accommodate a large amount of materials and equipment. It was not designed to allow more than one person to work on it at the same time.
BSCs are designed for a single operator. All the standards utilized for their design and certification are based on ONE person positioned in the center of the front of the cabinet.

With two people working together in front of the cabinet, the airflow reaching the intake vent of the equipment changes. Under these conditions, the protection factor/performance envelope could be jeopardized, potentially resulting in a loss of protection. Also, when more than one person is working in the cabinet, there is more potential for turbulence of the air curtain and contamination as a result of moving things not only in and out of the cabinet, but also within the cabinet.

To protect researchers and research materials, laboratories should limit the number of simultaneous users by scheduling BSC use.

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**HUMAN RESEARCH PROTECTION PROGRAM NEWS**

**Departmental Designation**
Revisions have been made to the staff dedicated to manage your Institutional Review Board (IRB) protocols (i.e., departmental designation).

► Get the updated departmental designation list.

**New Webpage for Policies, Procedures, Guidance and Templates**
The current human research protection program (HRPP) policies, procedures, templates and guidance have been moved to a new location online.

► HRPP Policies and Procedures

**Naming Consent Forms in ePas**
When initially saving consent forms to the ePAS file, the consents should be given generic names, such as "Main", "Main – Healthy Controls," "Assent," "Addendum 1," "Genetic," etc. No dates or version numbers should be included in the name. The name of the study can be included, i.e., "(STUDY NAME) Main", etc., but it is not necessary.

Version numbers and dates can be used when uploading revised versions of consents in the future, because the name initially given to the consent never changes in the ePas system. Therefore, accurate record of current consent versions and dates will not be affected in your records.

**Using the "Upload Revision" Versus "Add Buttons" in ePas**
When saving consent forms to the ePAS file, the "Add" button should only be used if a new type of consent is being added to the study (i.e., one that does not already exist as part of the study). The “Upload Revision” button should always be used when uploading revised versions of currently existing consent forms.

For example, if the study has never had a Genetic consent, and a Genetic consent is now being added to the study, use the “Add” button. However, if a revision is being made to the existing Genetic consent, select the “Upload Revision” button located next to the Genetic consent to upload the revised version.

**Reliance on External IRBs**
To facilitate review by the approved commercial IRBs (WIRB-Copernicus IRB, Schulman Associates IRB, and Quorum Review IRB), investigators/sponsors/CROs can now submit new studies directly to the approved commercial IRB (this process is in place for Schulman Associates and Quorum Review, and anticipated shortly for WIRB-Copernicus IRB); UC HRPP staff will no longer submit new studies to these IRBs. Researchers are responsible for meeting UC institutional requirements (e.g., abbreviated ePas submissions, disclosure of conflict of interest for all key personnel, completion of training by all
key personnel, compliance with conflict of interest management plans, compliance with HIPAA language requirements, indemnification) as well as any requirements of the commercial IRB. Updates to the external submission webpage are forthcoming.

E-Signatures
The University of Cincinnati Board of Trustees has adopted a rule permitting the use of electronic signatures in university transactions. Electronic signatures have the same legal effect as manual signatures. Encryption and other UC Information Security requirements must be met prior to implementation.

Collaborating With Other Institutions
We have standing agreements with many institutions that allow reliance on another IRB so that only one IRB reviews. When collaborating with other institutions, contact the UC HRPP office prior to submitting your study or amendment in ePas to ensure that there is a shared understanding of the project and any institutional authorization agreements are in place or in the process of being obtained. This will prevent delays with starting and competing research activities.

Conditional IRB Approval
Conditional IRB approval is not approval to move forward with study activities. Study teams cannot conduct study activities on a new study or expired study undergoing continuing review until all conditions of approval have been met. Full Board and expedited research submissions given conditional approval will have approval letters issued using the conditional approval date as the date approved with an additional comment as to when conditions were met. If a continuing review is conditionally approved prior to expiration, then resolution of contingencies after expiration will not be considered a lapse in approval. Regardless, sites cannot proceed with study activities after expiration until all conditions have been met and approval documents released.

U.S Department of Veterans Affairs Clinical Research Sites
Expired studies require a full board vote from the Veterans Affairs (VA) R&D Committee in order to reopen study activities at the VA. Continuing reviews conditionally approved by the IRB prior to expiration, but not given final approval until after the expiration date of the study will still require this additional R&D review and approval in order to continue study activities, because it is considered a lapse in approval. Researchers are responsible for complying with UC HRPP policies and procedures as well as any regulations, policies and procedures for the use of a VA Medical Center for research purposes.

Cognitively Impaired Participants Checklist
When completing the checklist for enrolling study participants who are, or may become, cognitively impaired, stop if you answer "no" to question one (Will the research study enroll participants who have impaired decision-making capabilities or are legally incompetent?). You do not need to complete the remainder of the form. The requirements pertaining to the enrollment of cognitively impaired study participants (e.g., surrogate consent) does not apply to your study.

IRB Approval Letters
Please ensure that the ePas submission smart form includes all of the documents that require IRB review and need to be listed on the approval letter. During the initial submission, ensure that you are selecting the “Upload Revision” option when documents have been modified to avoid duplications on the final approval letter. Also, ensure you include a clean copy of revised informed consent forms in addition to the redlined version in order to have a IRB approved clean version available for use.

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The Purpose of Regulatory Inspections
Most Authorized Users (AU) and radiation workers will eventually be involved in an inspection by the Ohio Department of Health, and all will be audited by staff from the Radiation Safety Office. The best way to prepare for an inspection is to maintain a good radiation safety program including an awareness and understanding of policies, generating and maintaining records, and supporting a well trained staff.

Remember that an inspector’s goal is to review the performance of the Radiation Control and Safety Program and to identify actual or potential regulatory concerns. Provide all requested records promptly. You should always answer questions honestly, don’t hesitate to say, “I don’t know, but I will find out” or “I don’t understand the question.” The Radiation Safety Office will help you to correct any deficiencies or answer any questions that you have.

The following are examples of questions you may be asked by an auditor:

- What radionuclides do you work with?
- What training have you had?
- How did you get your RAM?
- Where is your RAM stock stored?
- How do you assure security of your RAM?
- What do you do with your empty RAM shipment box?
- How much RAM do you use at a time?
- How do you keep track of your RAM inventory?
- What do you do prior to working with RAM?
- How do you survey your work area?

Satisfaction Survey
The Radiation Safety Office strives to provide quality customer service. To aid in our continuous improvement, we are asking that you please provide us with feedback about our service.

▶ Radiation Safety Office Satisfaction Survey

TRAINING OPPORTUNITIES

SAVE THE DATE: Human Subjects Protection Conference
The 17th Annual Human Subjects Protection Conference will take place on Thursday Oct. 1, 2015.

SAVE THE DATE: IRB 250 Conference
Public Responsibility in Medicine and Research (PRIM&R) will be hosting an IRB 250 Conference on Friday Oct. 2, 2015.