Spring 2014

Spring is finally upon us and typically means increased turnover in personnel and increased exposure to laboratory risks. Remember to train and update personnel on protocols and to properly protect yourself from exposure to laboratory risks.

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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SPOTLIGHT ON: Problems with multiple IRB submissions

ePAS forces modifications to a protocol (continuing review/progress reports, amendments, etc.) to be processed sequentially. This can be a huge problem when you want to make a simple administrative modification ahead of it in the pipeline. The company that makes ePAS (Huron/Click Commerce) is working on this issue; in the meantime we have developed a work around. If you have a time-sensitive modification that needs to jump the queue and be approved prior to a previously submitted modification please let your dedicated Human Protections Administrator know.

Export Controls

Export Control is more than national security and it carries personal fines and jail time; if you don’t know ask!

- University activities involving the use of export controlled information, items, equipment, or technology received from outside the university (the use of 3rd Party Export Controlled Technology or Information) are NOT protected under the Fundamental Research Exclusion and all research involving the use of export restricted technology is subject to ALL export controls.
- Tangible products of fundamental research (models, instruments, devices) ARE subject to Export Controls
- Information associated with a patent which is not in the patent itself or product made as a result of the patent can still be export controlled and licensable. For additional details see Part 734.3(b)(1)(iv) of the EAR and review the Advisory Opinion dated 1/11/2006.

The Fundamental Research Exclusion ONLY applies to information, NOT developed products

The fundamental research exclusion does not apply if you do not intend to publish any of the work, if you make side deals, or agree to publication restrictions or approval by the sponsor prior to publication.

Things to consider
Are you working with controlled technology?
Has your research (sponsored/non-sponsored) led to a development of an item?
Would you like to sell it?
Would you like to ship it to another researcher/institution?
For more information, please contact the Export Controls Director Tara Wood at woodt4@ucmail.uc.edu or 513-556-1426.

IACUC NEWS

Enhancing Literature Search for Alternatives
Literature searches for alternatives are receiving increased scrutiny by regulatory agencies. As a result, future protocol reviews will focus on enhancing these search strategies. The type of search structure we will be looking for will include linking the various names for the species, multiple alternatives terms, and scientific terms relevant to the study. **Example:** Title Search: (rat OR ratus OR rodent) AND (alternative* OR simulat* OR virtual OR in vitro) AND (cancer* OR tumor* OR metastasis*). For more information, go to https://awic.nal.usda.gov/

HUMAN RESEARCH PROTECTION PROGRAM NEWS

Revision to Departmental Dedication
The updated departmental dedication chart below contains the current distribution; revisions are updated on the website.

<table>
<thead>
<tr>
<th>UC Contact Person</th>
<th>Departments</th>
</tr>
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**Exempt Studies in Researcher’s Gateway are expiring**
Whether a human subjects research study is exempt or not, all UC Institutional Review Board (IRB) policies and procedures must be followed, including the submission of study amendments. Certain modifications may result in the reclassification of the research to nonexempt status. For those researchers who have active exempt protocols, you will have until Sept. 1, 2014, to close those studies or move them into the ePAS system. If the applicable study has not been moved into the ePAS system by that time, then subsequent amendments must be preceded by a new study submission in the ePAS system.

**Closing Conversion Window in ePAS**
For those researchers who have not completed the conversion process in ePAS, you will have until June 1, 2014, to finish moving studies over into the ePAS system. If the applicable study conversion has not
been completed by that date, then the study status will change to withdrawn and a new ePAS submission will be required to proceed with study activities.

Reliance on Another IRB
Investigators must submit a research study to the ePas system in order for UC IRB to approve another organization as the IRB of record for the study, however, the IRB of record is not responsible for ensuring UC institutional requirements (e.g., conflict of interest, completion of required training, indemnification, etc.). Each investigator is responsible for updating changes in research personnel, conflict of interest, required training, as well as updating initial IRB approval, continuing review and study completion information. Note that without initial approval and continuing review updates the ePas system will show that the study has expired while approval is still active with the IRB of record. This does not mean that IRB approval, as issued from the IRB of record, has expired. Timely ePas updates will ensure a record of institutional compliance. Please direct questions and concerns to Kareemah Mills at IRB@ucmail.uc.edu.

Who Can Sign an Informed Consent?
If a potential research participant cannot provide consent, Ohio law lays out a prioritized hierarchy for who can sign. In decreasing order of preference the list is: (1) the potential participant’s legally authorized representative (LAR), (2) the potential participant’s spouse, (3) the majority of adult children of the potential participant, (4) the potential participant’s parents, (5) the majority of the potential participants adult siblings, and (6) the nearest blood or adoptive adult relative. The consent is revocable at any time by someone with a higher legal priority.

Tip: Student Research
Study activities may not begin until IRB approval has been obtained. In order to avoid research delays, begin discussing your research with your faculty advisor and request IRB guidance early in the research process. Links below may be useful for understanding the decision making process for determining when a study is classified as an activity involving human subjects research.

http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html#c1
http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html#c2

BIOSAFETY NEWS
Animal Containment – Viral Vector Experiments
To ensure safety and compliance with federal regulations, the animal containment policy has been revised to include any viral vector with the ability to infect human cells (vectors with human tropism) and cells that have been infected/ transduced with those vectors. Animals inoculated with human-tropic vectors or cells carrying those vectors must be handled inside of a biosafety cabinet and the waste must be treated as biohazardous for a minimum of 72 hours; after the minimum 72-hour period and first cage change, animals may return to standard housing.

New Online Training: Viral Vectors
The use of viruses as vectors to deliver genetic material into cells has become very common. It is important for users to understand the origins of these tools and the potential safety implications. The Biosafety Office has launched the online version of this training, which can be found at http://researchcompliance.uc.edu/Biosafety/Training/ViralVectorWebtraining.aspx. Online training can be supplemented by in person training provided by the Biosafety Office. Starting this month, the IBC will require that individuals listed on IBC protocols involving viral vectors take this training as condition for approval.

For more information, please contact the Biosafety Office at 513-558-6182 or espinoma@ucmail.uc.edu.

RADIATION SAFETY
Radiation Safety is now delivering packages and calibrated survey meters to laboratories. Additionally, on the Reading Campus Radiation Safety is now:
- Delivering to the laboratories packages, dosimeters, surveys, and picking up dosimeters and survey meters for calibration. The office will attempt to deliver/pick up on Tuesday and Thursday afternoons; we will call to coordinate times. The drop off box is still an option for exchanging badges.
- Radiation Safety Office staff office hours at the Reading Campus will be between 1 and 2 p.m. on Tuesday and Thursday only.
- The Radiation Safety Office staff will continue to provide same-day delivery of packages arriving on Monday, Wednesday and Friday.

The Radiation Safety Office will email/voice mail to arrange drop-off or pick-up times with AUs and
Radiation Workers for whom the preceding schedules will cause any inconvenience.

EDUCATIONAL OPPORTUNITIES
Clinical Research Forum
University of Cincinnati, Cincinnati Children’s Hospital Medical Center/Office for Clinical and Translational Research, Cincinnati Department of Veterans Affairs Medical Center and the Center for Clinical and Translational Science and Training (CCTST) are co-sponsoring the 2014 Office for Human Research Protection (OHRP) Regional Community Forum (RCF) Clinical Research and All That Regulatory Jazz!

The one-day Forum will be presented on Wednesday, May 21, 2014, at the Kingsgate Marriott Conference Center, and will focus on ethical issues for protecting human subjects and some of the innovations on the research horizon. In addition to keynote speakers, curriculum tracks/breakout sessions include: regulatory, biobanking, technology and internet-based research, novel research, and network-based research. Clinical research presentations, updates and panel discussions will be delivered by representatives from OHRP, as well as regional academic researchers and experts from the four partnering institutions.

The registration fee for Clinical Research and All That Regulatory Jazz! is $150. This activity has been approved for AMA PRA Category 1 Credit™. Additional program and registration information can be found at www.cincinnatichildrens.org/ohrp-rcf.

SAVE THE DATE! Human Subjects Protection Conference
The 15th annual regional Human Subjects Protection Conference, “Don’t Stop Believin’,” is Sept. 12, 2014, at the Northern Kentucky Convention Center. This conference will have great presentations on the role of engaged and empowered patients in medical research, protecting research participants in the digital age, improving communication between IRB and investigators, human subjects protection issues in translational research, and informed consent in behavioral research and more.

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