As the Research Integrity Officer the most common allegation I receive is of plagiarism, the use of someone else's words (or ideas) without appropriate attribution. Reputations can be tarnished by the inadvertent (or intentional) replication of someone else's words without citation. To provide UC researchers with a tool to confirm appropriate attribution, UC has purchased a license for iThenticate plagiarism detection software. This software is provided so that our faculty, staff, and students can use it to evaluate works on which they are an author. If you would like to scan your work prior to publication please contact me and I will set up an account.

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

IN THIS ISSUE:

Human Research Protection Program News
IACUC Update
Biosafety News
Radiation Safety Information
Export Control Update
Training Opportunities

HRPP NEWS
Source Documentation for Research Studies
Source documents, original records and certified copies of original records, may include clinical findings, research observations, or other records of research procedures. Source documents are important for establishing supporting documentation to demonstrate when, how, and who carried out study activities. Case report forms may be used as source documents when allowed by the investigational protocol. Photocopies of source documents are acceptable when certified. Ensure that there are appropriate source documents for all study procedures, and that there are standardized processes in place for certifying copies of source documentation.

ClinicalTrials.gov Registration
The Food and Drug Administration Amendments Act or FDAAA was enacted on September 27, 2007 and mandates the types of trials and the information that must be posted on ClinicalTrials.gov. The International Committee of Medical Journal Editors (ICJME) also mandates trial registration and updates. FDAAA requires registration all of trials for drugs, biologics, and medical devices excluding Phase I drug studies and small device feasibility studies no later than 21 days after the first patient is enrolled. ICMJE requires registration of all human research projects that prospectively assign human subjects to an intervention or comparison group for the purpose of examining a relationship between a medical intervention and a health outcome before the first subject is enrolled.
Changes to the Informed Consent Template for Research Involving Imaging
The informed consent template has recently been updated to reflect a change in process for imaging conducted for research purposes. Until recently, if you ordered imaging for a clinical trial, it was expected that you also ensured a read of the image by Radiology even if the scans were sent to a central reading core. This is because the scans end up in the medical record regardless of where your research read is done. Unfortunately, many study budgets did not provide the funding to cover the cost of Radiology’s read of the scan.

If you are conducting research involving imaging and you do not plan for a local read of the scan, you must use the language in the informed consent document that clearly indicates to the patient that the scan is for research purposes only. If that language is not present in the informed consent document, then the local read will occur and you will receive an invoice for the reading.

To view the updated informed consent forms, please visit our ePAS documents web page. These documents are listed as “Consent Template” and “Consent Template with HIPAA Language”.

Tips to Determine ClinicalTrials.gov Registration

1) Ensure that you are both identifying whether or not your study is an applicable trial under FDAA. There is a decision tree on the UC ClinicalTrials.gov Fact Sheet. The UC ClinicalTrials.gov Fact Sheet may be accessed here.

2) If you are not required under FDAAA to register your trial, verify that you do not have a journal requirement to register the study.

IACUC SEMI-ANNUAL INSPECTIONS

IACUC Inspections will be occurring again this spring. We have developed a checklist to assist you in assessing your labs compliance. Please visit our website to view this document.

BIOSAFETY NEWS

Lab Inspections: Inventory of Agents (NEW)
Beginning March 2015, a new audit item will be included in the biosafety inspection check list. The Biosafety Office will start verifying if labs have an inventory of biologic toxins and (potentially) infectious agents. An inventory record should have information on all such items present in the lab, including name and location. For information on how to get prepared for a lab inspection and for an example of an inventory record, please go to http://researchcompliance.uc.edu/Biosafety/Labinspections.aspx

Dual Use Research and Dual Use Research of Concern

Some scientific and technological advances that provide great benefits to society can also be used maliciously. For example, research on the origins of virulence, the development of vaccines, and the genetic manipulation of biological agents are simultaneously relevant to public health and potential weaponization. Research yielding new technologies or information with the potential for both benevolent and malevolent applications is referred to as "dual use research."

A small subset of life sciences research with the highest potential for yielding knowledge, products, or technology that could be directly misapplied to threaten public health or national security is referred to as "dual use research of concern (DURC)."
DURC Oversight
The U.S. government has developed a policy regarding the oversight of DURC that will become effective in September of 2015. The policy includes the requirement for institutions to review research and research proposals to identify those that qualify as DURC and to ensure that acceptable risk-reducing mitigation plans are in place.
UC’s Institutional Biosafety Committee (IBC) has developed a formal process for the review of potential DURC projects. For more information, please go to
http://researchcompliance.uc.edu/Biosafety/DURCreview.aspx

Does my research have potential to be classified as DURC?
At this point, the government DURC policy applies to 15 specific pathogens and toxins and the DURC definition further specifies seven types of experiments. To better understand the DURC requirements or if research meets the DURC criteria, please review the training slides provided by US Department of Health and Human Services.

- back to top -

RADIATION SAFETY
Upcoming Inspection
Every two years, the Ohio Department of Health (ODH) inspects the University of Cincinnati Radiation Control and Safety Program (RCSP) which includes both UC and CCHMC. The next inspection is expected during the spring/summer of 2015. During the last inspection, the inspectors visited research labs, irradiators and medical areas. For more information about the pending inspection click here.

Changes to the Radiation Safety Office (RSOf)
Over the past year, there have been several changes made at the RSOf. These have been made in order to increase RSOf customer service, to enhance safety, and to help maximize the efficiency of the RSOf and the RAM-Use labs.

- Packages – the RSOf is now delivering RAM packages to labs
- Survey Meters – the RSOf will pick up and drop off survey meters from labs for calibration
- Inventories – AUs without RAM inventory will no longer receive and be required to sign “zero inventories” for unsealed RAM
- Dosimeters – monthly exchange of badges is now quarterly. Exchanges will occur in the first month of each quarter (January, April, July, and October)
- Annual Safety Retraining – Training is now available online and can be accessed here.

Satisfaction Survey
The Radiation Safety Office strives to provide quality customer service. To help improve our services, please visit the following link to provide us with value feedback about our service. RSOF Satisfaction Survey

- back to top -
EXPORT CONTROL
Please monitor our website for new guidance and information. The new year brings on new initiatives and increased compliance. If you are conducting restricted or sensitive research, make sure you and your staff complete annual online export control training. Remember, Export regulations are changing and include personal liability; this is definitely a case where it is worth asking in advance.

The export control office will provide department or group training for personnel that conduct export controlled activities. If you have not met with the export control officer and would like to conduct sensitive or restricted research, please reach out to schedule a meeting. Please contact the export control office at exportco@uc.edu or Tara Wood at 513-556-1426.

TRAINING OPPORTUNITIES

SAVE THE DATES!!!

Scientists Center for Animal Welfare will be hosting an IACUC training conference on May 13, 2015. For more information and to register go to SCAW’s website.

The 17th Annual Human Subjects Protection Conference “Takin’ Care of Business” will take place on Thursday October 1, 2015.

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