Fall 2015

Without documentation there is no proof that something happened. UC rule 10-43-18 mandates that original Scientific records and data be retained for at least 5 years after the end of the study regardless of funding. Funding agencies and regulators have mandatory record retention times that may exceed UCs.

Reproducible research


Mandatory Genomic Data Sharing for NIH funded research

If your proposed research will generate large-scale genomic data, regardless of species, NIH mandates that a genomic data sharing plan be developed and implemented. The grant PI is responsible for the data sharing plan(s) associated with the proposal. Genomic data sharing plans must include 6 elements: 1) The source of the data; i.e. the species (human, mouse, bacteria, etc.) and type of genomic information (transcriptome, gene expression, etc.) obtained; 2) The data repository; where the data will be submitted and if/how access will be restricted; 3) When data will be submitted and released (NIH has release mandates); 4) IRB Assurance of the plan (if human genomic information); 5) Appropriate Data use (justification for any data sharing restriction); 6) If needed, a request for exception to submit human genomic data may be presented if the study will not meet NIH's institutional certification criteria. The NIH policy and guidance is available at gds.nih.gov; Columbia has a helpful template at http://scholcomm.columbia.edu/wp-content/uploads/2015/08/NIH-GDS_Template_20150107_v02.docx

Investigators who intend to use human specimens collected or cell lines created after January 25, 2015, to generate genomic data may only do so with consent, even if the data are generated from specimens that are de-identified. NIH-designated data repositories will not accept genomic data derived from specimens or cell lines collected or created after January 25, 2015, without consent. NIH strongly encourages investigators seeking consent to include consent for future research use and broad sharing of genomic and phenotypic data generated from the specimens or cell lines. The guidance provides information to be tailored to individual studies and conveyed to prospective participants during the consent process in order to meet GDS Policy expectations. See, http://gds.nih.gov/pdf/NIH_guidance_elements_consent_under_gds_policy.pdf

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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ANIMAL CARE AND USE PROGRAM UPDATE

AAALAC Site Visit Preparation
In anticipation of the Spring 2016 Association for the Assessment and Accreditation of Laboratory Animal Care International (AAALAC) site visit, the Institutional Animal Care and Use Committee (IACUC), the IACUC office, and Laboratory Animal Medical Services (LAMS) personnel will be conducting walkthroughs of both LAMS facilities and satellite animal areas. Walkthroughs are intended to identify and address any potential weakness in our program and to familiarize research staff with the types of questions and potential concerns AAALAC may have during their visit. The IACUC, IACUC Office, and LAMS personnel are here to assist you and to help ensure a compliant, high-quality, animal research program.

IACUC Policy Update
It is recommended that you review all IACUC policies relevant to your animal use. All approved IACUC policies can be found on the IACUC website. IACUC #001 Offspring & Non-Traditional Procurement Policy has been modified. The policy was modified to reflect all species regardless of how they are obtained. Cage densities are based on LAMS SOPs and are in alignment with The Guide for the Care and Use of Laboratory Animals (8th edition, 2011) as reflected in LAMS SOPs.

LAMS Security/Facility Access
For security and safety reasons, please ensure you do not "tailgate" when entering any LAMS facility. If multiple people are entering at once, you do not need to wait for the door to close each time; 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 you are not approved to work independently in a facility, and must be escorted and supervised at all times. Please contact LAMS staff at 513-558-5171 or email LAMS@ucmail.uc.edu if you have questions.

Animals and Occupational Health and Safety
Risks associated with work involving animals can include allergens, bites/scratches, and potential disease transmission. If you suffer from asthma, allergies, or are immunosuppressed, you are at greater risk and should consult with a physician. To be an approved user on an IACUC protocol you must complete a Health Questionnaire. Individuals not listed on an IACUC protocol (e.g., visiting scientists who will be at UC for less than 14 days and individuals attending short duration training sessions), must be directly supervised by someone approved to work on the associated IACUC protocol. Prior to working with animals, visitors and students must document review and understanding of material that discusses risks associated with animal exposure. The program overview pamphlet can be downloaded from the IACUC website. Return the signed OHS form documenting review to LAMS (mail code 0571 or scan/e-mail to LAMS@ucmail.uc.edu). Please contact a member of LAMS staff at 513-558-5171 or email LAMS@ucmail.uc.edu if you have questions regarding OHSP and animal exposure.

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BIOSAFETY NEWS

Biosafety Lab Inspections – Corrective Action Assurance
In keeping with regulatory mandates the Biosafety Office inspects the BSL2 laboratories at least once per year on behalf of the Institutional Biosafety Committee (IBC). For the inspection check list and more information about lab inspections please go to http://researchcompliance.uc.edu/Biosafety/Labinspections.aspx. Inspections may require corrective actions. PIs are required to provide a written response within 7 business days of the inspection report documenting resolution. If the corrective actions cannot be completed within this time frame PIs should contact the Biosafety Office to discuss alternatives and facilitate resolution.

COI NEWS

New Research Compliance Coordinator
Please welcome Carol Ann Taylor to the Conflict of Interest Office. Her experience includes 17 years as a Regulatory Affairs consultant for Procter and Gamble Pharmaceuticals, owning her own business, and teaching computer science. She has created and maintained a Health Care Documentation System, as well as the associated user training and technical support for electronic submissions/publications. She will be assisting Holly Bante’s efforts to ensure COI compliance.

EXPORT CONTROLS UPDATE

Export Controls Applicability
Export Controls apply to all U.S. persons and foreign nationals with U.S. technology and/or who are employed by a U.S. company. Failure to comply may result in fines and penalties including jail time. If you are traveling abroad, hand-carrying or shipping items, and or hosting/employing a foreign person, ensure that you conduct Restricted Party Screenings on the foreign entities (i.e. company, person, etc.) and that the activity does not require a license or exception/exemption. Check out “what to do before and after travel” for guidance on safeguarding your electronic devices. When you are working remotely always use VPN to access UC information and emails, even when receiving emails on your phone while out of the country. If you haven’t done so, review the export controls website for more detailed guidance and links to training. For more information contact the Export Controls Director, Tara Wood.

HRPP NEWS

Revisions to Common Rule
The Department of Health and Human Services (DHHS) has released proposed changes to the regulations that govern federally funded research involving human subjects (aka the Common Rule). If you do IRB-regulated research these changes will impact you. You have the opportunity to provide feedback on the proposed changes and influence the final rule; for more information see the Notice of Proposed Rulemaking.
**Access to De-identified Patient Information Through i2b2**
Since the data available through i2b2 is de-identified (all 18 federal HIPAA identifiers are removed) and obfuscated (purposely clouded), it is not individually identifiable and does not constitute human subjects research. Researchers are not required to obtain IRB approval for using this research tool. Researchers may not use the data retrieved using i2b2 to identify or contact any individual or to attempt to learn the identity of any household, family, person, establishment or sampling unit included in these data. A request for elevated access to identifiable information, must be approved by the IRB.

**Determining Whether An Activity is Human Subjects Research**
It can be difficult to determine whether or not a project requires oversight by the IRB. At the UC, the IRB must determine whether or not a project meets the definition of human subjects research and requires IRB oversight. The following definitions are used to determine whether activities that involve human subjects require IRB review.

*Human subject* means a living individual about whom an investigator (whether professional or student) conducting research obtains, (1) Data through intervention or interaction with the individual, or (2) Identifiable private information.

*Research* means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

A "systematic investigation" typically involves a predetermined method for studying a specific topic, answering a specific question, testing a specific hypothesis or developing a theory.

"Generalizable knowledge" is intended to expand understanding of a condition or population, or add to the body of knowledge regarding a field of study. The targeted population, data collected and analysis of those data results in knowledge that answers a research question or addresses the need for information in a scientific discipline. *Most masters and doctoral level research is intended to produce generalizable knowledge.* Please see [Policy_III_07_Determining_Human_Subjects_Research](http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html#c1) for more information.

**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#c1)
[http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html#c2](http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html#c2)

**Approvals for case reports:** It is generally the case that reporting on a single case does not meet the definition of human subjects research requiring IRB oversight. This creates some confusion on how to make sure the right consents and approvals are in place. If you plan on writing up a case as a case report, you should

- request a determination of ‘not human subjects research’ from the IRB
- obtain an authorization for use of the patient’s private health information as required by HIPAA
- obtain permission to use photographs or other images;

The HIPAA authorization and permission to use images are governed by the health system, not by the university. UC Health has a template HIPAA authorization you can use. They also have a policy and permission forms for use of images. These are available from the UC Health Office of Clinical Research

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HIPAA Authorization
The HIPAA Privacy Rule gives individuals the right to be informed of the privacy practices of their health care plans and health care providers. It also gives individuals the right to be informed of their privacy rights with respect to their personal health information (PHI). The Privacy Rule requires authorization for uses and disclosures of PHI not otherwise allowed by the HIPAA Privacy Rule. The notice of privacy practices and privacy rights with respect to PHI is NOT the same as the HIPAA Authorization Form used in research to authorize non routine uses and disclosure of PHI. Research that involves identifiable medical records or identifiable biological materials as well as research that will contribute new information to the medical record is covered by the HIPAA Privacy Rule. In these cases, study participants need to sign a HIPAA Authorization Form in addition to an informed consent form if a Waiver of Authorization from the IRB has not been obtained. The language in the HIPAA Authorization Form may be provided to the potential study participant as a standalone document or as part of the study informed consent form.

ClinicalTrials.gov Database
- If you are struggling to enter results into ClinicalTrials.gov for parallel design, crossover design, diagnostic accuracy or bioequivalence studies, refer to the helpful hints document via the link below. It includes examples of how the tables will look in the subsections. [http://prsinfo.clinicaltrials.gov/ResultsExamples.pdf](http://prsinfo.clinicaltrials.gov/ResultsExamples.pdf)
- If you are required to submit results to ClinicalTrials.gov after a trial has been terminated without ever enrolling a participant, then set the Overall Recruitment Status to “Withdrawn,” and submit the completed record to your administrator.
- If you are required to submit results to ClinicalTrials.gov after a trial has been terminated after enrolling at least one participant, you can specify zero for the number of participants analyzed in each arm/group and leave the data fields blank. This is performed under the Outcome Measures subsection.

Certification of Secondary Source Documents
Original study records are the standard, however, in some instances you may need to certify paper or electronic copies of originals. A procedure should be in place that is consistent with applicable regulations, as well as institutional and departmental policies. The procedure should describe the following:
- The process for verifying that the secondary source is an exact copy with all of the attributes and information as the original
- The process for identifying and documenting the person responsible for certifying the copy as an accurate and complete representation of the original
- The process for obtaining a signed/initialed and dated document from the person responsible for verifying the copy that will indicates certifiable requirements are met

Social Media
Study specific Facebook pages and Twitter accounts may be used to advertise UC IRB approved studies and to recruit potential study participants. These advertisements must be submitted to the IRB for review and approval, and researchers must use the approved language. To prevent confidentiality breeches and the release of sensitive information the advertisements may not invite prospective study participants to communicate using personal email or social messaging.

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UC’s radioactive material (RAM) license requires personnel to wear dosimeters when using RAM that emits gamma or x-rays or beta energy greater than 250 keV; exceptions must be pre-approved by the Radiation Safety Committee. Dosimeters are available from the Radiation Safety Office (RSOf). To obtain a dosimeter, complete the "Radiation Worker/Dosimetry Application" form and return it to the RSOf.

Dosimeters should be stored in a cool, dry area away from all sources of radiation and chemically active gases or vapors. If you have been issued a dosimeter to monitor your radiation exposure, you should follow a few simple rules to ensure that the dosimeter accurately records your radiation exposure.

- Wear only your assigned dosimeter; never wear another worker’s dosimeter.
- Wear your whole body dosimeter between your collar and waist. If you have one, wear your ring dosimeter beneath your gloves with the label on the palm side of the hand that handles the radiation source and thus has the greatest potential for exposure.
- Do not store your dosimeter near radiation, chemical, or heat sources.
- If you suspect contamination on your dosimeter, return it immediately to the RSOf; you will be given a new, uncontaminated dosimeter.
- Never intentionally expose your dosimeter to any radiation.
- Do not wear your dosimeter during personal medical or dental procedures (e.g., x-rays, tests, nuclear medicine, etc.). They are strictly for occupational use.
- Return your dosimeter to the RSOf at the end of the monitoring period.

Dosimetry reports are sent to the RSOf from Landauer. You will be notified immediately of any levels of concern. You can request your entire UC exposure history at any time by calling 558-4110.

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