October 2010

It’s a new academic year, so please remember that as you add new students or fellows, they need to be trained and added to your protocols.

Thanks to all who participated in the CTSA-sponsored Forum on Intellectual Property. We are planning a forum focused on bio-banking later this year. The CTSA will sponsor forums as long as we have topics that you want discussed, so please let us know if there are topics of particular interest to you.

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

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SPOTLIGHT ON: RESEARCH SUPPORT SERVICES

Did you know that the Center for Clinical and Translational Science and Training (CCTST) has a “concierge” function to provide trainees, entry-level and established faculty, with resources in protocol development, biostatistical/bioinformatics support and community-based research? You can find out more and access these services at cctst.uc.edu.

Additionally, the Clinical Trials Office (CTO) can help UC Health Researchers with marketing and business development, study placement, contracts and budgets, and participant recruitment. The CTO comprises a medical director, Mike Spigarelli, MD, PhD, a business director, Mindy Muenich, and a marketing and recruiting coordinator, Jake Matig. Lona Joiner coordinates the contract review process and provides administrative support.
ORCRA NEWS

Mandatory Pre-review of Medical IRB Protocols
The University of Cincinnati strives to ensure that our research meets the highest level of scientific integrity and to ensure that human study participants are enrolled in high-quality research projects.

As described in Human Research Protection Policy III.01 REVIEW BY THE INSTITUTIONAL REVIEW BOARD OF HUMAN SUBJECTS RESEARCH, in order to approve human subjects research, the Institutional Review Board (IRB) shall determine that “Scientific or Scholarly Review by qualified individual(s) has demonstrated that (a) the research uses procedures which are consistent with sound research design; (b) the research design is likely to answer the proposed scientific question, and (3) the importance of the knowledge expected to result justifies approval of the research. Such review shall be certified by the academic department chair or responsible administrator.”

In keeping with these standards and the recommendations of the Institute of Medicine, scientific review prior to submission to the IRB for all non-exempt medical human research protocols, except those solely involving pre-existing records and/or specimens will soon be required prior to submission to the IRB. This scientific pre-review will not replace IRB review, but the results will help the IRB complete their deliberations with a more complete understanding of the importance of the scientific question being addressed, as judged by experts in the field. Pre-review is already in place for both oncology and Cincinnati Department of Veterans Affairs Medical Center studies and serve as examples of how pre-review facilitates the IRB review process.

The process for scientific pre-review will be accountable at the level of the academic unit (department, division, center, etc.). Each academic unit (division, department, etc.) engaged in non-exempt medical human subjects research must have a scientific pre-review process by Jan. 1, 2011. A template checklist to use as a starting point can be found at http://researchcompliance.uc.edu/irb/Scientific_Review.html.

Each academic unit should customize their process to fit their individual needs. Academic units may choose to accept the review of protocols that have already been reviewed and approved (Center, NIH, multi-center, industry sponsored, etc.); however, they are advised that external reviewers may not always have their depth of scientific knowledge and the application submitted and reviewed by NIH may not have sufficient details to ensure a comprehensive scientific review. Upon completion of review by the academic unit, the following should be included along with the protocol to IRB:

- all pertinent correspondence between reviewers and investigators clearly communicating to IRB all concerns regarding science and their resolution
- documentation that concerns were addressed

Each academic unit (division, department, etc.) engaged in non-exempt medical human subjects research must have a scientific pre-review process in place by Jan. 1, 2011. Please note that the Center for Clinical and Translational Science and Training (CCTST) can provide support for pre-review of study design and implementation.

If you have additional questions or concerns please contact us at research.compliance@uc.edu. We are happy to answer questions and/or meet with you/your faculty to facilitate implementation.

IACUC NEWS

Electronic Submission of Non-Traditional Procurement Forms
In order to facilitate the timely and accurate submission of non-traditional procurement forms used to
report in-house breeding or acquiring exotic species, a new web-based form has been developed. This form has been designed to prevent the most common errors seen during submission. You are strongly encouraged to begin using this form for all future submission. All reports submitted after Sept. 30, 2010, must use the electronic form (access the form here.) Effective Nov. 29, 2010, orders for animals may be placed electronically. To access the form, go the LAMS website and select “Animal Ordering,” “Per Diem & Other Charges,” then select “Animal Requisition Form.”

NOT-OD-10-128: Clarification on the Role of the IACUC
The National Institutes of Health (NIH) issued a notice to “clarify how the Vertebrate Animal Section (VAS) of applications for grants, fellowships, and cooperative agreements is evaluated as part of the NIH peer review process and is considered as part of the overall scoring. Further clarification is provided on the oversight role of the Institutional Animal Care and Use Committee (IACUC) and review responsibility of NIH Scientific Review Groups (SRG).” More information at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-128.html.

IRB NEWS/NEW OR UPDATED HRP POLICIES AND PROCEDURES

Revised IRB Web Page
Thanks to your feedback, we have revised the Institutional Review Board (IRB) website to make it more user friendly. If you have suggestions on additional changes that would make it easier to find what you need please let us know.

Satisfaction Survey
We value your comments and you are always welcome to provide it directly to whomever you are working with in the office; however, if you would prefer to use a survey to provide feedback please visit http://tinyurl.com/38cdaax to take the UC IRB Feedback Survey. While the survey allows you to provide contact/follow-up information it is otherwise anonymous.

Informed Consent Expiration
Please note that if you are doing research, you will receive an Informed Consent Document (ICD) that is IRB stamped “Approved” at the time your initial submission is approved, at the time of continuing review and for any modifications submitted that require changes to the ICD. You must use the most current “Approved” ICD at all times. If you have received a more recent ICD, please implement a plan at your site to ensure this ICD has replaced prior versions.

Responsibility for Registering Clinical Trials
National Institutes of Health (NIH), Industry, and multi-site trials must be registered on clinicaltrials.gov. This role is performed by the study sponsor. The clinicaltrials.gov registration system requires the administrative organization to be named sponsor. This meaning of ‘sponsor’ is different from the Food and Drug Administration (FDA) meaning and may be confusing.

Investigator initiated trials and research in which the principal investigator holds the IND or IDE are administratively maintained by the University of Cincinnati. Julie Waltz Gerlach is the clinicaltrials.gov administrator for these studies. If you have any questions about registration of a clinical trial please contact her at julie.gerlach@uc.edu. Remember: When administering clinicaltrials.gov for investigator initiated and/or studies in which the principal investigator has their own IND/IDE, UC is solely facilitating maintenance and accuracy of the clinicaltrials.gov website and is assuming no other responsibilities associated with sponsor.

What Is a Sponsor?
The FDA defines sponsor in the Code of Federal regulations (CFR 312 and 812) as follows: “a person or other entity that initiates but does not actually conduct the investigation.” In many but not all cases, the sponsor is also the funding organization.

Principal investigators holding their own INDs or IDEs are considered to be the sponsor and are considered to meet the federal definition of sponsor-investigator (21 CFR. 50.3).
The sponsor is responsible for regulatory oversight of the study. The University of Cincinnati is not a sponsor as defined by CFR 312 and 812. According to UC HRRP Policy III.01: “Review by the Institutional Review Board of Human Subjects Research”: “Under no circumstances will the University take on the role as sponsor.”

IND/IDE Assistance Program
The IND/IDE Assistance Program (IAP) is an educational and assistance resource for faculty researchers conducting clinical research as sponsor-investigators with FDA regulated products. A sponsor-investigator is defined by the federal regulations as an individual who both initiates and actually conducts the investigation. These individuals are responsible for maintaining Investigational New Drug (IND) or Investigational Device Exemption (IDE) applications. All IND and IDE applications must be reviewed and approved by prior to submission to FDA and IRB approval will be delayed until IAP has approved. Additionally, IAP will visit sites to ensure that the required maintenance reports have been submitted to the FDA, to verify appropriate overall study conduct, and to facilitate compliance with all relevant regulations.

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QUALITY IMPROVEMENT TIPS FOR INVESTIGATORS

FDA Inspections
Taking time at the end of each day during an FDA inspection to meet with the agency inspector and discuss observations may help clear up potential misunderstandings. Investigators have the right to review the Establishment Inspection Report (EIR) during a closeout discussion. The study team should note anything that is not entirely accurate and bring it to the attention of the inspector at that time. If you are anticipating an FDA audit, please contact Angela Braggs-Brown. She can help you prepare and respond appropriately when actions are indicated. Additionally, any documentation from the FDA should be included in your IRB progress reports.

Notes-to-File
Notes-to-file do not correct inaccurate or incorrect documentation. Notes-to-file are tools designed to explain or clarify a given situation when there is no other way to provide the information. When creating a note-to-file, include the date, study title, protocol number, and clearly state the issue or explain what issue is being addressed. Only include the facts. Notes-to-file should be signed by the writer and co-signed by the principal investigator to demonstrate awareness of the issue. A copy should be maintained in the study file.

Reporting Requirements
Some departments and most external facilities require reporting of study activities that are outside of the IRB review. This reporting includes, but is not limited to, initial submission of a protocol, adverse events and changes to the research. It is the responsibility of the principal investigator to ensure that these reporting requirements are met. If you have questions or concerns, please feel free to contact your department head or the IRB Office at (513) 558 5259 or irb@ucmail.uc.edu.

FDA Final Rule on Safety Information Reporting Requirements
Please note that the FDA has issued final rule on safety information reporting requirements during clinical trials. Read more at fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm227386.htm.

Research Compared to Standard of Care
Any “test” done for research purposes should remain in the research world. Actual test results should not be given to the treating team, nor should they be put in the medical record unless the test was done through usual hospital processes (usually as a purchased service). Ideally, the potential need to directly alert a patient’s clinical team of research test results for the purpose of addressing an urgent safety issue is addressed via a disclosure in the informed consent document. Under this process, if there are findings that are of “clinical importance,” the treating team would be told. Any test that was not done as part of usual hospital processes and is thus not part of the medical record should not be used for medical decision making—the clinical team should determine how to react to being told of a “clinically important” finding.
The overall priority, regardless of consent document, is the welfare of the participant. If a research test indicates something serious, it may be considered an SAE and the treating team may need to be immediately notified to prevent adverse outcomes for the patient. This should be documented accordingly.

All research consents should contain language that indicates communication between research and treating teams might occur, e.g. "The researchers may communicate with your health care providers if they find anything that might impact your usual medical care."

BIOSAFETY NEWS

IBC Registration for Core Facilities
The support services and technology provided by core facilities are critical to facilitate basic and translational research programs. Those facilities should be registered with the Institutional Biosafety Committee (IBC) in case experiments involve the use of recombinant DNA, biohazardous agents (e.g., bacteria, viruses, fungi, protozoa, prions) and/or human source materials (e.g., blood, bodily secretions and tissues, primary and established cell lines). IBC registration should not only apply to the core facilities but also to their users. Because of that, the IBC counts on the cooperation of the institution’s core facilities verifying IBC compliance of their collaborators. To simplify this process, the biosafety office has developed communication procedures which can be found at http://researchcompliance.uc.edu/biosafety/documents/Core_Facilities_and_IBC_Compliance.html.

RESEARCH COMPLIANCE EVENTS/TRAINING OPPORTUNITIES

Comprehensive Chemical Hygiene Plan
Did you know that every department or program that works with chemical substances should put together a comprehensive chemical hygiene plan? The faculty in the chemistry department and Environmental Health & Safety (EH&S) are working together to develop and implement a chemical hygiene plan template that may be used at the departmental or laboratory level. In the meantime, if you need help contact EH&S at ehs.uc.edu/contact.asp.