Responsible Conduct of Research Training

I wanted to make you aware of important seminar progress that we offer as part of our regulatory compliance and clinical research support center. Seminars are held 1st Wednesday each month Noon to 1pm (website) This program concerns 9 elements of Responsible Conduct of Research and includes the following:

Your Scientific Reputation

Although elements that comprise a scientific reputation are difficult to define precisely, a good scientific reputation has a substantial downstream impact on one’s research success. Being a responsible, contributing member to the research community and displaying impeccable professional conduct have important ramifications on one’s scientific reputation.

Research Misconduct

Specifically means: Fabrication, falsification, plagiarism and other forms of misrepresentation of ideas, and other serious deviations from accepted practices in proposing, carrying out, reviewing, or reporting results from research. Under University of Colorado policy, it also includes failure to comply with established standards regarding author names on publications. With questions or concerns contact: Research Integrity Officer (RIO)- Dr. Alison Lakin (303) 724 0982 or Chair of the Research Ethics Committee -Dr. John Repine (303) 724 4783

Mentorship and Collaboration

Mentor selection should be approached in a systematic fashion to ensure that expectations of each party can and will be met. Certain features in a qualified mentor are easy to discover (research support, prior trainees, and areas of expertise). Others, more nebulous, include working style and communication skills. Open honest dialogue in the mentor-mentee relationship favors both research and career goals being met successfully.

Translational Research

Translational research is complex, typically involving multiple investigators employing a variety of experimental models, technologies, and research strategies. Projects often require multiple institutional committee reviews and may involve export controls, biological shipping, or HIPAA. This course will familiarize researchers with the institutional resources available to safely navigate translational research projects.

Data

Best practices for collection and storage of research data are of paramount concern when developing reproducible research. Also important is establishing who "owns" the data and developing a data-sharing plan. Furthermore, statistical analyses need to be carried out in a rigorous and transparent manner that maximizes accuracy and minimizes bias.

Safe Lab Practices

Promoting a culture of safety is everyone’s responsibility. This course addresses laboratory safety resources, and the role of mentor-mentee relationships in cultivating a safe environment. Academic research laboratories employ chemical, infectious and radioactive hazards. Safe practices are a collaborative effort between the PI, researchers and Environmental Health and Safety.

Authorship

Substantive contribution to the manuscript is required for authorship (concept/design; data acquisition; analysis/interpretation; draft, critical revision; final approval and public accountability for work). Consider how this applies to collaborative, multi-author papers. Avoid plagiarism (appropriating another's ideas without giving credit); this is a form of research misconduct, which can include self-plagiarism.

Peer Review

Evaluation of grant applications and manuscripts by colleagues with appropriate knowledge and experience determines which papers are published and which grants are funded. Reviewer responsibilities include responsiveness, competence, impartiality, confidentiality and constructive approach to criticism. Appropriate peer review supports the advancement of scientific research.

Conflict of Interest

Includes any situations in which financial or other personal considerations may adversely affect, or have the appearance of adversely affecting, an employee’s professional judgment in exercising any duty or responsibility in administration, management, instruction, research and other professional activities. As a resource for faculty, a centralized Conflict of Interest and Commitment Office reviews all financial at least annually.
New Federal Statute for Research on Newborn Dried Blood Spots

Congress has created a new provision under Amendment 12 that will be applicable to federally funded research using newborn dried blood spot. Effective March 16, 2015, research involving newborn dried blood spots (whether identifiable or deidentified) is considered to be human subjects research under 45 CFR Part 46, and the IRB cannot approve a waiver or alteration of consent for federally funded research.

Amendment 12 was enacted as a provision of the Newborn Screening Saves Lives Reauthorization Act of 2014, which is an extension of Newborn Screening Saves Lives Reauthorization Act of 2008. Newborn dried blood spots are collected from all babies born in the United States in order to conduct mandatory screening for serious medical conditions. Oftentimes, leftover blood spots were kept for research purposes without the informed consent of the parents or legal guardians. Prior to Amendment 12, IRBs used to review research involving biological samples that are not linked to identifiable information as NSHS or exempt research. Neither require obtaining informed consent. Privacy advocates have objected to the release of dried blood spots to researchers without parental knowledge or consent. Amendment 12 requires that all research on newborn dried blood spots be considered human subjects research regardless of whether or not the samples are identifiable. Additionally, the IRB cannot approve waivers or alterations of informed consent for research involving newborn dried blood spots unless the research fits into one of the Exempt categories. If the IRB determines that the research does not fit into an Exempt category, prospective informed consent must be obtained.

COMIRB has recently updated the SmartPDF Application form to incorporate this change (Section G). If you have any questions, please contact us for assistance (303-724-1055).