Research Administration Open Forum

FEBRUARY 17, 2016
VPR/OSP Update

CHRISTA JOHNSON
VPR/OSP Updates

- Departure of Kathy Partin
- Christa’s Areas of Responsibility
- Diane Barrett, new Director of Sponsored Programs
- Karen Dobos, new Director of RICRO
- Uniform Guidance Committee Update
NIH Update

DAVE DOTY
NIH Applications Update

Some new NIH policies require additional data collection and updates to their application forms. NIH is implementing a 2 phase roll out. Phase 1 (Forms-C) took effect 1/24/16. Phase 2 (Forms-D) updates are expected by 3/25/16 and take effect on or after 5/25/16.

    The planned changes focus on the following areas:
    • Rigor and transparency in research
    • Vertebrate animals
    • Inclusion reporting
    • Data safety monitoring
    • Research training and training tables
    • Assignment request form
    • Font requirements
    • Biosketch clarifications

NIH Salary Cap

• Executive Level II – was set at $183,300.

• Effective January 10, 2016, the cap was increased to $185,100.

• See NOT-OD-16-045
GxP Update

CAT BENS
Colorado State University
Research and Manufacturing of Regulated Product: Update

Office of the Vice President for Research
Research Integrity and Regulatory Compliance Review (RICRO)
17 February 2016
What are Regulated Products?

- FDA: Food, Drugs and Cosmetics
  
  Drugs: A substance or device intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease or intended to affect the structure or any function of the body, including biological products intended for human use.

- EPA: Pesticides and Toxic Substances

- USDA: Veterinary Biologics
What are Regulated Products?

**Human and Animal Drugs**

- Food and drug additives
- Biologics
- Pesticides

**Animal food additives**

- Medical devices and electronic products
What are the Relevant ‘GXP’ Regulations?

• Good Laboratory Practices - Standards of conduct for non-clinical research intended to be submitted in support of an application for a marketing or research permit.

• Good Clinical Practices - Standards for clinical research intended to be submitted for both human and animal clinical trials.

• Good Manufacturing Practices - Standards under which products are manufactured, aimed at ensuring that products are consistently manufactured to a quality appropriate to their intended use.
Regulated Product Pathway

GLP  GCP  GMP

Basic Research  Preclinical Development  Clinical Trials  FDA Filing/Approval

- Conception
- Design
- Sterilization
- Design Controls
- Mechanical Testing
- Biocompatibility
- Packaging
- Labeling
- Validation Development
- Animal Efficacy
- Ethics Review
- Regulatory Review IDE
- Regulatory Review PMA/510(k)
- Feasibility
- Efficacy
What are the main challenges?

- Increasing number of regulated product research conducted
- Increasing diversity in regulated product research
- Generally uneducated faculty and sometimes sponsors
- Facility can engage in regulated product research for which CSU becomes the ‘Test Facility’ without us being aware of this vulnerability
- Sponsors can submit data without our knowledge
CSU Quality Management System

- Policy
- MRDA/TO/Quality Agreements
- Protocol/Quality Manual
- Standard Operating Procedures
- Benchtop Instructions/Data collection
Strategies?

- Regulated Products Research and Manufacturing Policy with EC Support
- Awareness (as early as possible) and Support
  - OSP/RICRO Partnership and education
  - Departmental partnership and education
  - MRDA/Task Order Review
  - IACUC/IRB/BSC screening
- RICRO QA Support Tool Development
  - Regulatory Decision Trees/Wizards
  - Website Support
  - SOPs and templates
- Laboratory Consultations
  - Individualized Training
- QAU Inspectional Oversight
- Campus-wide Inspectional Readiness Program
- BioMARC Quarterly QA Meetings and Biannual Management Review Meetings
- QA Advisory Board
Quality Program

QUALITY PROGRAM
Research Integrity & Compliance Review Office

Contact Us
Mission
Training
QA Services & GxP
ClinicalTrials.gov
IND/INAD/IDE Support
Investigator’s Brochure
Use of Computers in Research
FDA Guidance on Cell-Based Products
Proposal Guidance – Research Integrity and Responsible Conduct of Research (RCR) Requirements

NIH, NSF, and USDA have specific requirements for some funding mechanisms to document RCR and/or data integrity activities. Please contact the RCR Coordinator if you have any questions.

NIH
- Enhancing Reproducibility through Rigor & Transparency Guidance [NOT-OD-15-103] requires specific language in R01 funding mechanisms. A delineation of the requirements can be found here. ☞ More...
- Individual Development Plans for Graduate Students and Postdoctoral Fellows requires that a formal mentoring plan (IDP) be generated for all trainees [NOT-OD-13-033 and NOT-OD-14-113].
- Sample NIH Mentoring Plans ☞ More...

NSF
- Section 7008: Mentoring Plans for all postdoctoral fellows, (42 USC 1862a)
  - Each proposal that contains postdoctoral researchers must include, as a supplementary document, a description of the mentoring activities that will be provided for such individuals. The mentoring plan must not exceed one page.
  - Mentoring activities may include career counseling, training in preparing grant applications, guidance on ways to improve teaching skills, and training in research ethics.
  - In addition, all progress reports for research grants that include funding to support postdoctoral researchers must include a description of the mentoring activities provided to such researchers.
- Sample NSF plans ☞ More...
- Section 7009: RCR Instruction (42 USC 1862o-1)
  - CSU PIs are currently in compliance with Section 7008 by virtue of the establishment of the CSU institutional RCR training program. According to the CSU policy, PIs must require RCR instruction for all undergraduates, graduates, and postdoctoral fellows who are paid salary on the NSF/USDA NIF grants. Additionally, CSU policy requires faculty, research scientists, and research associates funded by USDA NIFA to take RCR training. No additional actions are needed at the time of grant submission; nor are additional progress report actions needed.
- FAQs about NSF RCR requirements

USDA
- Responsible and Ethical Conduct of Research
  The responsible and ethical conduct of research (RCR) is critical for excellence, as well as public trust, in science and engineering. Consequently, education in RCR is considered essential in the preparation of future scientists. By accepting a NIFA award the grantee assures that program directors, faculty, undergraduate students, graduate students, postdoctoral researchers, and any staff participating in the research project receive appropriate training and oversight in the responsible and ethical conduct of research and that documentation of such training will be maintained. Grantees are advised that the documentation of the training are subject to NIFA review upon request. ☞ Read more...
CSU Research Success

- Faculty/BioMARC
- Sponsored Programs/Dept Review Offices
- OVPR
- Federal Agencies
- Research and Compliance
- RICRO
- Sponsor
Questions, Comments, Ideas?
eRA Update

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Questions?