Regulatory Compli e

The Fundamentals of Sponsored Project Administ t CSU

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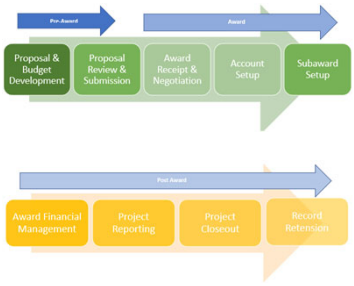

Sponsored Project Lifecycle

https://www.research.colostate.edu/osp/

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Relevant CSU Units & Terminology

Kuali: Software system comprised of modules used by CSU in support of the management of sponsored projects and regulatory compliance.

Office of Sponsored Programs (OSP): Central CSU administrative unit that authorizes and submits proposals on behalf of CSU and receives/negotiates awards.

Office of the Vice President for Research (OVPR):
Sponsor: Central CSU administrative unit providing support and services for research activities at CSU.

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Research Integrity & Compliance Review Office (RICRO): Central CSU unit that assists researchers, staff, and faculty oversight committees in maintaining an ethical environment in research and teaching.

Research Integrity Officer (RIO): Individual at CSU who oversees research integrity, misconduct, and conflict management at CSU.

Secure & Global Research (SGR): Central CSU administrative unit providing training and resources for investigators conducting restricted research, working with controlled technology, controlled unclassified information (CUI), export-controlled information, and international collaborations. SGR also oversees the Conflict of Interest (COI) disclosure process at CSU.

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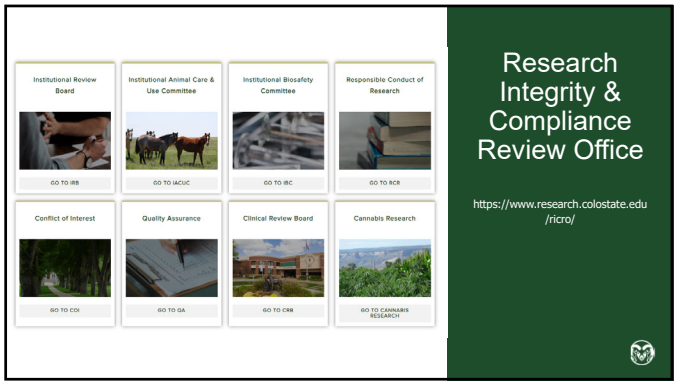

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Institutional Review Boards & Protocols

- Investigators wishing to conduct research involving human subjects must submit protocols to one of two Institutional Review Boards (IRBs) for approval.
- Protocols are developed, submitted, and reviewed in Kuali Protocols.
- Protocol approval must be in place prior to conducting research, regardless if funding is in place.
- Some awards stipulate a Single IRB for review.

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Research?	Human Subjects?
▪ 45 CFR 46 (Common Rule) defines 'Research' as a systematic investigation (gathering and analysis of information) designed to develop or contribute to generalizable knowledge.	▪ 45 CFR 46 (Common Rule) defines 'Human Subjects' as a living individual about whom information or biospecimens are obtained through intervention or interaction with living individuals. It also includes obtaining, using, studying, analyzing, or generating identifiable private information or identifiable biospecimens.

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Levels of IRB Review

Exempt	Human subject research not subject to 45 CFR 46 due to specific criteria
Expedited	Human subject research involving no more than minimal risk but does not meet exemption criteria
Full	Human subject research with protected populations; potentially harmful procedures; etc. that does not meet exempt / expedited criteria

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At the Proposal Stage

- Most federal agencies require proof of approved protocols prior to releasing an award (aka Just-in-time).
- Some proposals include several studies. All studies must be reviewed and approved.
- Most agencies require proof of the institution's Federal Wide Assurance (FWA).
- CSU must ensure that subrecipients hold an active, current FWA.

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Changes to Proposed Activities

- Institution and PI are responsible for notifying sponsors of a change in scope or IRB required modifications.
- PI must notify IRB of any changes in proposed activities as a result of agency review.
- PI is responsible for obtaining IRB approval of changes to approved activities.

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Research Involving A[illegible]al Su[illegible]s

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Policies and Regulations

- CSU IACUC Policies
- Animal Welfare Regulations (USDA)
- Public Health Policy (NIH/OLAW)
- And other applicable guidance (AAALAC, Guide, Ag Guide)
- Additional committee for client-owned animals and consent forms: Veterinary Teaching Hospital Clinical Review Board (VTH CRB)

What is an "animal"?

- Use of live vertebrate animal in research / teaching by / for CSU
- Examples: Client-owned animals enrolled in vet clinical trials, livestock at ARDEC, livestock used in teaching at VTH, wildlife field studies, CEMML management work, "traditional" biomedical research, etc.

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IACUC Protocols

- Investigators wishing to conduct research involving live vertebrate animals must submit protocols to the Institutional Animal Care & Use Committee (IACUC) for approval.
- Online system used is Kuali Protocols (KP)—same as IRB.
- Different documentation options: IIA or MOU, IACUC Waiver, IACUC Protocol, or VTH CRB Protocol approval must be in place prior to conducting animal activities.

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At the Proposal Stage

- Most federal agencies require proof of approved protocols prior to releasing an award (aka Just-in-time).
- Some proposals include several studies.
- Most agencies require proof of the institution's OLAW Assurance
- CSU ensures that subrecipients have an OLAW Assurance for PHS-funded animal activities.

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Prior to Release of Funds: Congruency

Grant to Protocol Congruence is required by NIH/OLAW, covers a number of Public Health Service Agencies and a few others.

Check for general agreement between activities described in the VAS/Research Strategy (or Materials & Methods) section of the grant and the applicable IACUC protocol.

CSU Attending Veterinarian and his staff perform this review during protocol review.

Congruency is the responsibility of the institution, not the IACUC. This is just how CSU chooses to carry out this responsibility.

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Changes to Proposed Activities (Amendments)

- CSU and PI are responsible for notifying sponsors of a change in scope or procedure/activity.
- PI must submit an amendment to change their IACUC protocol and notify their program officer of the change (congruency).
- PI is responsible for obtaining IACUC approval of changes to approved activities. CSU is also responsible that PI follows through.

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Research Involving P[illegible]ntially Biological Hazardous Materials

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Biohazardous Materials?

- Recombinant DNA or synthetic nucleic acid molecules (r/sNA); includes gene editing tools, such as CRISPR, TALENS, and ZFNs.
- Any infectious agents or biological toxins
  - HHS and USDA Select Agents and Toxins
- Agents and/or experiments identified as having Dual Use Research of Concern (DURC) potential
- Human body fluids or tissues

Policies and Regulations

- *NIH Guidelines for Research Involving Recombinant DNA or Synthetic Nucleic Acid Molecules* (NIH Guidelines)
- CDC/HHS *Biosafety in Microbiological and Biomedical Laboratories* (BMBL);
  - Federal Select Agent Program (FSAP)
- *USG Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern*
- OSHA's *Bloodborne Pathogens Standard*

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Institutional Biosafety Committee & Approvals

- Investigators wishing to utilize biohazardous materials must submit an approval request to the Institutional Biosafety Committee (IBC).
- Two-forms, submitted via IBC Online Database:
  - Agent Approval Request Form (AARF)
  - Project Approval Request Form (PARF)
- AARF/PARF approval must be in place prior to ordering or using biohazardous materials, regardless if funding is in place.

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Levels of IBC Review

Designated Review	Low risk agents and/or activities; use of human samples
Full IBC	Higher risk agents and/or activities; use of recombinant or synthetic nucleic acids; use of select agents; agents or experiments with DURC potential
+ IRE Review	Research involving a subset of agents and/or experiments that meet the criteria for DURC potential must also be reviewed by the IRE

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At the Proposal Stage

- Some federal agencies require proof of IBC approval prior to releasing an award (e.g., ONR)
- Some proposals include several studies. All studies must be reviewed and approved by the appropriate compliance committees
- Some agencies require CSU's SA registration number
- For subawards involving DURC agents, CSU must ensure that subrecipients have appropriate DURC polices in place

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Changes to Proposed Activities

- Institution and PI are responsible for notifying sponsors of a change in scope or IBC required modifications.
- PI must notify IBC of any changes in proposed activities as a result of agency review.
- PI is responsible for obtaining IBC approval of changes to approved activities (AARFs and PARFs).

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Responsible Conduct in Research (RCR)

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Tenets of RCR

- Social Responsibility
- Scientific Rigor & Reproducibility
- Data acquisition, management, sharing, and ownership
- Mentor / trainee responsibilities
- Publication practices and responsible authorship/ peer review
- Peer review
- Human / animal subjects
- Research misconduct (fabrication, falsification, plagiarism)
- Conflict of interest/commitment
- Safety & Sustainability

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CSU RCR Training Requirements

NSF, NIH and USDA-NIFA all have RCR training requirements

National Institutes of Health (NIH) and National Science Foundation (NSF)

Undergraduate Students: Online RCR training only

Graduate Students / Postdoctoral Fellows: Online RCR and approved face-to-face training

United States Department of Agriculture-National Institutes of Food and Agriculture (USDA-NIFA)

Undergraduate Students, Research Scientist/Associate, Faculty: Online RCR training only

Graduate Students / Postdoctoral Fellows: Online RCR and approved face-to-face training

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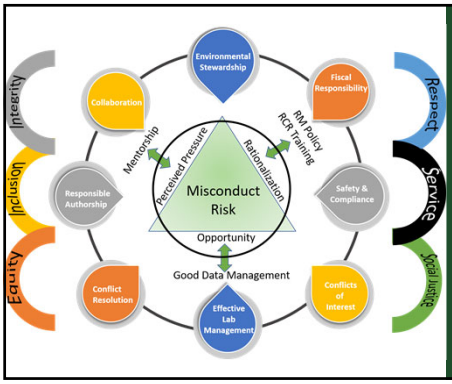

RCR is Necessary Regardless of Funding!

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Conflict of Interest (COI)

COI occurs when a party has competing interests or loyalties because of their duties to more than one person or organization.

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Financial Conflict of Interest (fCOI)

Federal agencies are concerned about financial conflicts of interest in research when an investigator has a significant financial interest that may compromise, or have the appearance of compromising, professional judgment in the design, conduct, or reporting of research.

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Federal Disclosures

- Federal disclosures are required for significant financial interests (SFI) for the investigator, spouse, and dependents related to investigator's institutional responsibilities.
- Disclosures apply to all individuals responsible for the design, conduct, or reporting of research.
- Disclosures may be required at time of submission for funding.
- Proof of fCOI training may be required by some agencies.

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PHS Agency Requirements

A potential fCOI exists when an investigator's significant financial interest could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

Several federal and non-federal agencies use the Public Health Service (PHS) fCOI regulations.

A list of current agencies requiring adherence to the PHS fCOI Regulation found on the RICRO website: https://www.research.colostate.edu/coi-policy/

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Sponsored Programs Considerations

- Annual COI Disclosure Required – every 12 months. https://www.research.colostate.edu/ricro/coi/
- Unit review for Other Support in sponsor-required documents
- Federal Sponsors are increasingly concerned about investigators reporting potential conflicts.
  - NIH and NSF have updated guidance on what must be disclosed in the Other Support (NIH) and Current & Pending Support (NSF)
    - NIH-Disclosures-Table.pdf
    - NSF Pre-award and Post-award Disclosures Relating to the Biographical Sketch and Current and Pending Support

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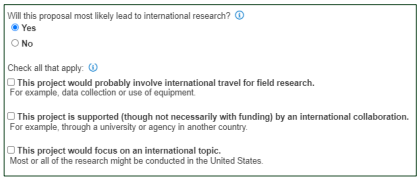
Sponsored Programs Considerations

- Federal sponsors are increasingly concerned about potential foreign influence
- KR PD Standard Questionnaire asks questions regarding International Research



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Research Involving Controlled Unclassified Information (CUI) & Export-Controlled Information

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Controlled Unclassified Information (CUI)

- Information that must be protected when being accessed, processed, or transmitted from non-federal systems.
- Control requirements may be found in sponsored agreements with federal and non-federal entities.

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Export Controls

Export Controls – U.S. laws and regulations that regulate and restrict the release of critical technologies, information, and services to foreign nationals, within or outside of the United States, and foreign countries for reasons of foreign policy and national security.

Export – Transmission of items, technologies, services, and data outside the U.S.

Deemed Export – Release of technology, items, data to a non-U.S. person.

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Sponsored Programs Considerations

- Fundamental Research Exclusion (FRE) impacted when CSU or investigator accepts publication restrictions
- KR PD Standard Questionnaire asks questions regarding Export-controlled and Controlled / Classified Information & Foreign Travel

Do you anticipate that this project will involve restrictions such as export controls, controlled unclassified information (CUI), or classified information and/or work?
- (•) Yes
- ( ) No

This project would likely involve export controls.
- ( ) Yes
- ( ) No

This project will probably include controlled unclassified information (CUI).
- ( ) Yes
- ( ) No

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Resources

Office of Sponsored Programs (OSP)
https://www.research.colostate.edu/osp/

Office of the Vice President for Research (OVPR)
https://www.research.colostate.edu/

Research Integrity & Compliance Review Office (RICRO)
https://www.research.colostate.edu/ricro/

Secure & Global Research (SGR)
https://www.research.colostate.edu/sgr/

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