Sponsored Programs Compliance

Sponsored Programs Workshop
May 8, 2013
Overview of Workshop

- Introductions
- Sponsored Programs Compliance
- Responsible Conduct of Research / Ethics
- Financial Conflict of Interest
- Animal Subjects
- Human Subjects
- Q & A
Sponsored Programs Compliance

Compliance is guided by

- Policies and Regulations – CSU, SJSU, SJSURF, City, County, State, Federal, Sponsor
- Federal - OMB Circulars, Department of Health and Human Services - Office for Human Research Protections, US Department of Agriculture - Animal Welfare Act
- Award Stipulations or Contract Clauses
What is the difference between the Research Foundation and the Tower Foundation?

- The **Tower Foundation** is the University’s **philanthropic foundation** and was established to encourage connections between alumni, donors and the community. The Tower Foundation is dedicated to growing the university's endowment through donations, bequests, and major gifts.

- The Tower Foundation works with faculty and university administration to **develop requests for gifts submitted to private foundations, and those proposals** are reviewed and authorized by the AVP for Graduate Studies and Research.

- The **Research Foundation and the Tower Foundation consult with each other as needed and work together to ensure consistency with university priorities**.
Who is Responsible for Compliance Assurance

- **The Associate Vice-President of Graduate Studies and Research** is the chief research officer of SJSU and the president’s designee to approve proposals submitted for external funding. In her role as AVP, Dr. Pamela Stacks reviews and signs every proposal that is submitted from SJSU. [www.sjsu.edu/gradstudies](http://www.sjsu.edu/gradstudies)

- **The SJSU Research Foundation** has been designated by the SJSU president to serve as the campus *Sponsored Programs Administrator* or SPA. The SJSU Research Foundation is authorized to develop and submit proposals (pre-award), as well as receive and administer awards (post-award). Jerri Carmo is Interim Chief Operating Officer and Director of Sponsored Programs for both Pre-Award and Post-Award. [www.sjsufoundation.org](http://www.sjsufoundation.org)

Together **GS&R and SJSURF** manage the process of developing and submitting proposals to external sponsors and ensuring compliance.

- **Committees – Institutional animal Care & Use Committee (IACUC)**
  Institutional Review Board (IRB)
Responsible Conduct of Research
NSF and NIH

Jerry Flanzer, Assoc. Dean of Research, GS&R

(First,) do no physical or psychological harm during their participation.

Safeguard participants’ data.

Monitor data to ensure no harm and to find surprisingly better results!

Include your procedure in your application.

Protect people.
Protect their data.
Research Integrity

(beyond fiscal, and human and animal rights)

- Honesty - conveying information truthfully and honoring commitments.
- Accuracy- reporting findings precisely and taking care to avoid errors.
- Efficiency - using resources wisely and avoiding waste.
- Objectivity - letting the facts speak for themselves and avoiding improper bias.
Regulations plus

Resources to help navigate the responsible research waters include

- Copies of institutional research policies
- Links to state and federal policies
- Required forms and instructions for completing them
- RCR training programs
- List of key personnel and resources to turn to. (SJSURF to the rescue!)
- Objectivity - letting the facts speak for themselves and avoiding improper bias.
The San Jose State University is committed to the ethical principles for the protection of human subjects in research as set forth in the Belmont Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1979)

The ethical principles are:
- Respect for persons - which includes the requirement of a voluntary informed consent process
- Beneficence – which entails an obligation to protect persons from harm by minimizing risks and maximizing benefits
- Justice – which requires that selection of subjects be fair and equitable and that particular care be taken when working with populations (i.e. children, decisionally impaired) whose status puts them in a vulnerable position.
The Animal Care and Use Committee is committed to responsible oversight of the use of vertebrate animals in research, testing and exhibition in accordance with Public Health Service Policy. The Committee assures that all use of animals at San Jose State University is in compliance with the Animal Welfare Act, the Public Health Service Policy on Humane Care and Use of Laboratory Animals, the Guide for the Care and Use of Laboratory Animals and all other applicable federal, state and local regulations, policies and procedures.
Data and safety Monitoring Plan

Data and Safety Monitoring Plans (DSMP) are meant to assure that each clinical investigation has a system for appropriate oversight and monitoring of the conduct of the clinical investigation. This oversight ensures the safety of the participants and the validity and integrity of the data.

It is the policy of the NIH that each Institute and Center (IC) should have a system for the appropriate oversight and monitoring of the conduct of clinical trials to ensure the safety of participants and the validity and integrity of the data for all NIH-supported or be conducted clinical trials. The data and safety monitoring functions and oversight of such activities are distinct from the requirement for study review and approval by an Institutional Review Board (IRB).
Training!!!!!!!!!!!!!!!!!!!!!

Faculty and Students

Who must receive the RCR training?

NSF expects institutions to be able to verify that those students (undergraduates and graduates) and postdoctoral researchers who receive NSF funds (support from salary and/or stipends to conduct research on NSF grants) will obtain RCR training.

However, NSF anticipates that institutions will develop their RCR training programs in a manner that helps prepare the next generation of researchers, including the consideration of risks or other factors associated with student and postdoctoral researcher participation in research.
Grant Compliance and Oversight

http://grants.nih.gov/grants/compliance/compliance.htm

Admin requirements     Cost principles     Audit Requirements

College & Universities

A-110 (2 CFR Part 215) Formerly at (45 CFR Part 74)

A-21 (2 CFR Part 20)

A-133
Certificates of Confidentiality: Human Subjects

Everything you ever wanted to know and then some


As a public service, the NIH Office of Extramural Research offers a free tutorial on Protecting Human Research Participants that institutions may elect to use to fulfill requirement for education in the protection of human subjects

http://phrp.nihtraining.com/users/login.php
Everything you wanted to know and then some – on SJSURF website


- In compliance with federal regulations San Jose State University and the San Jose State University Research Foundation require Principal Investigators and other key personnel on a sponsored project to disclose Significant Financial Interest
Mandated registration-available through Graduate Studies and Research Website and SJSURF:

Collaborative Institutional Training Initiative (CITI)
https://www.citiprogram.org/Default.asp

Financial Conflict of Financial (+) interest (potential gain)
- Entire portfolio that you control, not just direct relationship to the study
- Issue of Appearance
- If unavoidable, report, report, report
- If circumstances change, report, report, report
- NIH FCOI Tutorial (on SJSURF website)
Yes - there are policies and rules to follow. They are there to keep you out of trouble, but they won’t stop you from achieving your goals.
IRB and IACUC Coordinators

Alena Filip, IRB Coordinator, (408) 924-2479 or alena.filip@sjsu.edu
Human Subjects – Institutional Review Board (IRB)

The collection of data from humans, including surveys, interviews, questionnaires, web forms, evaluations in which opinions are sought, etc., all require IRB review (application or request for exemption). Requires NIH Online Training (2 hours).

GS&R IRB: [http://www2.sjsu.edu/gradstudies/Research/irb.html](http://www2.sjsu.edu/gradstudies/Research/irb.html)

Larry Young, IACUC Coordinator, (408) 924-4929 or lyoung@science.sjsu.edu
Animal Subjects – Institutional Animal Care and Use Committee (IACUC)

SJSU has established an IACUC, which is qualified through the training and expertise of its members to oversee the institution's animal care and use program, university facilities, and all animal-related activities.

GS&R IACUC: [http://www.sjsu.edu/gradstudies/iacuc/](http://www.sjsu.edu/gradstudies/iacuc/)