Responsible Conduct of Research

Sponsored Programs Workshop
October 1, 2015
Overview of Workshop

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

Guided by:

- Policies and Regulations – CSU, SJSU, SJSURF, City, County, State, Federal, Sponsors


- Award Stipulations or Contract Clauses

- SJSU Research Foundation and University Advancement staff help SJSU ensure adherence.
What is the Difference Between the Research Foundation and the Tower Foundation?

The **SJSU Research Foundation** is a non-profit auxiliary of SJSU, delegated the authority by CSU and SJSU to submit proposals and accept awards for external funding on behalf of SJSU.

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.

SJSU Corporate and Foundation Relations is under University Advancement and works with faculty and university administration to **develop requests for gifts, contributions, and grants submitted to private foundations and corporations. Those proposals** are reviewed and authorized by the AVP of Research, SJSU Office of 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 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/research/](http://www.sjsu.edu/research/)

- **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). [www.sjsu.edu/researchfoundation/](http://www.sjsu.edu/researchfoundation/)

- **The Tower Foundation** and **Corporate and Foundation Relations** also ensure compliance for externally funded philanthropic gifts and endowments.

- Together **SJSU and the Research Foundation** 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)
Basic Premise
Responsible Conduct of Research

- Do no physical or psychological harm during participation.

- Safeguard participant data.

- Ethics
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.
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 ([http://www.sjsu.edu/research/faculty-training/](http://www.sjsu.edu/research/faculty-training/))
- Key personnel and resources to turn to. (Research Foundation and Office of Research to the rescue!)
- Objectivity – letting the facts speak for themselves and avoiding improper bias.
San José 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 **Institutional Animal Care and Use Committee (IACUC)** is committed to responsible oversight of the use of vertebrate animals in research, testing, and exhibition in accordance with the Public Health Service Policy.

The Committee assures that all use of animals at San José 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 Plans (DSMPs) 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, for example, 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).
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 at large, not just those receiving external funding for research.
Federal contracts and grants Administrative Requirements, Cost Principles, and Audit Requirements are now all rolled up into one guidance called the Uniform Guidance – UG.
Certificates of Confidentiality

Everything you ever wanted to know and then some
Kiosk
http://grants.nih.gov/grants/policy/coc/

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 requirements for education in the protection of human subjects.

http://phrp.nihtraining.com/users/login.php
In compliance with federal regulations San José State University and the San José State University Research Foundation require principal investigators and other key personnel on a sponsored project to disclose significant financial interest.
Mandated Registration

Available through SJSU Office of Research and the SJSU Research Foundation

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 the Research Foundation website)
Human Subjects and Animal Subjects
A Different Process for Different Work

**Before** commencement of work!!

- Exclusion (2-5 business days)
- Exemption (7-10 business days)
- Expedited Review (one month)
- Full Review (no summer and winter schedule)
- Registration (2-5 business days)
Exclusion

The (only) Two Criteria for Review

🎯 Is your work research?
- A *systematic investigation* designed to contribute to *generalizable knowledge*
- Usually includes a publication/dissemination component

🎯 Does your work involve human subjects?
- Direct interaction/intervention with individuals
- Analysis of or access to private records
Exemption

Oversight Without a Formal IRB Review

- Research that’s no greater than minimal risk
- No protected groups – children, pregnant women, prisoners.
- Must fit into at least one of the prescribed categories (see exemption screening form)
- Office of Research screens for eligibility and registers the research
- Complete protocol required
Formal (non-exempt) IRB Review Categories

“Expedited” is defined by how well you have prepared your protocol.

**Expedited Review**
- **Default** review process if research is not eligible for exemption
- One reviewer evaluates and approves the protocol

**Full Review**
- IRB member optional recommendation
- A majority of committee members must decide
- Problematic protocols/ethical concerns

"Expedited" is defined by how well you have prepared your protocol.
IRB Registration

One Form for (Almost) Everything Else

Express your intent to conduct human subjects research if you are:

- An SJSU investigator with a pending grant
- An SJSU investigator with IRB approval from an outside institution
- An outside investigator with IRB approval from home institution

No review takes place!

Creates a paper trail for documenting compliance
IRB How?

As in, “How Do I Get the Ball Rolling?”

Utilize the many resources available:

- IRB website:
  http://www.sjsu.edu/research/irb/index.html

- IRB checklist
  http://www.sjsu.edu/research/docs/irb-checklist.pdf

- IRB FAQs:
  http://www.sjsu.edu/research/docs/irb-procedures.pdf

- Contact the IRB coordinator. . .
Alena Filip
IRB/Thesis Coordinator
Phone: 408-924-2479
Email: Alena.Filip@sjsu.edu
Location: ADM 223
Address: Office of Research
San José State University
One Washington Square
San José, CA 95192-0025
Animal Subjects Regulatory Oversight & Policies

- U.S. Department of Agriculture, Animal Care Division
  SJSU Registry # 93-R-0427

- PHS Policy, Office of Laboratory Animal Welfare - Institutional Assurance with NIH & NSF
  SJSU Assurance # A3648-01

- SJSU Senate Policy S14-6

- IACUC Guidelines and Animal Welfare Policies

- SJSU is not an AAALAC accredited institution
IACUC Definitions

- **Animal** – vertebrates, venomous inverts, fertile eggs

- **Non-living tissue** – tissue, serum, scat, feather & fur

- **Activity** – manipulation, holding, harassment, baiting, trapping, breeding, tracking, surgery, etc.

- **Facility** – sites used to manipulate, transport or hold animals, including off-campus performance sites.

- **Personnel** – direct contact w/animals and the PI
Protocol for Animal Care & Use

- To be approved by the IACUC **before** the activity commences.

- Contact IACUC Coordinator for any questions if activity is covered by IACUC or not.

- IACUC exemption notices can be issued.

- Electronic copy of submission (including permits) and one signed hard copy for file.
Protocol Submission Forms

- Care and Use of Live Vertebrate Animals
- Use of Non-living Animal Tissues
- Observational Animal Studies
- Care and Use of Invertebrates & Fertile Eggs
- Request for Alternate IACUC Approval
- IACUC Approval Exemption Form
Protocol Submission Tips

Attach cover letter.

Include images in narrative to help describe procedures or equipment.

Veterinary consult for painful/distressful procedures.

Allow time for IACUC Coordinator to assist with polishing the submission.

Submit protocol application 60 days before you wish to begin (2 weeks for abbreviated forms).
Protocol Review Procedures

- IACUC meets third Friday of the month (except July)

- Applications received on the 1\textsuperscript{st} of the month will be placed on the IACUC meeting agenda for that month.

- Reviewer remarks will be routed to protocol director for clarification before the IACUC meeting.
Approval Period & Annual Review

- Three year maximum approval for any one application; then full *de novo* review.

- Protocols are reviewed annually on the anniversary date every year they are valid.

- IACUC office will send out request for annual review 30 days before anniversary (not available online).
Protocol modifications must be submitted in writing and granted written approval before any change is instituted.

Minor vs. significant changes to a protocol.

Administrative Changes – add personnel or approval extension.
Training Requirements

- Collaborative Institute Training Initiative (CITI) offers online tutorials and test modules
- “Working with the IACUC” for investigators & students.
- Species-specific and wildlife modules
- Refresher course (every 3 years)
- Proof of online training from outside institutions may be accepted.
Contact Information

Larry Young
Animal Care Facilities Manager
IACUC Coordinator
Veterinary Nursing Supervisor

Animal Care Department Office
Duncan Hall Room 244 – desk 408-924-4929
lawrence.young@sjsu.edu
http://www.sjsu.edu/research/iacuc/
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.
October 15, 2015
Introduction to the SJSU Research Foundation – Focus on Pre-Award
MLK Library 255/257
11:30 a.m. – 1:00 p.m.

November 19, 2015
Grant Proposal Development – Taking a Bite Out of Forms
MLK Library 255/257
11:30 a.m. – 1:00 p.m.