Institutional Responsibilities in Research Management

Ann Pollack
Assistant Vice Chancellor - Research

September 29, 2009
Conducting Research: shared responsibilities

- UCLA agrees to provide space, resources, facilities, ethical reviews, administrative support, policies, procedures, etc. with every proposal submitted.

- With every award accepted, UCLA agrees to ensure that monies will be spent appropriately, auditable records will be kept and reports submitted.

- PI is primarily responsible for the design, conduct and reporting of the research.

- Resulting IP reviewed and possibly protected by The Regents.
An Increasingly Regulated Environment

- Federal
- State of California
- University of California
- UCLA
- Sponsors
Research Support

CONTACTS & GRANTS

Material Transfer Agreements

Internal University Funds

Gifts

Unfunded

Research
Research Support

- Contracts & Grants
- Technology Licensing
- Purchasing
- Material Transfer Agreements
- Health Sciences COI Policies
- Gifts

Research Support
Institutional Responsibilities

- Human and Animal Research Subject protection
- Conflict of Interest Reviews
- Research Integrity policies
- Recombinant DNA/Biohazard Reviews
- Managing use of Select Agents
- Ensuring open environment
- Export Control and Foreign Assets Control Regulations
- Protecting Academic Freedom (publication rights, intellectual property)
- Effort Reporting
- Consistency in Budgeting and Spending
- Reducing Institutional and Personal Risk (indemnification and subject injury language)
- Confidentiality and Non-disclosure Agreements
- Accountability for equipment, money and loaned materials
- Reporting to the Government
- Monitoring Subrecipients
- Maintaining Core Facilities
- Cost Sharing/Matching
- Human Embryonic Stem Cell Reviews (ESCRO) and Research Oversight
- Laboratory Safety
- And more…
How can the institution be affected by questionable or bad behavior?

- Suspension or termination of research
- Disallowance of award funding
- Questions about the integrity and reputation of the researcher
- Loss of public trust and confidence in research outcomes
- Damage to institutional reputation
- Possible violation of University policy or regulations or law
- Concerns about violating the rights and welfare of human research subjects
- Penalties and Fines
- Lawsuits
- Jail sentences
Budgeting and Spending

- OMB Circular A-21 (Cost Principles)
  - Cost Accounting Standards
  - Effort Reporting Requirements
  - Direct vs. Indirect Costs
- Negotiated Facilities and Administrative rate (Indirect Costs)
- Sponsor policies
- Assurance of appropriate controls
Human Research Protection Programs
(More Information on Oct. 13th)

- The Common Rule (45 CFR Part 46) - outlines institution’s responsibilities for conducting research involving human subjects:
  - Institutional Review Board (IRB)
  - Informed Consents
  - Federalwide Assurance (FWA)
  - Reporting noncompliance
  - FDA regulations (21 CFR Part 50) - clinical studies
- AAHRP Accreditation
Animal Research Subject Protection

- Animal Welfare Act
- HHS regulations
- Department of Agriculture regulations
- Animal Welfare Assurance

- AALAC accreditation
- Animal Review Committee
- Reporting noncompliance to Federal Government (OLAW)
Human Embryonic Stem Cell Research  (More Information on November 3)

- California Institute for Regenerative Medicine (CIRM)
  - Regulates stem cell research
  - Provides funding through grants, loans, and research facilities
  - CA law and UC Policy requires ESCRO review and approval of all human embryonic stem cell research (hESC) and IRB review and approval of certain hESC research
- March 9, 2009 - President Obama issued Executive Order (EO) 13505
  - Removing Barriers to Responsible Scientific Research Involving Human Stem Cells
  - NIH may support and conduct responsible, scientifically worthy human stem cell research, including hESC research, to the extent permitted by law
- July 7, 2009
  - Final NIH Guidelines for Human Stem Cell Research
    - Establishes policy and procedures under which the NIH will fund human embryonic stem cell research
    - Establishes a new NIH Registry of hESCs eligible for use in NIH funding
    - Centralizes the procedures for NIH review of hESCs for inclusion on the Registry
- 2010 Injunction
Research Misconduct: More Nov 17

Falsification, Fabrication and Plagiarism

- Federal definition and agency-specific regulations
- University must have policy and procedures for responding to allegations of research misconduct
- Vice Chancellor Research = Research Integrity Officer
- Annual report and renewal of assurance
- Required reporting to sponsors and government
Conflicts of Interest

- Research
- Conflicts of Commitment
- Purchasing of Goods and Services
- Use of University Property and Facilities
- Personnel
- Inventions, Patents and Licensing, More on Oct 20
Conflicts of Interest in Research

- Federal regulations
- California regulations
- Required disclosures of individual financial interests by PIs and all others who share responsibility for the design, conduct or reporting of research
- Required policies and reviews
- Required reporting to sponsors
"You're off the hook—in order to have a conflict of interest, you gotta have an interest in the first place."

THE CHRONICLE OF HIGHER EDUCATION

MARK LITZLER
Financial Conflicts of Interest

- Recognition of the possibility that a financial interest might bias research
- Distinctions between financial interests and conflicts of interest
- Challenge of managing, reducing or eliminating conflicts of interest
- Increased public scrutiny and pressure to ensure that all financial interests are disclosed, reviewed and reported
- Interest by professional organizations, media, and federal agencies in going beyond current regulations
Focus of conflict of interest review by the CIRC

- Magnitude and nature of the research
- Roles of the investigator
- Involvement of students/postdocs/fellows
- Adherence to University guidelines and policies
- Appropriate use of University facilities
- Rights to publish and distribute results
- Ability to separate University commitments from outside activities or build firewalls
Sample “Management Plans”

- Disclose financial interests in publications, presentations and informed consent forms
- Limit annual income from sponsor to $10,000 during the study
- Ask another investigator to recruit and enroll subjects
- Prohibit acquisition of additional equity during study
- Reduce or eliminate financial interests
  - Sale of stock
  - Blind trust
  - Resignation from Board of Directors
- Oversight (Data Safety Monitoring Board or other)
- Tell all study personnel of the financial interests
New Concerns

- Institutional Conflicts of Interest
- Conflicts of Interest involving clinical practice and treatment
- Conflicts of interests involving pre-clinical research
Coming soon - changes to Public Health Service regulations

- Significant changes
- No additional funding
- Mandated annual disclosure of all financial interest related to institutional responsibilities (not just PHS–supported research)
- Required assessment of disclosures to determine which are related to PHS funded research
- Mandatory posting of some financial interests on a publicly accessible website
- Required report to PHS of management details
"Under disclosure rules, I'm required to tell you I own stock in the company whose drug I'm prescribing."