Just the Facts 204: Research Compliance for Research Administrators

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Public Trust

- The conduct of research is a privilege granted by society, not an inalienable right
- The granting of the privilege is based on the public's trust that research will be conducted responsibly
- Erosion of that trust can result in the public's withdrawal of the privilege
- Public trust is maintained through accountability

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Federal Scientific Misconduct Policy (42 CFR Part 93)

Misconduct is –

Fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results

- Fabrication is making up data
- Falsification is manipulating, changing, or omitting data or results
- Plagiarism is taking another's ideas without giving appropriate credit
- It does NOT include honest error or honest differences in interpretations or judgments of data

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Research Misconduct

- Institutions must develop policies and procedures to deal with allegations of misconduct to include:
  - Definitions
  - Description of inquiry and investigational phases
  - Imposing sanctions
  - Process for protection of whistleblowers
  - Reporting to agency (process, timing)
  - Retention of records
  - DHHS requires submission of Annual Report on Possible Research Misconduct

Responsible Conduct of Research

- Responsible conduct of research is defined as the practice of scientific investigation with integrity. It involves the awareness and application of established professional norms and ethical principles in the performance of all activities related to scientific research.

New Guidelines

- New NIH guidelines for Instruction in the Responsible Conduct of Research
- Update released 11/24/09
- NIH requires all trainees, fellows, participants, and scholars receiving support through any NIH training, career development award (individual or institutional), research education grant, and dissertation research grant must receive instruction in responsible conduct of research
- Policy takes effect with all new and renewal applications submitted on or after January 25, 2010 and for all continuation (Type 5) applications with deadlines on or after January 1, 2011.

Conflict of Interest -What Is It?

- Conflict of Interest (COI) involves a situation in which a researcher has financial or other personal considerations that may compromise, or have the appearance of compromising, his/her professional judgment or integrity when conducting or reporting research.

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Circumstances Creating Conflict

- Ownership and equity
- Outside management positions
- Paid consulting
- Honoraria
- Recruitment bonuses/incentives
- “Finders fees”

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Federal Policy Mandates

- Maintain an appropriate written and enforced policy
- Designate an institutional official
- Require disclosure of financial interests prior to submission of application for funding

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Federal Policy on Disclosure

- Required for all NSF and PHS funding applications
- Applies to those involved with the design, conduct, or reporting of research
- Related financial interests must be disclosed
- Financial interest defined as $10,000 annual income or 5% equity, whichever is less

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Financial Conflict of Interest

- Specific criteria for review will be at institution's descretion
- Management of conflicting financial interests must be done
- Applications must contain certifications
- Institutional records are subject to federal review

Institutional policy must be in compliance with federal regulations/policies.

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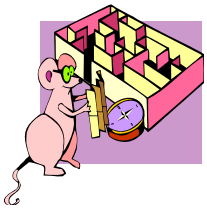
Human Subjects and Animals in Research



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Human Subject Ethical and Regulatory Guidance

- National Research Act (1974)
- Belmont Commission
- Belmont Principles
  - Respect for Persons
- Federal Regulations
  - 45 CFR Part 46 – "Common Rule" DHHS
  - 21 CFR Part 50, 56 - FDA

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Government Oversight

- Office of Human Research Protection (OHRP) DHHS
- Food and Drug Administration (FDA)

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Basic Regulatory Requirements

- Institutional Assurance
- Review of research by an Institutional Review Board (IRB)
- Informed consent of subject

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Required Review Considerations

- Risks to subjects are minimized
- Risks are reasonable in relation to benefits
- Selection of subjects is fair and equitable
- Participation is voluntary with appropriate informed consent
- Appropriate monitoring of data to protect subjects
- Adequate provisions to protect privacy

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Levels of Review

- Exempt
- Expedited
- Full Committee Review

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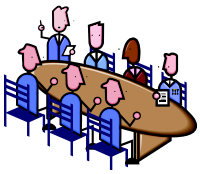
IRB Authorities

- Approve
- Require modifications
- Disapprove



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Use of Animals Regulations

- Public Law 89-544 – The Animal Welfare Act (1966 amended 1970, 1976, 1985)
  - Implementing Regulations – 9 CRF Subpart A
  - U.S. Department of Agriculture
- Public Law 99-158 –The Health Research Extension Act "Animals in Research" (1985)
  - Implementing regulations – PHS Policy on Humane Care and Use of Laboratory Animals
  - Guide for the Care and Use of Laboratory Animals
  - Office of Laboratory Animal Welfare (NIH)

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Regulatory Requirements

- USDA
  - Animals =mammals (exceptions)
  - Registration
  - IACUC
    - 3 members
    - Review program
    - Inspect facilities
    - Approve all activity using animals
    - Authorized to suspend activity
    - Annual inspection by agency
- PHS
  - Animals = vertebrates
  - Assurance – Condition of funding
  - National Research Council Guide to Care and Use
  - IACUC
    - 5 members
    - Others same as USDA
  - Agency inspections are mainly "for cause"

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IACUC Functions

- Semi-annual review of institutional animal care program
- Semi-annual review of animal facilities
- Report results of reviews to Institutional Official including noted deficiencies and recommendations
- Review, and if warranted, investigate concerns involving care and use of animals
- Review and approve, require changes, withhold approval of proposed research activities using animals
- Review and approve, require modification to changes in on-going activities
- Be authorized to suspend activities involving animals

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IACUC Review Criteria

- Procedures will avoid or minimize pain
- Appropriate sedation, analgesic, or anesthesia if more than minor pain
- Painless method of euthanasia if animals would experience chronic or severe pain
- Living conditions are appropriate and contribute to health and comfort
- Medical care available and provided by qualified veterinarian
- Personnel conducting procedures are appropriately trained and qualified

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Accreditation - AAALAC

- Association for Assessment and Accreditation of Laboratory Animal Care
- Private, non-government organization
- Voluntary peer review
- Regular site visits to the institution
- "Gold Standard" – uses USDA and PHS as the minimum standards

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The Health Insurance Portability and Accountability Act (HIPAA)

- Congress recognized that advances in electronic technology could erode the privacy of health information.
- Federal privacy protections for individually identifiable health information.
- 45 CFR 160 and 45 CFR 164

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PHI –Protected Health Information

- Maintained by covered entity
- Recorded in any medium
- Relates to past, present and future
- Identifies individual or could reasonably be used to identify the individual

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Research Use of PHI

- Research is not exempt from HIPAA
- Institution may not use or disclose PHI for research *except as permitted* in the regulations
- What are the exceptions?
  - Signed authorization from patient
  - Waiver of authorization

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Signed Authorization

- Authorization may be combined with research Informed Consent Document
- One signature – two purposes
  - Authorizing covered entity to disclose PHI to the research team
  - Documenting voluntary participation in a research study

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Waiver of Authorization

- Separate waiver from 45 CFR46 waiver of consent regulations
- Must be approved by IRB or privacy board
- Minimum necessary requirement applies

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What are Export Controls

- US laws that regulate the distribution of strategically important products, services, and information to foreign nationals and foreign countries. These things may be important for foreign policy reasons, as well as national security.

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What is an Export?

- Transferring to anyone or taking an export controlled item, material, or technical information outside of the U.S.
- Transferring/disclosing export controlled information within the U.S. to a foreign person from a country for which a control exists (deemed export)
- Performing defense services for the benefit of a foreign person or entity, in the U.S. or abroad from a country for which a control exists

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Responsible Federal Agencies

- State Department
  - Inherently military technologies—International Traffic in Arms Regulations (ITAR)
- Commerce Department
  - "Dual-Use technologies (primarily civil use)—Export Administration Regulations (EAR)
- Treasury Department, Office of Foreign Assets Control (OFAC)
  - Prohibits transactions with countries subject to boycotts, trade sanctions, embargoes

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Licensing and Exclusions

- An export license may be required before a controlled item or material may be exported
- If a license is required and denied, export or deemed export is prohibited
- Most university research and teaching qualifies for regulatory exclusions or license exemptions

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Exemptions/Exclusions

- Public domain (ITAR) / Publicly available (EAR)
- Educational Exemption (ITAR, EAR)
- Fundamental Research Exemption (ITAR, EAR)
- Bona Fide/full time Employment Exclusion (ITAR only)

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Fundamental Research Exclusion

- Is destroyed if the University accepts any contract clause that:
  - Forbids the participation of foreign nationals;
  - Gives the sponsor a right to approve publications resulting from the research; or
  - Otherwise operates to restrict participation in research and/or access to and disclosure of research results
  - Protect fundamental research exclusion by eliminating contractual clauses that destroy our ability to claim the exclusion

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Implications of Export Laws

- No effect on vast majority of university research
- But potential impact on
  - Ability of foreign students to participate in research involving a controlled technology (mostly under ITAR)
  - Ability to provide services (including training in the use of controlled equipment) to foreign nationals (ITAR, EAR, OFAC)
  - Ability to send controlled equipment to foreign countries (ITAR, EAR, OFAC)

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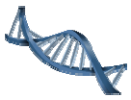
Other Compliance Issues

- Recombinant DNA
- Select Agents or Toxins
- Human Pathogens



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Questions????