# Research Compliance

# 2015

Flash Cards on Research Compliance: "Simplicity is the Key" David E. Danner©2015, J.D.; B.B.A. (TSU Class of 1991) Research and Sponsored Programs Tennessee State University

#### • SUBJECT: Animal Welfare

- RULE: Get university approval before starting research on animals: Animal Care and Use Committee (Dr. Richard Browning, x5837; Legal Counsel Laurence Pendleton, x7925).
- SOURCE: 9 Code of Federal Regulations (CFR), Part 3
- INFO: U.S. Department of Agriculture

https://awic.nal.usda.gov/final-rules-animal-welfare-9-cfr-part-3

https://www.tnstate.edu/research/compliance/index.aspx

- SUBJECT: Biosafety
- RULE: Get university approval before starting research with biosafety implications: Biosafety Committee (Dr. Mohammad Karim, x5344; Legal Counsel Laurence Pendleton, x7925).
- SOURCE: 42 Code of Federal Regulations (CFR), Part 73
- INFO: U.S. Department of Health & Human Services

http://www.cdc.gov/biosafety/publications/bmbl5/

https://www.tnstate.edu/research/compliance/biosafety.aspx

#### • SUBJECT: Costs

- RULE: Avoid unallowable costs, or expenditures, to the grant or external award from a federal agency or entity (Phyllis Danner, RSP Director, x1621; Legal Counsel Laurence Pendleton, x7925).
- SOURCE: OMB Circular A-21 [as relocated to 2 CFR, Part 200] entitled Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards ("Super Circular").
- INFO: The White House, Office of Management and Budget (OMB)

http://www.whitehouse.gov/omb/grants\_docs

- SUBJECT: Debarment and Suspension
- RULE: Disclose to the university any restrictions on research activity (Mike Batson, Internal Audit, x7656; Legal Counsel Laurence Pendleton, x7925).
- SOURCE: Executive Order 12549 (February 18, 1986) and Executive Order 12689 (August 16, 1989), and other debarment and suspension laws and regulations.
- INFO: The White House, Office of Management and Budget (OMB)

http://www.archives.gov/federal-register/codification/executiveorder/12549.html

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http://www.epa.gov/isdc/eo12689.htm

#### • SUBJECT: Discrimination, Title VI

- RULE: Title VI of the Civil Rights Act of 1964 prohibits discrimination based on race, color, or national origin in programs or activities which receive federal financial assistance (Tiffany Cox, EEO Director, x7494; Legal Counsel Laurence Pendleton, x7925).
- SOURCE: Title VI of the Civil Rights Act of 1964 (42 U.S.C. [United States Code] 2000d et seq.)
- INFO: U.S. Department of Education

http://www2.ed.gov/about/offices/list/ocr/docs/hq43e4.html

#### • SUBJECT: Discrimination, Title IX

- RULE: Title IX of the Education Amendments of 1972 prohibits discrimination based on sex in programs or activities which receive federal financial assistance (Tiffany Cox, EEO Director, x7494; Legal Counsel Laurence Pendleton, x7925).
- SOURCE: Title IX of the Education Amendments of 1972 (20 U.S.C. 1681)
- INFO: U.S. Department of Education

http://www2.ed.gov/about/offices/list/ocr/docs/tix\_dis.html

#### • SUBJECT: Discrimination, Disability

- RULE: Section 504 of the Rehabilitation Act of 1973 prohibits discrimination based on disability in programs or activities which receive federal financial assistance (Tiffany Cox, EEO Director, x7494; Patricia Scudder, Director, Disabled Student Services, x7400; Legal Counsel Laurence Pendleton, x7925).
- SOURCE: Section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 701 et seq.)
- INFO: U.S. Department of Education

http://www2.ed.gov/about/offices/list/ocr/504faq.html

- SUBJECT: Discrimination, Disability (EEO)
- RULE: The Americans With Disabilities Act (ADA) of 1990 prohibits employment discrimination based on disability (Tiffany Cox, EEO Director, x7494; Legal Counsel Laurence Pendleton, x7925).
- SOURCE: Americans with Disabilities Act of 1990 (42 U.S.C. 12101 et seq.)
- INFO: U.S. Department of Education; U.S. Department of Justice (DOJ)

http://www2.ed.gov/about/offices/list/ocr/504faq.html http://www.ada.gov/

#### • SUBJECT: Discrimination, Title VII (EEO)

- RULE: Title VII of the Civil Rights Act of 1964 prohibits employment discrimination based on race, color, sex, religion, or national origin; or, pregnancy (1978 Amendment)(Tiffany Cox, EEO Director, x7494; Legal Counsel Laurence Pendleton, x7925).
- SOURCE: Title VII of the Civil Rights Act of 1964 (42 U.S.C. [United States Code] 2000d et seq.), as amended; Tennessee Human Rights Act (Tenn. Code Ann. 4-21-401 et seq.); Executive Order 11246 (September 24, 1965) as amended by Executive Order 11375 (October 13, 1967) and as supplemented by 41 CFR [Code of Federal Regulations] 60-1.1.
- INFO: U.S. Equal Employment Opportunity Commission (EEOC)

http://www.eeoc.gov/laws/statutes/titlevii.cfm

- SUBJECT: Discrimination, Age (EEO)
- RULE: Age Discrimination in Employment Act of 1975 prohibits employment discrimination based on age (Tiffany Cox, EEO Director, x7494; Legal Counsel Laurence Pendleton, x7925).
- SOURCE: Age Discrimination in Employment Act of 1975 (42 U.S.C. 6101 et seq.)
- INFO: U.S. Equal Employment Opportunity Commission

http://www.eeoc.gov/laws/types/age.cfm

- SUBJECT: Drugs
- RULE: The unlawful manufacture, distribution, dispensation, possession or use of a controlled substance is prohibited in the covered workplace (Linda Spears, HR Director, x5282; Legal Counsel Laurence Pendleton, x7925).
- SOURCE: Drug Free Workplace Act of 1988 (41 U.S.C. 701).
- INFO: U.S. Department of Labor

http://www.dol.gov/elaws/asp/drugfree/org\_grnt.htm

#### SUBJECT: Environment

- RULE: Get university approval, and state permits, before starting research with environmental implications, including biosafety and radiation implications (Dr. Mohammad Karim, x5344; Legal Counsel Laurence Pendleton, x7925).
- SOURCE: Clean Air Act (42 U.S.C. 7401 et seq.) as supplemented by the Tennessee Air Quality Control Act (T.C.A. 68-201-101); Clean Water Act, or the Federal Water Pollution Control Act (33 U.S.C. 1251 et seq.), as supplemented by the Tennessee Water Quality Control Act (T.C.A. 69-3-101)
- INFO: U.S. Environmental Protection Agency

http://www2.epa.gov/laws-regulations/compliance

Tennessee Department of Environment and Conservation

http://www.tennessee.gov/environment/permits/

- SUBJECT: Export Control
- RULE: Do not share, transmit, or collaborate any military, sensitive, or other restricted research data, or other articles, with foreign nationals or nations, without a license (Mike Batson, Internal Audit, x7656; Legal Counsel Laurence Pendleton, x7925).
- SOURCE: Arms Export Control Act (22 U.S.C. 2778) as supplemented by the Export Administration Regulations (EAR) of the Department of Commerce at 15 CFR 730 to 744 and by the International Traffic in Arms Regulations (ITAR) of the Department of State at 22 CFR 122 to 130
- INFO: U.S. Department of State

http://www.state.gov/strategictrade/overview/

https://www.bis.doc.gov/index.php/regulations/commerce-control-list-ccl

https://www.bis.doc.gov/index.php/licensing

• EXAMPLE: UT Professor Convicted

http://www.businessweek.com/articles/2012-11-01/why-the-professorwent-to-prison; http://exportcontrol.utk.edu/

#### • SUBJECT: Conflicts of Interest (COI)

- RULE: Avoid outside interests or commitments, which significantly interfere with the employee's duties to the university or the employee's judgments, and avoid even the appearance of such interference (Mike Batson, Internal Audit, x7656; Legal Counsel Laurence Pendleton, x7925).
- SOURCE: Tennessee Board of Regents (TBR) Policy 1:02:03:10
- INFO: Tennessee Board of Regents (TBR) COI Policy; Tennessee State University (TSU) Internal Audit

https://policies.tbr.edu/policies/conflict-interest https://www.tnstate.edu/internalaudit/

- SUBJECT: Financial Conflict of Interest (FCOI)
- RULE: Complete FCOI training and, if PHS funding is sought, disclose to the university, no later than the date of application to the external funder, all significant financial interests (42 CFR 50.603) of the investigator (including immediate family) (i) which would reasonably appear to be affected by the research or educational activities funded or proposed for funding by this proposal; or (ii) in entities whose financial interests would reasonably appear to be affected by such activities (Phyllis Danner, RSP Director, x1621; Legal Counsel Laurence Pendleton, x7925).
- SOURCE: 42 CFR, Part 50, Subpart F entitled Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding Is Sought
- INFO: National Institutes of Health
- http://grants.nih.gov/grants/policy/coi/
- TRAINING: <u>http://grants.nih.gov/archive/grants/policy/coi/tutorial/fcoi.htm</u>

#### • SUBJECT: Human Subjects

- RULE: Get university approval before starting research on human subjects: Institutional Review Board (IRB) Committee (Dr. Pamela Burch-Sims, x7043; Legal Counsel Laurence Pendleton, x7925)
- SOURCE: 45 Code of Federal Regulations (CFR), Part 46
- INFO: U.S. Department of Health & Human Services

http://www.hhs.gov/ohrp/humansubjects/commonrule/

https://www.tnstate.edu/research/compliance/index.aspx

#### • SUBJECT: Intellectual property (IP)

- RULE: Report all discoveries, and other IP, to the university, for both determination and processing of protections, ownership, commercialization, and profit-sharing between investigator and institution (David E. Danner, J.D., x2934; Legal Counsel Laurence Pendleton, x7925).
- SOURCE: Bayh-Dole Act or the Patent and Trademark Law Amendments Act (35 U.S.C. 200 et seq.) as supplemented by Department of Commerce regulations at 37 CFR, Part 401
- INFO: Section 800.00, TSU Principal Investigator's Handbook; U.S. Patent and Trademark Office

http://www.tnstate.edu/research/compliance/

http://www.uspto.gov/news/speeches/2010/Kappos\_Bayh\_Dole\_Act\_Remarks.jsp

**Flash Cards on Research Compliance**: "Simplicity is the Key", (©2014-2015 David E. Danner) Tennessee State University (TSU), Research and Sponsored Programs (RSP)

- SUBJECT: Lobbying (Disclosure of Private Funds)
- RULE: If funds other than federal funds appropriated by an Act of Congress have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any federal agency, a Member of Congress, or an officer or employee of Congress or a Member of Congress in connection with this federallysupported contract, grant, loan, or cooperative agreement, Grantee shall complete and submit Standard Form (SF) LLL, *Disclosure of Lobbying Activities*, in accordance with its instructions (Mike Batson, Internal Audit, x7656; Legal Counsel Laurence Pendleton, x7925).
- SOURCE: Byrd Anti-Lobbying Amendment (31 U.S.C. 1352)
- INFO: TSU Subaward-Subrecipient Agreement

http://www.tnstate.edu/legal/contracts.aspx

#### • SUBJECT: Lobbying (Prohibition on Grant Payments)

- RULE: No federal funds appropriated by any Act of Congress can be paid, by or on behalf of Grantee, or Contractor, to any person for influencing or attempting to influence an officer or employee of any federal agency, Member of Congress, or an officer or employee of Congress or a Member of Congress in connection with the awarding of a federally-supported contract, the making of any federal grant, the making of any federal loan, the entering into of any cooperative agreement, and the extension, continuation, renewal, amendment, or modification of any federal contract, grant, loan, or cooperative agreement (Mike Batson, Internal Audit, x7656; Legal Counsel Laurence Pendleton, x7925).
- SOURCE: Byrd Anti-Lobbying Amendment (31 U.S.C. 1352)
- INFO: TSU Subaward-Subrecipient Agreement

http://www.tnstate.edu/legal/contracts.aspx

- SUBJECT: Privacy and Data Protection
- RULE: Protect student data (Mike Batson, Internal Audit, x7656 ; Dr. John Cade, Student Affairs, x5107 [TSU ID Theft Prevention Policy]; Legal Counsel Laurence Pendleton, x7925).
- SOURCE: Family Educational Rights and Privacy Act, or FERPA, (20 U.S.C. 1232g), as supplemented by Department of Education regulations at 34 Code of Federal Regulations (CFR), Part 99.
- INFO: U.S. Department of Education http://www.ed.gov/policy/gen/guid/fpco/ferpa/index.html

#### • SUBJECT: Procurement

- RULE: Buy American-made products, if federal funds are being used to make the purchase, unless a waiver is obtained (Joel Sims, Procurement Director, x5146; Legal Counsel Laurence Pendleton, x7925).
- SOURCE: Buy American Act of 1933 (41 U.S.C. 10a-10d) as supplemented by the regulations of the Department of the Interior at 43 CFR 12.700 to 12.830
- INFO: U.S. Department of Transportation

http://www.dot.gov/highlights/buyamerica

#### • SUBJECT: Radiation Safety

- RULE: Get university approval before starting research with radiation implications: Radiation Safety Committee (Dr. Mohammad Karim, x5344; Legal Counsel Laurence Pendleton, x7925).
- SOURCE: 10 Code of Federal Regulations (CFR), Part 20
- INFO: U.S. Nuclear Regulatory Commission

http://www.nrc.gov/reading-rm/doc-collections/cfr/parto20/

http://www.tnstate.edu/research/compliance/

- SUBJECT: Responsible Conduct of Research (RCR)
- RULE: Fabrication, Falsification, and Plagiarism are prohibited: Research Integrity Committee (Dr. Terrance Johnson, x5748; Legal Counsel Laurence Pendleton, x7925).
- SOURCE: Department of Health and Human Services (DHHS) including but not limited to 42 CFR Parts 50 and 93, and the regulations of the National Science Foundation (NSF) at 45 CFR 689.1, including the confidentiality provisions at 42 CFR 93.108
- INFO: Section 520.00 of TSU Principal Investigator's Handbook; Office of Research Integrity (ORI), Department of Health and Human Services (DHHS)

#### http://ori.hhs.gov/

#### SUBJECT: Terrorism and Trafficking

- RULE: Do not conduct research, or other activity, with any individual or entity that may be involved in either terrorism or human trafficking (Mike Batson, Internal Audit, x7656; Legal Counsel Laurence Pendleton, x7925).
- SOURCE: Office of Foreign Assets Control (OFAC) of the Treasury Department including but not limited to 31 CFR 500 to 599; the Trafficking Victims Protection Act of 2000 (22 U.S.C. 2104(g)) as supplemented by OMB regulations at 2 CFR 175.15
- INFO: U.S. Treasury Department

http://www.treasury.gov/about/organizationalstructure/offices/Pages/Office-of-Foreign-Assets-Control.aspx

http://www.treasury.gov/resource-center/sanctions/Pages/default.aspx

- SUBJECT: Texting while Driving
- RULE: Do not engage in text messaging on electronic equipment, supplied by the government while driving, or using such while driving on government business (Mike Batson, Internal Audit, x7656; Legal Counsel Laurence Pendleton, x7925).
- SOURCE: Executive Order 13513 (October 1, 2009)
- INFO: U.S. Government Printing Office

http://www.gpo.gov/fdsys/pkg/FR-2009-10-06/pdf/E9-24203.pdf

- SUBJECT: Travel
- RULE: Use U.S. Flag carriers for all air travel, including cargo, funded by the U.S. government (TSU Travel Office, x1891; Legal Counsel Laurence Pendleton, x7925).
- SOURCE: Fly America Act (49 U.S.C. 40118) as supplemented by the federal procurement regulations at 41 CFR 301-10.131 to 30-10.143
- INFO: U.S. General Services Administration

http://www.gsa.gov/portal/content/103191

#### • SUBJECT: Wages and Hours

- RULE: Follow all wage and hour rules for contract employees on public building or public works (e.g. campus facilities)(Ron Brooks, Facilities, Assoc. VP, x4898; Legal Counsel Laurence Pendleton, x7925).
- SOURCE: Copeland "Anti-Kickback" Act (18 U.S.C. 874 and 40 U.S.C. 3145) as supplemented by Department of Labor regulations at 29 CFR, Part 3, the Davis-Bacon Act (40 U.S.C. 276a et seq. and 40 U.S.C. 3141 et seq.) and the Contract Work Hours and Safety Standards Act (40 U.S.C. 327 et seq.) as supplemented by Department of Labor regulations at 29 CFR, Part 5
- INFO: U.S. Department of Labor

http://www.dol.gov/compliance/laws/comp-copeland.htm

#### RSP Team: Contacts

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