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Compliance Workbook

1015 18th Street, NW, Suite 901 | Washington, DC 20036

Research Integrity Resources

National Science Foundation:

https://www.nsf.gov/od/oise/intl-research-integrity.jsp

https://www.nsf.gov/oig/reports/

Health and Human Services Office of Research Integrity – Case Summaries:

http://ori.hhs.gov/case_summary

National Institutes of Health:

https://grants.nih.gov/policy/research_integrity/index.htm

U.S. Export Regulations

The U.S. government controls certain technologies that it considers to be strategically important for:

- National Security Reasons
- Nuclear Non-Proliferation Reasons
- Missile Technology Controls
- Anti-Terrorism
- Chemical & Biological Controls
- Regional Stability
- Crime Control Measures
- Anti-boycott Reasons

Foreign Persons – sometimes called Foreign Nationals

In the context of the export regulations a Foreign Person is:

- Any person who is NOT a:
    - U.S. citizen
    - U.S. Permanent Resident (Green Card). A green card indicates that the holder is a lawful permanent resident of the U.S.
    - Person who has been granted political asylum by the U.S.
- Any foreign corporation, entity, partnership or group that is not incorporated or organized to do business in the U.S.
- Any foreign government
- An individual (including U.S. citizens) who represents a foreign government or foreign organization

Three agencies – three regulations

Department of Commerce: Export Administration Act

- Export Administration Regulations (EAR)
- Covers commercial technologies
- Covers "dual use" technologies (i.e., civil + military applications)
- Entity list – 15 CFR Part 744, Supplement No. 4
- Commerce Control List - 15 CFR Part 774
- **Examples:** computers, software, sensors, lasers, toxins, pathogens, night vision goggles or cameras

http://www.bis.doc.gov/index.php/regulations/export-administration-regulations-ear

Department of State: Arms Export Control Act

- International Traffic in Arms Regulations (ITAR)
- Covers commodities and technologies with a predominantly military use or space application *(Defense Articles)*
    - **Examples:** drones, satellites, some vaccines, submarine technology, some electronic equipment
- Covers *Defense Services* (Furnishing of assistance or training to foreign persons regarding *Defense Articles*)
- U.S. Munitions List - 22 CFR Part 121

https://www.pmddtc.state.gov/regulations_laws/itar.html

Department of Treasury: Office of Foreign Assets Control ("OFAC")

- Administers and enforces economic and trade sanctions against targeted foreign countries, terrorists, international narcotics traffickers, and those engaged in activities related to the proliferation of weapons of mass destruction.
- Target specific nations in controlling significant financial transactions or services.
    - Prohibits payments or providing "value" to nationals of sanctioned countries/activities.

http://www.treas.gov/offices/enforcement/ofac/

https://www.treasury.gov/resource-center/sanctions/Programs/Pages/Programs.aspx

Fundamental Research Exclusion

Defined by National Security Decision Directive 189:
"Fundamental research" means basic and applied research in science and engineering, the results of which ordinarily are published and shared broadly within the scientific community, as distinguished from proprietary research and from industrial development, design, production, and product utilization, the results of which ordinarily are restricted for proprietary or national security reasons.
http://fas.org/irp/offdocs/nsdd/nsdd-189.htm

Defined in the regulations: 15 CFR 734.8 (EAR) and 22 CFR 120.11 (ITAR)

- Applies to research data and information
- Applies to research performed on campus here in the U.S. if there are no restrictions on publication or dissemination of the research results
- Does not cover:
    - Exports of hardware, software and technology
    - Encryption software
    - Dealing with prohibited parties or entities
    - Transactions involving embargoed-sanctioned countries
    - Research where there is no intention to publish the results
    - Research conducted outside of the United States
- **These award terms can negate the FRE:**
    - Publication restrictions
        - Terms that require approval or consent to publish
        - Other publication, access or dissemination restrictions imposed by the sponsor
        - A "side" agreement allowing sponsors to approve publication of or restrict access to project results (examples: correspondence between PI and sponsor; confidentiality agreement that includes publication restriction)
    - Participation restrictions
        - Terms that restrict participation of foreign nationals in the project limit your ability to assign students, fellows, staff and investigators to the project without approval

Prohibited/Restricted Parties

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

http://developer.trade.gov/consolidated-screening-list.html

Subscription services are also available to facilitate screening.

OFAC Sanctions and Embargoes

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

- ***Comprehensive Sanctions***: Generally prohibit **all** imports and exports of materials, financial transactions of any kind, and/or providing services of any kind. Most transactions require a specific license or exemption from OFAC.
- ***Limited Sanctions*****:** Block specific practices. Most research and business activities may be conducted without an OFAC special license, so long as specific criteria are met for a General License.
- ***Regime or List-Based Sanctions*****:** Block specific property of targeted foreign governments, regimes, supporters and persons that are not necessarily country-specific, but which may be owned, controlled by, or acting for or on behalf of, targeted countries or entities as a front organization.

EAR (Dept. of Commerce) country sanctions:

- https://www.bis.doc.gov/index.php/policy-guidance/country-guidance
- Most export restrictions are determined by the technology or product to be exported and the country of destination
- EAR Part 744 – Supplement 4 – Entity List
  https://www.bis.doc.gov/index.php/policy-guidance/lists-of-parties-of-concern/entity-list
  - Lists certain entities subject to license requirements for specified items
  - **Examples (April 2016):** Kitro Corporation (Canada); Sichuan University (China); 54th Research Institute of China; Northwestern Polytechnical University (China); Ben Gurion University (Israel); Pyramid Technologies (U.A.E.)

ITAR (Dept. of State) proscribed countries list (22 CFR 126.1):

--limits provision of Defense Articles and/or Defense Services as described in the regulation

https://www.pmddtc.state.gov/embargoed_countries/

Defense Articles/Services Defined (ITAR):

Defense Article: 22 CFR 120.6

Any item or technical data listed on the United Stated Munitions List (USML) (22 CFR §121.1). This term includes technical data recorded or stored in any physical form, models, mockups or other items that reveal technical data directly relating to items designated in § 121.1 of this subchapter. It does not include basic marketing information on function or purpose or general system descriptions.

Defense Service: 22 CFR 120.9

(1) The furnishing of assistance (including training) to foreign persons, whether in the United States or abroad in the design, development, engineering, manufacture, production, assembly, testing, repair, maintenance, modification, operation, demilitarization, destruction, processing or use of defense articles;
(2) The furnishing to foreign persons of any technical data controlled under this subchapter (see § 120.10), whether in the United States or abroad; or
(3) Military training of foreign units and forces, regular and irregular, including formal or informal instruction of foreign persons in the United States or abroad or by correspondence courses, technical, educational, or information publications and media of all kinds, training aid, orientation, training exercise, and military advice.

Technical data: 22 CFR 120.10

(1) Information, other than software as defined in § 120.10(a)(4), which is required for the design, development, production, manufacture, assembly, operation, repair, testing, maintenance or modification of defense articles. This includes information in the form of blueprints, drawings, photographs, plans, instructions or documentation.

(2) Classified information relating to defense articles and defense services;

(3) Information covered by an invention secrecy order;

(4) Software as defined in § 121.8(f) of this subchapter directly related to defense articles;

(5) This definition does not include information concerning general scientific, mathematical or engineering principles commonly taught in schools, colleges and universities or information in the public domain as defined in § 120.11. It also does not include basic marketing information on function or purpose or general system descriptions of defense articles.

The intended use of the article or service after its export (i.e., for a military or civilian purpose) is not relevant in determining whether the export is subject to the ITAR controls.

Red flags (review triggers) and sample websites

- Traveling outside the United States
  - http://orc.osu.edu/regulations-policies/exportcontrol/travel/

- Project work done abroad (by institution personnel or subrecipients)
- Collaborating with a researcher or institution from outside the United States
  - http://orc.osu.edu/regulations-policies/exportcontrol/collaborations/

- Shipping material or equipment internationally
  - http://blink.ucsd.edu/sponsor/exportcontrol/intlshipping.html

- Hiring a foreign person
  - http://www.umaryland.edu/ord/export-compliance/procedures/form-i-129-visa-petition/

- Hosting foreign persons/nationals from sanctioned or embargoed countries
- Providing tours and visits of university facilities to foreign persons/foreign nationals
  - http://www.umaryland.edu/ord/export-compliance/procedures/international-visitors/
  - http://researchintegrity.gatech.edu/about-export/foreign-visitors

Sample FAQs: http://exportcontrol.utk.edu/faq/

Sample decision tree: https://doresearch.stanford.edu/research-scholarship/export-controls/export-controls-decision-tree

Review questions (sample)

- What information, technology or technical data is involved? Is it controlled?
    - Project/research is related to nuclear, chemical, and/or biological weaponry, missiles, unmanned vehicles, encryption technologies or other items listed on the ITAR U.S. Munitions List (USML)?
    - Project involves research containing source code for encrypted software (other than publicly available software distributed at no charge)?
    - Project involves receiving nuclear, military or space related information, technical data, equipment, or software?
- Who will receive services, information, technology or technical data (individuals and entities)? Who will benefit from services provided?
    - Are any parties restricted?
- What is the destination country?
    - Do any embargoes or sanctions apply?
- What is the end use of the item?
- Does the Fundamental Research Exclusion apply?
    - Can research be published without restriction?
        - What you can publish (sponsor review OK, but not approval/consent)
        - When you can publish (other than routine delay for review/protection of IP)
        - How you can share, distribute, or use results
    - Does the award restrict participation of foreign nationals?

PENALTY EXAMPLES:

- OFAC: Criminal – University – A fine of up to $1,000,000 for each violation
- OFAC: Criminal – Individual – A fine of up to $1,000,000 or up to twenty years in prison, or both, for each violation
- ITAR: Civil penalty up to $500,000 fine for each violation
- ITAR: Criminal penalty, willful violation, up to $1,000,000 fine and/or imprisonment not more than 10 years
- EAR: Civil penalty up to $500,000 fine for each violation
- EAR: Criminal penalty, fine of up to five times the value of the exports or reexports involved or $50,000, whichever is greater and/or imprisonment not more than 5 years; in more egregious cases of willful violation, fine of up to $250,000 and/or imprisonment not more than 10 years

EXAMPLE COMPLIANCE CASES:

- Roth case, University of Tennessee:
  Why the Professor Went to Prison
  http://www.bloomberg.com/news/articles/2012-11-01/why-the-professor-went-to-prison
- Graduate student, Iowa State University:
  - Accused of scheming to illegally export defense articles (ITAR-controlled) with military application to the People's Republic of China
    http://amestrib.com/news/isu-grad-student-accused-trying-sell-military-secrets-china
  - Sentenced – to 18 months in federal prison, and will be deported from the US after completing the sentence
    https://www.justice.gov/opa/pr/chinese-nationals-sentenced-new-mexico-conspiring-violate-arms-export-control-act

Related Laws

Trading with the Enemy Act (1917) authorized the use of economic sanctions against foreign nations, citizens and nationals of foreign countries, or other persons aiding a foreign country and is the oldest such statute still in use by the United States. 50 U.S.C. App. §§§§ 1-44

International Emergency Economic Powers Act (1977), 50 U.S.C. §§ 1701-1707

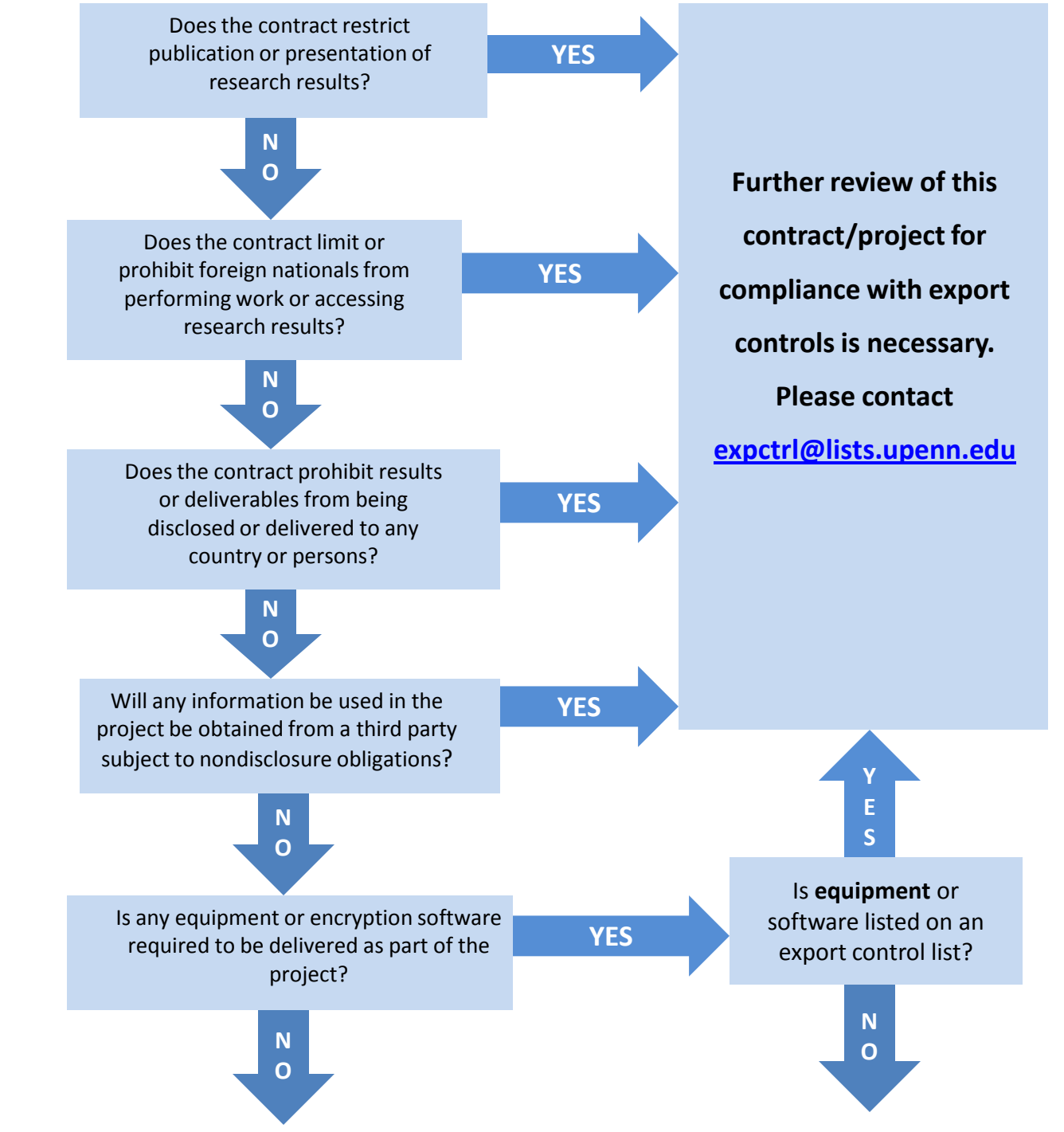
USA PATRIOT Act (Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001) – makes it a crime to provide material support to a foreign organization engaged in terrorist activity. https://www.justice.gov/archive/ll/highlights.htm

USA FREEDOM Act of 2015 (Uniting and Strengthening America by Fulfilling Rights and Ensuring Effective Discipline Over Monitoring Act of 2015) https://www.congress.gov/bill/114th-congress/house-bill/2048/text

Examples of other U.S. agencies with regulations that affect international collaborations

- Nuclear Regulatory Commission (Nuclear imports/exports)
- Department of Energy (Assistance with foreign atomic energy activities)
- Bureau of Alcohol, Tobacco, Firearms and Explosives
- Patent and Trademarks Office (Foreign IP licenses)
- Customs and Border Protection (Imports/Exports)
- US Bureau of the Census (Foreign trade statistics)
- US Fish & Wildlife Service (Certain flora and fauna)
- Animal and Plant Health Inspection Service (Animals & plants, soil & organisms)
- Food and Drug Administration (imports of samples of food, drugs, tobacco, cosmetic, etiological agents, med devices)
- Federal Aviation Administration (Hazardous materials)
- Drug Enforcement Agency (controlled substances)
- Department of Commerce, Bureau of Industry and Security, Anti-boycott Regulations
- Department of Justice, Foreign Corrupt Practices Act (15 U.S.C. §§ 78dd-1, et seq.)
- U.S. Citizenship and Immigration Services (Visas)

Is your project in compliance with export controls?



THE UNIVERSITY OF ALABAMA OFFICE OF RESEARCH
AWARD REVIEW RECORD -- EXPORT CONTROL

Title of Sponsored Research _____
Proposal/Award Number:_____
Principal Investigator:_____
Department_____ College:_____
Sponsor:_____

PART 1: PROPOSAL/AGREEMENT REVIEW (To be completed by Grant and Contract Specialist)

Does the contract contain any clause that: **Clause reference**

a. references U.S. export regulations? ☐ Yes ☐ No _____
University Counsel Comments:_____

b. restricts non-U.S. entity participation based on country of origin ☐ Yes ☐ No _____
University Counsel Comments:_____

c. Prohibits access by non-U.S. citizens to project information? ☐ Yes ☐ No _____
University Counsel Comments:_____

d. prohibits the hiring of non-U.S. persons? ☐ Yes ☐ No _____
University Counsel Comments:_____

e. addresses the use of proprietary information? ☐ Yes ☐ No _____
University Counsel Comments:_____

f. grants the Sponsor a pre-approval right over research publications? ☐ Yes ☐ No _____
University Counsel Comments:_____

g. grants the Sponsor a right to prepublication review for matters other than the inclusion of patent and/or proprietary Sponsor information? ☐ Yes ☐ No _____
University Counsel Comments:_____

h. allows the Sponsor to claim resulting research information as proprietary or trade secret? ☐ Yes ☐ No _____
University Counsel Comments:_____

i. requires the delivery of an object, article, or thing (does not mean a final report)? ☐ Yes ☐ No _____
University Counsel Comments:_____

j. Will work be performed at a location other than "accredited institution of higher learning in the U.S."? ☐ Yes ☐ No _____
University Counsel Comments:_____

k. provides a thing of value to any embargoed country? ☐ Yes ☐ No _____
University Counsel Comments:_____

Completed by:_____ Sent to University Counsel: _____
Grant and Contract Specialist Date Date

Reviewed by University Counsel: _____
Date

If you answered Yes to any of the questions above, you should consult with the UA Office of Counsel. After such consultation, it may be determined that an Export Control issue exists. In such event, the Principal Investigator Must Complete Technical Review Part II.

PART II: TECHNICAL REVIEW
(To be completed by Principal Investigator)

To All Principal Investigators: The Office of Research has determined that the sponsored research agreement for the project identified above contains provisions that may require University compliance with export control laws and regulations that are issued by the Department of Commerce, State and/or Treasury. A final determination of the application of those regulations to this particular project depends on whether the research falls within a category of technology the government has determined raises particular issues of national security or economic interest. As the Principal Investigator for the project, you are the person most qualified to decide if your research falls within covered areas. **Please note that your project should be reviewed periodically as the applicability of export control regulations could change based on the direction of the research, changes in the status of controlled information and technology or changes in the law and regulations.**

Procedures: In collaboration with the Associate Vice President for Research (AVPR), you will have to review descriptions of technologies that are controlled by the International Traffic in Arms (ITAR) or Export Administration Regulations (EAR), and review the regulations issued by the Office of Foreign Assets control (OFAC) and decide if the subject matter involved in this falls within the scope of any of these regulations. These regulations are available through links provided on the Office of Research website or in hard copy format in the Office of Research. If you have any questions, contact Carpantato Myles, Research Compliance Officer, at 348-5746 or cmyles@fa.ua.edu.

CERTIFICATION
(Please complete and return to Grant and Contract Specialist assigned to this Project.)

I have reviewed the relevant EAR, ITAR, and OFAC regulations with the AVPR. I herby certify that the information provided by me to the AVPR is true and correct. I understand that the AVPR has relied on the information provided by me in assessing the applicability of EAR, ITAR, AND OFAC regulations. Based on my representations, we have determined that Proposal/Award Number _____: (select the appropriate response)

☐ 1. Does not involve technologies that are covered by either the EAR or the ITAR:
☐ 2. May involve technologies that are covered by either EAR or ITAR:
☐ 3. Is dominated by EAR or ITAR-governed technology, specifically
(Identify category by name and section)

_____

☐ 4. Includes discrete, easily identifiable and separable research components that are within the scope of an ITAR-governed technology, specifically (identify category by name and section)

_____

☐ 5. Includes discrete, easily identifiable and separable research components that are within the scope of an EAR-governed technology, specifically (identify category by name and section)

_____

☐ 6. Provides a thing of value to an embargoed country under OFAC regulations.

I understand that if boxes 2, 3, 4, 5, or 6 have been checked, this matter will be referred to the AVPR for further action.

Printed Name, PI	**PI's Signature**	**Date**
Cindy Hope	**AVPR Signature**	**Date**

UNM Travel Review Form

For travel outside of the Continental United States

Please ***electronically*** fill out the following form (you do **NOT** need to print this form) and email it to the appropriate export control office each time you will be traveling outside of the continental U.S. Please complete and submit this form a minimum of four weeks prior to all International Travel OR as Soon as you know that export certification or review may be required as it can take up to two (2) months to complete such a process, this review is also required if you are transporting items/software/data either outside of the U.S. and/or collaborating with foreign nationals, foreign educational institutions, or foreign businesses. Please select your Export Control office below

☐ Main& Branch Campuses: export@unm.edu, 277-2968 ☐ HSC: HSCexport@salud.unm.edu, 272-5993 / 272-8675

Last Name:	First Name:
PDS/HSC ID#:	Date:
Dept.:	
Title:	
Email:	Office Phone:
Date travel begins:	Date of return to US:

1. Purpose of Travel:
   ☐Attend Conference ☐Present paper/lecture ☒Sabbatical ☐Teaching
   ☐Research ☐Vacation/Professional Leave ☐Consulting ☐Lead Study Abroad Program
   ☐Other

2. Is travel University funded? ☐Yes, indicate funding source below ☐No
   ☐ College, Dept. Funds ☐Grant – U.S. Federal ☐Personal/ outside funding ☐Other:

3. Please list county(ies) or non-continental U.S. location(s) to be visited. Include countries you may transit through (i.e., stop and change airlines, flights, etc.):

4. Will you be taking any equipment or items (biological samples, laptop, software, smart phone, GPS Unit, diagnostic kits, etc.) out of the U.S. (include all UNM owned items whether or not they have a tag#)?
   ☐Yes, please describe equipment or items below ☐No, Skip to **Question 11**

	Description	Brand & Model	Serial #	UNM Tag#
Ex	Laptop	Lenovo Thinkpad X21	A335 B752	N00499877
1				
2				
3				
4				

5. I will take the item(s) and its software abroad ONLY as a "Tool of the Trade" to conduct university business.
   ☐Yes ☐No

6. I will return the item(s) and its software to the U.S. no later than 12 months from the date of export unless they are certified by me, in writing, to have been consumed or destroyed abroad during this 12 month period. (If destroyed abroad you will need to provide documentation [police/accident reports, destruction records, etc.] with your certification).
   ☐Yes ☐No

7. I will maintain the item and its software under my "effective control" (defined as retaining physical possession of an item or maintaining it in a secure environment) while abroad. ☐Yes ☐No

8. I will not take any item or software to any country other than the ones I previously listed unless I notify the Export Control Office in writing and receive written approval from the Office before traveling to other countries. ☐Yes ☐No

9. I have added third-party software (i.e., software not owned by UNM, examples might be software owned by LANL, Sandia, AFRL, etc.) to this (any of these) item(s). ☐Yes, please describe below ☐No

10. Are you working on an export controlled project? ☐Yes ☐No

11. Do you have a security clearance? ☐Yes ☐No

12. Are you working on classified contract? ☐Yes ☐No

13. Will you be accompanied by students from UNM or other U.S. based institutions?
☐Yes, Please follow UNM Policy 2710 ☐No

14. If you are doing research while abroad please list where (the country) and with whom (institutions and/or individuals) this research will take place.

15. Have you reviewed applicable host country regulations for obtaining a VISA for research purposes?
☐Yes ☐No (Contact the respective host country consulate in the U.S. and immigration/customs enforcement for the host location.)

16. Will you be transporting any encrypted software/technology/items/data? ☐Yes, describe below ☐No

17. Have you reviewed the travel.state.gov website for travel warnings and alerts? ☐Yes ☐No (Please go to www.state.gov and review all travel warnings and alerts for the countries you will visit or transit through)

18. Have you and all others traveling for this project met with EOHS or SHAC and/or reviewed the CDC website for health risks associated with the countries to which you will travel? ☐Yes ☐No, (Please contact EOHS 272-8043, EOHS@Salud.unm.edu for employees or SHAC 277-3136, http://shac.unm.edu for students before departure)

19. If your travel is federally funded, does your travel comply with the U.S. "Fly America" Act? ☐Yes ☐No, if there are compliant options available, you may not be reimbursed.

20. Have you had an international travel briefing for this trip? ☐Yes ☐No, Contact Deb Kuidis, 277.0732, dkuidis@unm.edu for an international travel briefing before you leave.

I certify that the information provided is true to the best of my knowledge, and by clicking yes I agree to inform the Export Control Office (Main & Branch Campuses: export@unm.edu or HSC: HSCexport@salud.unm.edu) if any of the information on this form changes and/or if any equipment I take out of the U.S. is lost or stolen. ☐Yes I agree
Your Name

Internal Use Only – Export Control

☐Visual Compliance check ECCN:
Comments:
Reviewed by: Date:

UCF
Stands For Opportunity

Visa Applicant Deemed Export Questionnaire for Sponsored & Non-Sponsored Activities

Instructions: The questionnaire must be answered by the sponsoring faculty member and not by someone acting on behalf of the sponsor for all H-1B, H-1B1, L-1, O-1 non-immigrant worker visa applicants and J-1 applicants being sponsored by a technical college. Please answer the following questions to the best of your ability.

Faculty/Sponsor Name: _____ Beneficiary Name: _____

Department: _____ Phone: _____ Country of Citizenship: _____

Email: _____ Current Visa Type: _____ Requested Visa Type: _____

Dept. Coordinator: _____ Foreign University or Foreign Employer:

Email: _____ Phone: _____ _____

1. Will the beneficiary be provided access to any controlled UCF-owned technical data or technology (hardware or software) that is considered proprietary or confidential to UCF or any third party?

   ☐ Yes ☐ No ☐ Unknown/Unsure

2. Will the beneficiary be provided access to any controlled technical data or technology (hardware or software) furnished to UCF that is proprietary or confidential to a sponsor or third party? This includes U.S. government furnished technical data with access, publication, participation or dissemination restrictions or other restrictive markings, as well as ITAR-controlled information, articles, and software.

   ☐ Yes ☐ No ☐ Unknown/Unsure

3. Will the beneficiary be provided access to any government furnished equipment, information, or software specifically designed or developed for military or space applications?

   ☐ Yes ☐ No ☐ Unknown/Unsure

4. Will the beneficiary participate in sponsored research?

   ☐ Yes ☐ No ☐ Unknown/Unsure

   a. Provide the UCF Account Number or Research Identification Number of the project(s): _____

   b. Project Sponsor: _____

   c. Is the sponsored research funded in whole or part by DoD, NASA, or defense industry sponsor(s)?

      ☐ Yes ☐ No ☐ Unknown/Unsure

   d. Are these sponsored research projects export controlled or subject to access, publication, participation or dissemination restrictions?

      ☐ Yes ☐ No ☐ Unknown/Unsure

   e. Will the beneficiary be provided access to any ongoing DoD, NASA or defense industry research or research results?

      ☐ Yes ☐ No ☐ Unknown/Unsure

   f. Please specify the research type:

      ☐ Basic ☐ Applied ☐ Advanced ☐ Development ☐ Testing ☐ Service Oriented

   g. Will the research results be published or taught in an official UCF course or otherwise shared with the interested public?

      ☐ Yes ☐ No ☐ Unknown/Unsure

5. Additional comments? _____

Faculty/Sponsor Name	Faculty/Sponsor Signature	Date

The person signing this is attesting that they have full knowledge of the scope of research work of the beneficiary.

Background

The U.S. Citizenship and Immigration Services (USCIS) now requires the UCF visa signatory for foreign nationals to perform a "deemed export attestation" and under certain circumstances obtain a "deemed export" license. The information on this form must be accurately collected from the faculty sponsor and is part of UCF's due diligence for deemed export controls. It will be used to submit responses to USCIS and assist with evaluating if a "deemed export" license is required. The government may have a policy of denying licenses with regard to certain types of technology. UCF has a compliance program in place to assist with this attestation requirement. Please contact the Office of Research & Commercialization, Export Control Officer at (407) 882-0660 should you require assistance. Additional information for hiring foreign nationals is available on the Export Compliance website at: http://www.research.ucf.edu/ExportControl/I-129.html

UCF Technical Colleges/Departments

The following departments are required to complete and submit this questionnaire for J-1 visa applicants.
H-1B, H-1B1, L-1, O-1 applicants, from all UCF departments are required to complete and submit this questionnaire.

Research Centers & Institutes
- Advanced Materials Processing and Analysis Center
- Center for Advanced Turbines & Energy Research
- Florida Solar Energy Center
- Florida Space Institute
- Institute for Simulation & Training
- Nanoscience Technology Center
- Siemens Energy Center

College of Sciences
- Biomolecular Science
- Biological Science
- Chemistry
- Forensic Science
- Physics

College of Engineering & Computer Science
- All Departments

College of Optics & Photonics
- All Departments

Controlled Technologies

Controlled technologies and any related technical data associated in any capacity with the following broad categories may require deemed export licensing. The technologies listed are not all inclusive. Additional information concerning these categories is available on the UCF Export Compliance website at: Export Administration Regulations (EAR) http://www.research.ucf.edu/ExportControl/ear.html ;
International Traffic in Arms Regulations (ITAR) http://www.research.ucf.edu/ExportControl/itar.html

General Technologies relating to:
- Conventional Munitions
- Nuclear Technology, Physics, or Engineering including Materials, Facilities & Research Equipment (Miscellaneous Items)
- Materials, Chemicals, Microorganisms and Toxins used in Chemical, Biotechnology and Biomedical engineering
- Materials Technology and Processing equipment/methods
- Electronics Design, Development and Production
- Advanced Computer and Micro-electric Technology
- Telecommunications Information Security related to cryptography
- Sensors and Lasers and direct energy systems
- Navigations, Avionics and Flight Controls usable in rockets or Unmanned Air Vehicles
- Marine Technology (propulsion systems)
- Robotics (AI, Automation, Machine tools)
- Rocket or Propulsion Systems, Space Vehicles, and Related Equipment
- Remote Sensing, Imaging, Reconnaissance (radar, satellites)
- Urban Planning/Civil Engineering

Assistance to foreign atomic energy activities (10 CFR 810):
- Unclassified nuclear research activities, instruction, assistance, or applied research

Military Technologies relating to:
- Firearms, Close Assault Weapons and Combat Shotguns
- Guns and Armament
- Ammunition/Ordinance
- Launch Vehicles, Guided Missiles, Ballistic Missiles, Rockets, Torpedoes, Bombs and Mines
- Explosives and Energetic Materials, Propellants, Incendiary Agents and Their Constituents
- Vessels of War and Special Naval Equipment
- Tanks and Military Vehicles
- Aircraft and Associated Equipment
- Military Training Equipment and Training
- Protective Personnel Equipment and Shelters
- Military Electronics
- Fire, Control, Range Finder, Optical and Guidance and Control Equipment
- Auxiliary Military Equipment
- Toxicological Agents, Including Chemicals Agents, Biological Agents, and Associated Equipment
- Spacecraft Systems and Associated Equipment
- Nuclear Weapons, Design and Testing Related Items
- Classified Articles, Technical Data and Defense Services Not Otherwise Enumerated
- Direct Energy Weapons
- Submersible Vessels, Oceanographic and Associated Equipment

Please return this form to:

International Services Center
P.O. Box 160130 - Orlando, FL 32816-0130
Phone: (407) 823-2337 - Fax: (407) 823 2526
iscadmissions@mail.ucf.edu

Policy Governing UMB Compliance with U.S. Export and Sanction Laws

1.0 Policy

The University of Maryland Baltimore (UMB) is committed to full compliance with all applicable laws governing U.S. sanctions, embargoes, traffic in arms, and the export of goods, assets, technology and information (collectively, "Export Control"). All UMB Personnel (defined in Section 3.0 below) are subject to this policy.

2.0 Background

This policy is designed to ensure that UMB complies with Export Control regulations.
Export controls are set forth in regulations administered by federal agencies including the U.S. Department of State, Directorate of Defense Trade Controls, the U.S. Department of the Treasury, Office of Foreign Assets Control, and the U.S. Department of Commerce, Bureau of Industry and Security. The controls restrict the export, re-export, transfer, retransfer, and disclosure of certain technical and scientific data, software, and tangible items. Sanctions and embargoes maintained by the U.S. restrict or prohibit financial and other transactions with sanctioned individuals, organizations and countries. The reach of the regulations is broad. Certain actions that might not be regarded as "export" in other contexts may constitute an export subject to regulations and embargoes. Violations of the regulations may lead to disciplinary action for individual UMB Personnel and may also result in civil or criminal penalties for individual UMB Personnel and for UMB itself.

3.0 Defined terms

In this Policy,

3.1 **Empowered Official** means a person who is legally empowered in writing by

the university to sign export license applications or other requests for approval on behalf of UMB.

3.2 **UMB Personnel** means all UMB employees, full-time and part-time, including student employees; students; consultants; visitors; and others using UMB Resources.

3.3 **UMB Resources** means all resources owned, leased, or otherwise utilized by UMB Personnel within the scope of UMB activities including education, research, health care and service.

4.0 Applicability

4.1 This Policy, its amendments and implementing procedures and guidelines, apply to all activities using UMB Resources and conducted by UMB Personnel that may result in an export or other transaction with a foreign national, entity, or country subject to Export Controls and requiring an export license or other government approval prior to the activity taking place ("UMB Activity").

4.2 UMB Personnel are responsible for complying with this Policy and UMB procedures implementing this Policy.

4.3 UMB Personnel will comply with the provisions of any license, conditions of any other government approval, policy or UMB-directed certification, technology control plan, or procedure when it has been determined that a UMB Activity involves an export or other transaction with a foreign national, entity or country subject to Export Controls.

5.0 Authority

5.1 The UMB President appoints one or more Empowered Officials for purposes of UMB compliance with export control regulations including those under U.S. Department of Commerce Export Administration Regulations (EAR, 15 C.F.R. 730-74) and U.S. Department of Defense International Traffic in Arms Regulations (ITAR, 22 CFR 120-130).

5.2 The Empowered Official is authorized to sign applications for export licenses and other requests for government approval on behalf of UMB. The Empowered Official has independent authority to: (i) inquire into any aspect of a proposed export, (ii) verify the legality of an export transaction and the accuracy of the information to be submitted; and (iii) refuse to sign any license application or other request for approval.

5.3 The Empowered Official may act through designees including the personnel of the UMB Office of Research and Development.

5.4 The Empowered Official has direct access to the President of UMB and to UMB's Office of University Counsel with regard to any matter concerning campus compliance with Export Control regulations.

6.0 Implementation

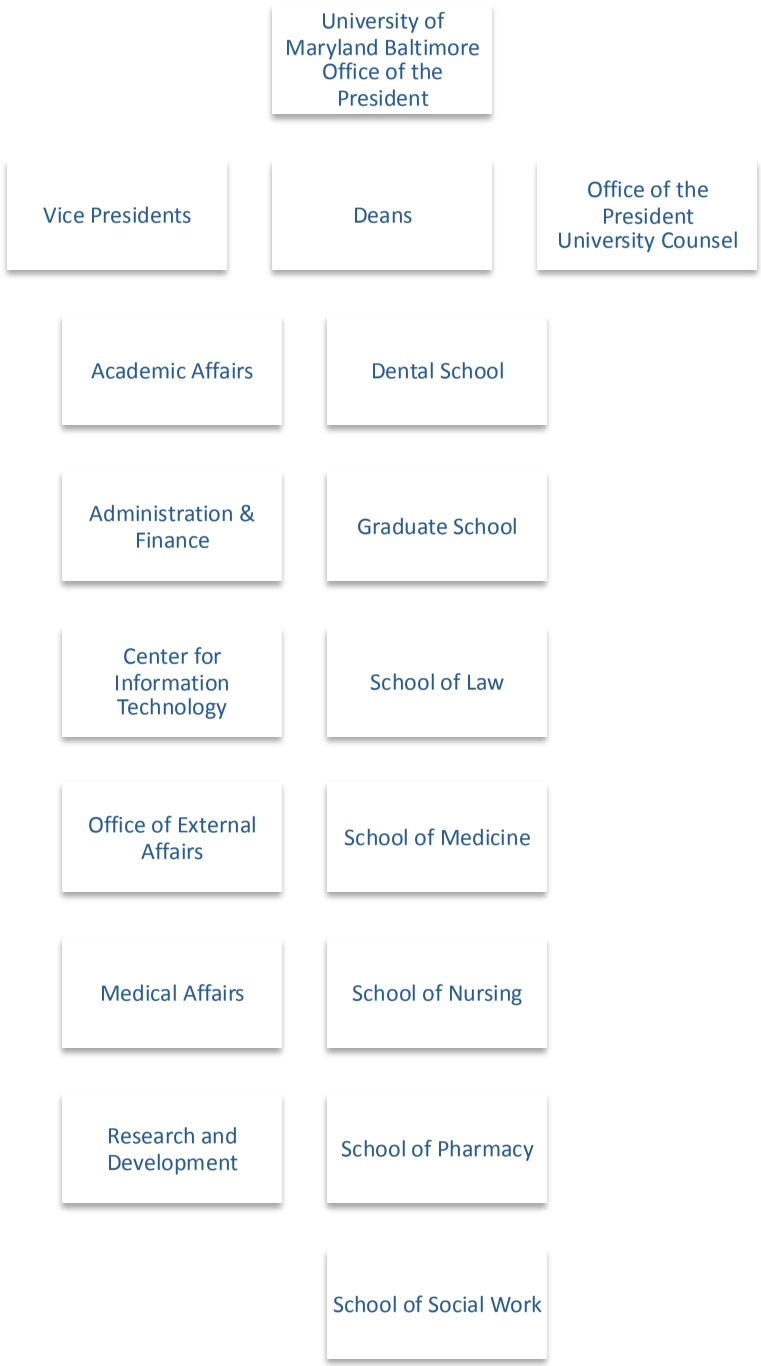
6.1 To implement this Policy, UMB will document and disseminate information on roles and responsibilities and procedures for identification, approval, and tracking of items or activities subject to Export Control laws. Record-keeping, awareness training, and procedures for self-assessments will be addressed by UMB.

6.2 The administrative unit at UMB that is charged with the responsibility for implementation of this Policy and development of related procedures is the Office of Research and Development.

6.3 The Office of Research & Development will implement this policy in a manner that is consistent with UMB's commitment to openness in research without restriction on dissemination of research results. (See University System of Maryland, IV-2.20 – Policy on Classified and Proprietary Work.)

7.0 Violations and Penalties

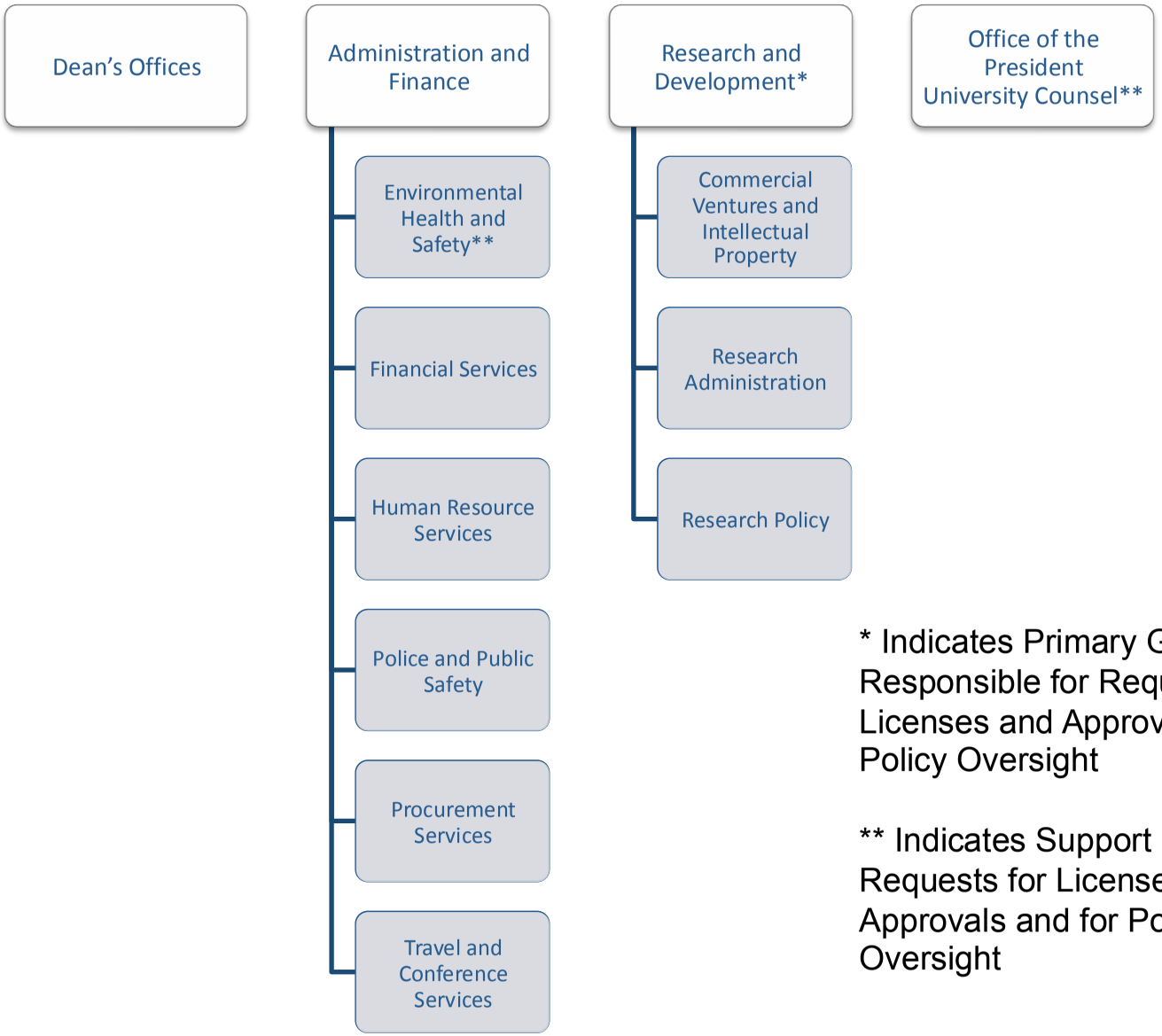
In addition to civil and criminal penalties that may apply under applicable law to individual UMB Personnel and to UMB, violation of Export Controls by UMB Personnel may subject the violator to remedial or disciplinary action by UMB for misconduct, including termination or dismissal, in accordance with applicable UMB and school policies and procedures.



Appendix A

University of Maryland Baltimore
Organization Diagram

Key Offices for Coordination of Export Control-related Procedures



* Indicates Primary Group Responsible for Requests for Licenses and Approvals and for Policy Oversight

** Indicates Support Group for Requests for Licenses and Approvals and for Policy Oversight

UNIVERSITY OF MARYLAND COLLEGE PARK
Institutional Review Board
Human Subject Research Determination

Principal Investigator	*Name of Principal Investigator*	Email Address	*PI's Email Address*

Student/Co-Investigators	*Student/Co-Investigators*	Email Address(es)	*Co-PI's Email Address*

Department	*Department*
ORA Proposal #	*ORA Proposal #*

1. Project Information:

A. **Provide a brief description of the project:** Describe the specific objectives, including background information and rationale for the proposed project. This summary should be written in a way that will be intelligible to non-specialists in your specific subject area.

Click here to enter text.

B. **Describe the subject population/type of data/specimens to be studied:** Identify who your subjects will be and indicate the type of data or specimens you will collect. Describe the methods in which the data or specimens will be collected, stored, and how confidentiality will be maintained.

Click here to enter text.

2. Determination of *Research* – 45 CFR 46.102 (d):

Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge (publication, presentation, etc.)

A. For existing specimens, was the data/specimen(s) obtained in a systematic manner?

○ No ○ Yes ○ Not Applicable ñ does not involve the collection of existing data

B. For future data collection, will the data/specimen(s) be obtained in a systematic manner?

○ No ○ Yes ○ Not Applicable ñ does not involve future data collection

C. Is the project designed to develop or contribute to generalizable knowledge (publication, presentation, etc.)?

○ No ○ Yes

D. Is the intent of the project to create an archive for the purpose of providing a resource for others to do research?

○ No ○ Yes

E. For research only involving coded private information or specimens, was the private information or specimens collected specifically for the currently proposed research project through an interaction or intervention with living individuals?

○ No ○ Yes ○ Not Applicable-does not involve coded private information/specimens

3. Determination of *Human Subject* – 45 CFR 46.102(f):

Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains **(1)** Data through intervention or interaction with the individual, or **(2)** Identifiable private information.

Intervention includes both physical procedures by which data are gathered and manipulations of the subject or the subject's environment that are performed for research purposes.

Interaction includes communication or interpersonal contact between investigator and subject.

Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

A. Does the study involve intervention or interaction with a ***human subject?***

○ No ○ Yes

B. Does the study involve access to identifiable ***private information***?

○ No ○ Yes

C. Are data/specimens received by the investigator with identifiable ***private information?***

○ No ○ Yes

D. Are the data/specimens coded such that a link exists that could allow the data/specimen(s) to be re-identified?

○ No ○ Yes

- If *Yes*: Is there a written agreement that prohibits the Principal Investigator, Co-Investigator, student investigator(s), and any other members of the research team from access to the link?

† ○ No ○ Yes (If Yes, please explain below.)

If yes, please explain here.

- Are there other legal requirements that prohibit the release of the key to the investigators, until the subjects are deceased?

† ○ No ○ Yes (If Yes, please explain below.)

If yes, please explain here.

Resources related to human subjects work performed outside the USA

The collaborating organization or the host country for an overseas project may have laws, regulations and standards applicable to human subjects research. As a general rule, the most stringent policy or regulation must be followed. Be sensitive to local laws and regulations that address data privacy and cross-border transport of biospecimens.

DHHS Office for Human Research Protections, international activities

http://www.hhs.gov/ohrp/international/index.html

World Health Organization:
Ethical standards and procedures for research with human beings

http://www.who.int/ethics/research/en/

International Compilation of Human Research Standards, 2016 Edition

http://www.hhs.gov/ohrp/sites/default/files/internationalcomp2016%20.pdf

*[Use of this sample animal study proposal is **not** required and is provided for the convenience of IACUCs at Assured institutions. Sections may be added, deleted or modified to meet the needs of individual programs.]*

Sample Animal Study Proposal

Please Leave Blank
Proposal #:
Approval Date:
Expiration Date:

Date:

A. ADMINISTRATIVE DATA

Department:

Principal investigator:

Mailing address:

Phone: Fax: E-mail:

Project title:

Initial submission: ☐ Renewal: ☐ Modification: ☐

Funding Source:

List the names of all individuals authorized to conduct procedures involving animals under this proposal and identify key personnel *[e.g., co-investigator(s)]*, providing their department, telephone, fax, and e-mail:

B. ANIMAL REQUIREMENTS

Genus: *[e.g., Mus]* Species: *[e.g., musculus]*

Strain, subspecies, or breed: *[e.g., C57BL/6]* Common name: *[e.g., Black6]*

Approximate age, weight or size:

Sex:

Bacteriological status: *[e.g., germfree (axenic), defined flora (gnotobiotic), specific pathogen free (SPF), conventional]*

Viral status: *[e.g., simian immunodeficency virus, simian retrovirus]*

Source(s): *[e.g., name of vendor or breeder, or bred in-house]*

Primary housing location(s): *[Facility manager must certify in Section S that facility has the resource capability to support the study. If animals will be housed in lab or anywhere else outside central facility for more than 12 hours, provide building and room number.]*

Location(s) where manipulation will be conducted:

Number of animals to be used:
Year 1: Year 2: Year 3:

Total number of animals to be used:

C. TRANSPORTATION

Transportation of animals must conform to all institutional guidelines/policies and federal regulations. If animals will be transported on public roads or out of state, describe methods you will use to comply with USDA regulations. If animals will be transported between facilities, describe the methods and containers that will be used. If animals will be transported within a facility, include the route and elevator(s) that will be used.

D. STUDY OBJECTIVES

Briefly explain the aim of the study and why the study is important to human or animal health, the advancement of knowledge, or the good of society in language that a layperson can understand. Please comment on whether the study unnecessarily duplicates other studies.

E. RATIONALE FOR ANIMAL USE

1. Explain your rationale for animal use. *[The rationale should include reasons why it is necessary to use animal models.]*

2. Justify the appropriateness of the species selected. *[The species selected should be the lowest possible on the phylogenetic scale.]*

3. Justify the number of animals to be used. *[The number of animals should be the minimum number required to obtain statistically valid results. Include justification for group size through a power analysis when possible.]*

F. DESCRIPTION OF EXPERIMENTAL DESIGN AND ANIMAL PROCEDURES

- Briefly explain the experimental design and specify all animal procedures. All procedures to be employed in the study must be described. This description should allow the IACUC to understand the experimental course of an animal from its entry into the experiment to the endpoint of the study. A flowchart may be an effective presentation of the planned procedure.
- A best practice is to provide an acceptable range of the specific items described below to allow flexibility in the use of professional judgment and avoid non-compliance due to work conducted off protocol as a result of overly restricted parameters.

Include the following specific information, if applicable:

- **Animal identification methods** *[e.g., ear tags, tattoos, collar, cage card, implant, etc.]*.
- **Methods of restraint** *[e.g., restraint chairs, collars, vests, harnesses, slings, etc.]*. Describe how animals are restrained for routine procedures like blood withdrawals. Prolonged restraint must be justified with appropriate oversight to ensure it is minimally distressing. Describe any sedation, acclimation or training to be used.
- **Experimental injections or inoculations** *[substances, e.g., infectious agents, adjuvants, etc.; dose, sites, volume, route, and schedule]*.
- **Blood withdrawals** *[volume, frequency, withdrawal site, and methodology]*.
- **Radiation** *[dosage and schedule]***.**
- **Food or fluid restriction** If food, or fluid, or both food and fluid, will be restricted, describe method for assessing the health and wellbeing of the animals. *[Amount earned during testing and amount freely given must be recorded and assessed to assure proper nutrition.]* If you are seeking a departure from the recommendations of the *Guide*, provide a scientific justification.
- **Pharmaceutical-grade and Non-pharmaceutical-grade Compounds** Identify any drugs, biologics, or reagents that will be administered to animals. If these agents are not human or veterinary pharmaceutical-grade substances, provide a scientific justification for their use and describe methods that will be used to ensure appropriate preparation and administration.
- **Other procedures** *[e.g., survival studies, tail biopsies]*.
- **Resultant effects**, if any, that the animals are expected to experience *[e.g., pain or distress, ascites production, etc.]*.

- **Other potential stressors** *[e.g., noxious stimuli, environmental stress]* **and procedures to monitor and minimize distress**. If a study is USDA Classification E, describe any non-pharmaceutical methods that will be used to minimize pain and distress.
- **Experimental endpoint criteria** *[e.g., tumor size, percentage body weight gain or loss, inability to eat or drink, behavioral abnormalities, clinical symptomatology, or signs of toxicity]* must be specified when the administration of tumor cells, biologics, infectious agents, radiation or toxic chemicals are expected to cause significant symptomatology or are potentially lethal. List the criteria that will be used to determine when euthanasia is to be performed. Death as an endpoint must be scientifically justified.
- **Veterinary care** Indicate the plan of action in case of animal illness *[e.g., initiate treatment, call investigator prior to initiating treatment, euthanize]*.
- **Surgical procedures** *[provide details of survival and non-survival surgical procedures in Section G.]*.

G. SURGERY

If surgery is proposed, complete the following:

1. Identify and describe the surgical procedure(s) to be performed. Include preoperative procedures *[e.g., fasting, analgesic loading]*, and monitoring and supportive care during surgery. Include the aseptic methods to be used.

2. Identify the individual(s) that will perform surgery and their qualifications, training, and/or experience.

3. Identify the location where surgery will be performed. *[building(s) and room(s)]*

4. If survival surgery, describe postoperative care that will be provided and frequency of observation. Identify the responsible individual(s) and location(s) where care will be provided. *[building(s) and room(s)]* Include detection and management of postoperative complications during work hours, after hours, weekends and holidays.

5. If non-survival surgery, describe how euthanasia will be provided and how death will be determined.

6. Are paralytic agents used during surgery? If yes, please describe how ventilation will be maintained and how pain will be assessed.

7. Has major or minor survival surgery been performed on any animal prior to being placed on this study? *[Major survival surgery penetrates and exposes a body cavity or produces substantial impairment of physical or physiologic functions or involves extensive tissue dissection or transection (such as laparotomy, thoracotomy, craniotomy, joint replacement, or limb amputation)]*. If yes, please explain.

8. Will more than one survival surgery be performed on an animal while on this study?
If yes, please justify.

H. PAIN OR DISTRESS CLASSIFICATION AND CONSIDERATION OF ALTERNATIVES

1. Pain or distress classification for USDA covered species. See Appendix 1 for classification definitions and examples.

2. Attachment 1, Explanation for USDA Classification E, must be completed for animals listed in Classification E.

Species (common name)	USDA Classification* B, C, D or E	Number of animals used each year			3 years total number of animals
		Year 1	Year 2	Year 3	

				Total number of animals	

3. Consideration of Alternatives

If any procedures fall into USDA's Classification D or E, causing more than momentary or slight pain or distress to the animals, describe your consideration of alternatives and your determination that alternatives are not available. Delineate the methods and sources used in the search. Database references must include databases searched, the date of the search, period covered, and the keywords used. Alternatives include methods that:

- refine existing tests by minimizing animal distress,
- reduce the number of animals necessary for an experiment, or
- replace whole-animal use with *in vitro* or other tests.

If you use ascites production to produce antibodies, you must provide the reason for not using an *in vitro* system. Note that you must certify in Section Q.5. that no valid alternative was identified to any described procedures which may cause more than momentary pain or distress, whether relieved or not.

I. ANESTHESIA, ANALGESIA, TRANQUILIZATION, OTHER AGENTS

For animals indicated in Section H.1. Classification D, specify the anesthetics, analgesics, sedatives or tranquilizers that will be used. *[A best practice is to provide an acceptable range of the specific items to allow flexibility in the use of professional judgment and avoid non-compliance due to work conducted off protocol as a result of overly restricted parameters.]* Include the name of the agent(s), the dosage range, route(s) and schedule of administration. If information is provided in Section R.5., above, please cross-reference. Describe tracking and security of controlled drugs (Drug Enforcement Agency requirements).

J. METHOD OF EUTHANASIA OR DISPOSITION OF ANIMALS AT END OF STUDY

Indicate the proposed method of euthanasia. If a chemical agent is used, specify the dosage range and route of administration. If the method of euthanasia is **not** consistent with the AVMA Guidelines for the Euthanasia of Animals, provide scientific justification as to why such method must be used. Indicate the method of carcass disposal if not described in Section K. below.

K. HAZARDOUS AGENTS

Use of hazardous agents requires the approval of the institutional Biosafety Office/Committee. Attach documentation of approval for the use of recombinant DNA or potential human pathogens.

Hazardous Agent	Yes	No	Agent	Date of Biosafety Approval	Tracking #
Radionuclides					
Biological Agents					
Hazardous Chemicals or Drugs					
Recombinant DNA					

Study Conducted at Animal Biosafety Level: 1 ☐ 2 ☐ 3 ☐ 4 ☐

Describe the practices and procedures required for the safe handling and disposal of contaminated animals and material associated with this study. Also describe methods for removal of radioactive waste and, if applicable, the monitoring of radioactivity.

Additional safety considerations:

L. BIOLOGICAL MATERIAL/ANIMAL PRODUCTS FOR USE IN ANIMALS

[e.g., cell lines, antiserum, etc.]

1. Specify Material:

2. Source: Material Sterile or Attenuated: Yes ☐ No ☐

   Has the material been tested for pathogens? (e.g., *MAP - Mouse Antibody Production; RAP - Rat Antibody Production; HAP - Hamster Antibody Production, PCR test)*

   Yes ☐ *[Attach copy of results]* No ☐

3. I certify that the tested materials to be used have not been passed through rodent species outside of the animal facility in question and/or the material is derived from the original tested sample. To the best of my knowledge the material remains uncontaminated with rodent pathogens.

   ☐ **Initials of Principal Investigator**

M. GENETICALLY ENGINEERED ANIMALS

Describe any anticipated phenotypic consequences of the genetic manipulations to the animals. Describe any special care or monitoring that the animals will require.

N. EXEMPTIONS FROM ENVIRONMENTAL ENRICHMENT FOR NONHUMAN PRIMATES OR EXERCISE FOR DOGS

1. For nonhuman primates, are you seeking an exemption for scientific reasons from the institution's plan for environment enrichment?

   Yes ☐ No ☐

   If yes, provide the basis of the request.

2. For dogs, are you seeking an exemption for scientific reasons from the institution's plan to provide dogs with the opportunity for exercise?

   Yes ☐ No ☐

   If yes, provide the basis of the request.

O. FIELD STUDIES

If animals in the wild will be used, describe how they will be observed, any interactions with the animals, whether the animals will be disturbed or affected, and any special procedures anticipated. Indicate if federal, state, and/or local permits are required and whether they have been obtained.

P. SPECIAL CONCERNS OR REQUIREMENTS OF THE STUDY

List any special housing, equipment, animal care or any departures from the *Guide [e.g., special caging, water, feed, waste disposal, environmental enrichment, etc.]*.

Q. PRINCIPAL INVESTIGATOR CERTIFICATIONS

1. I certify that I have attended the institutionally required investigator training course.

   Year of Course Attendance: Location:

2. I certify that I have determined that the research proposed herein is not unnecessarily duplicative of previously reported research.
3. I certify that all individuals working on this proposal who are at risk are participating in the institution's Occupational Health and Safety Program.
4. I certify that the individuals listed in Section A. are authorized to conduct procedures involving animals under this proposal, have attended the institutionally required investigator training course, and received

training in: the biology, handling, and care of this species; aseptic surgical methods and techniques (if necessary); the concept, availability, and use of research or testing methods that limit the use of animals or minimize distress; the proper use of anesthetics, analgesics, and tranquilizers (if necessary); and procedures for reporting animal welfare concerns.

5. For all USDA Classification D and E proposals (see section H.1.): I certify that I have reviewed the pertinent scientific literature and the sources and/or databases as noted in Section H.2. and have found no valid alternative to any procedures described herein which may cause more than momentary pain or distress, whether it is relieved or not.
6. I certify that I will obtain approval from the IACUC before initiating any significant changes in this study.
7. I certify that I will notify the IACUC regarding any unexpected study results that impact the animals. Any unanticipated pain or distress, morbidity or mortality will be reported to the attending veterinarian and the IACUC.
8. I certify that I am familiar with and will comply with all pertinent institutional, state, and federal rules and policies.

Principal Investigator

Name: Signature: Date:

R. CONCURRENCES

PROPOSAL NUMBER _____ (leave blank)

Supervisory concurrence as applicable:

Name: Signature: Date:

Safety Office/Committee Certification of Review and Concurrence:
[Required of all studies that use hazardous agents.]

Name: Signature: Date:

Facility Management/Veterinarian certification of resource capability in the indicated facility to support the proposed study:

Facility: Name: Signature: Date:

Facility: Name: Signature: Date:

Comments:

Attending Veterinarian certification of review and consultation on proper use of anesthetics and pain relieving medications for any painful procedures:

Name: Signature: Date:

[IACUC Office: add any additional concurrences that are needed e.g., radiations safety, Drug Enforcement Agency licensure, select agents.]

S. FINAL APPROVAL

Certification of review and approval by the Institutional Animal Care and Use Committee:

Name: Signature: Date:

List any attachments here:

Appendix 1 - USDA Classifications and Examples

Classification B: Animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery, but not yet used for such purposes.
Examples:

- Breeding colonies of any animal species (USDA does not require listing of rats, mice, birds) that are handled in accordance with IACUC approval, the *Guide* and other applicable regulations. Breeding colony includes parents and offspring.
- Newly acquired animals that are handled in accordance with IACUC approval and applicable regulations.
- Animals held under proper captive conditions or wild animals that are being observed.

Classification C: Animals upon which teaching, research, experiments, or tests will be conducted involving no pain, distress, or use of pain-relieving drugs.
Examples:

- Procedures performed correctly by trained personnel such as the administration of electrolytes/fluids, administration of oral medication, blood collection from a common peripheral vein per standard veterinary practice [dog cephalic, cat jugular] or catheterization of same, standard radiography, parenteral injections of non-irritating substances.
- Manual restraint that is no longer than would be required for a simple exam; short period of chair restraint for an adapted nonhuman primate.

Classification D: Animals upon which experiments, teaching, research, surgery, or tests will be conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs will be used.
Examples:

- Surgical procedures conducted by trained personnel in accordance with standard veterinary practice such as biopsies, gonadectomy, exposure of blood vessels, chronic catheter implantation, and laparotomy or laparoscopy.
- Blood collection by more invasive routes such as intracardiac or periorbital collection from species without a true orbital sinus *[e.g., guinea pigs]*.
- Administration of drugs, chemicals, toxins, or organisms that would be expected to produce pain or distress but which will be alleviated by analgesics, anesthetics, tranquilizers, or supportive care.

Classification E: Animals upon which teaching, experiments, research, surgery, or tests will be conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs will adversely affect the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests.
Examples:

- Procedures producing pain or distress unrelieved by analgesics such as toxicity studies, microbial virulence testing, radiation sickness, and research on stress, shock, or pain.
- Surgical and postsurgical sequella from invasion of body cavities, orthopedic procedures, dentistry or other hard or soft tissue damage that produces unrelieved pain or distress.
- Negative conditioning via electric shocks that would cause pain in humans.
- Chairing of nonhuman primates not conditioned to the procedure for the time period used.

NOTE REGARDING CLASSIFICATION E: An explanation of the procedures producing pain or distress in these animals and the justification for not using appropriate anesthetic, analgesic or tranquilizing drugs must be provided on **Attachment 1**. This information is required to be reported to the USDA, will be available from USDA under the Freedom of Information Act (FOIA), and may be publicly available through the Internet via USDA's website.

Attachment 1 - **Explanation for USDA Classification E**

[This report is required to accompany USDA Form 7023 to support any USDA Classification E listings.]

This document must be typed.

Name of investigator:

Animal study proposal title:

Species and number of animals listed in Classification E for each year:

Species:
Number of animals:
year 1 -
year 2 -
year 3 -
Total:

Description of project including reason(s) for species selection:

Provide a scientific justification to explain why the use of anesthetics, analgesics, sedatives or tranquilizers during and/or following painful or distressing procedures is contraindicated:

Signature of investigator:

Date:

Signature of IACUC Chairperson:

Date:

Memorandum to:

From: Institutional Animal Care and Use Committee

Subject: Semiannual Report of the Program Review and Facility Inspection

Date:

This report summarizes the IACUC's results of its most recent program review and facility inspection, as required by the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy), Section IV.B.1.-3., the *Guide for the Care and Use of Laboratory Animals* (*Guide*), and the Animal Welfare Act (AWA) regulations, as applicable. Submission of semiannual reports to the Institutional Official is a condition of this institution's Animal Welfare Assurance with the NIH Office of Laboratory Animal Welfare (OLAW).

Since the last review, the following changes have occurred in the institution's program for animal care and use (PHS Policy IV.A.1.a.-i.): [*optional*]

I. Description of the Nature and Extent of the Institution's Adherence to the PHS Policy, the *Guide*, and the AWA

Departures from the PHS Policy, the *Guide*, and the AWA.
Select A or B:

- ☐ A. There were no departures during this reporting period.
- ☐ B. The following departures have been reviewed and approved by the IACUC: [*include reason for each departure*]

II. Deficiencies in the Institution's Animal Care and Use Program

Animal Care and Use Program Review Date(s):
Select A or B:

- ☐ A. There were no deficiencies in the program during this reporting period.
- ☐ B. The following deficiencies have been identified: [*describe each deficiency, identify each deficiency as either minor or significant, and provide a reasonable and specific plan and schedule for the correction of each deficiency, deficiencies may be recorded on a separate table and attached, the last page of OLAW's Sample Semiannual Program Review and Facility Inspection Checklist provides a sample table*]

III. Deficiencies in the Institution's Animal Facility

Animal Facility Inspection Date(s):
Select A or B:

☐ A. There were no deficiencies in the animal facility during this reporting period.

☐ B. The following deficiencies have been identified: [*describe each deficiency, identify each deficiency as either minor or significant, and provide a reasonable and specific plan and schedule for the correction of each deficiency, deficiencies may be recorded on a separate table and attached, the last page of OLAW's Sample Semiannual Program Review and Facility Inspection Checklist provides a sample table*]

IV. Minority Views

Select A or B:

☐ A. No minority views were submitted or expressed.

☐ B. The following minority views were expressed: [*insert minority views here or attach*]

V. Status of AAALAC Accreditation [*identify accredited facilities, if applicable*]

VI. Signatures [*signatures of a majority of the IACUC members required by AWAR (§2.31,c,3), if applicable*]

Names of IACUC Members	Signatures

Resources and Useful Links: Animals in Research

Office of Laboratory Animal Welfare (OLAW)
http://grants.nih.gov/grants/olaw/olaw.htm

OLAW Frequently Asked Questions
http://grants.nih.gov/grants/olaw/faqs.htm

OLAW Educational Resources (Archive of Webinars & Podcasts)
http://grants.nih.gov/grants/olaw/educational_resources.htm

Guide for the Care and Use of Laboratory Animals, Eighth Edition
http://www.nap.edu/catalog/12910/guide-for-the-care-and-use-of-laboratory-animals-eighth

United States Department of Agriculture (USDA)
https://www.aphis.usda.gov/aphis/ourfocus/animalwelfare

Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC) International
http://www.aaalac.org/

American Association for Laboratory Animal Science (AALAS)
https://www.aalas.org/

Animal Welfare Information Center (AWIC)
https://awic.nal.usda.gov/

Institute for Laboratory Animal Research (ILAR)
http://dels.nas.edu/ilar/

Scientist Center for Animal Welfare (SCAW)
http://www.scaw.com/

Foundation for Biomedical Research
http://fbresearch.org/

Presentation:
"Grants Policy & Congruence"
OLAW Online Seminar:
https://grants.nih.gov/grants/olaw/120607_Congruence_slides.pdf

Resources related to animal research performed outside the USA

The collaborating organization or the host country for an overseas project may have laws, regulations and standards applicable to research using animals. As a general rule, the most stringent policy or regulation must be followed. Cross-border transport of biospecimens may be regulated by local laws and regulations, and/or may require USDA, CDC or Department of Commerce permits.

The International Guiding Principles for Biomedical Research Involving Animals (2012)

http://www.cioms.ch/images/stories/CIOMS/IGP2012.pdf

AAALAC International Regulations and Resources

http://www.aaalac.org/resources/internationalregs.cfm

The BIG and Small of Research Animals and Compliance

By Angela Yost

I'd wanted to start this article as a summary of sorts of what Research Administrators should know about animal research and compliance. Ironically, this month's theme, starting small and finishing big, is a literal description of the information that began to surface when researching this topic. What we as research administrators come across on a daily basis with Institutional Animal Care and Use Committee (IACUC) approvals, laboratory animals, and grant reviews is merely the tip of the iceberg.

I'd spoken with various people at varying institutions regarding issues of compliance, resources, and other topics of concern when it comes to animal research. These discussions illuminated the fact that there is so much more involved than I had imagined. The main point I'd taken away regarding offering assistance to your investigators on any questions they may have regarding animals – be it compliance or any other topic – point them to your institution's website(s) for IACUC and animal facilities. The "pros" in this field will handle the ins and outs of the in-depth questions your investigators will have.

Federal regulations, numerous guidance documents, and institutional policies shape how an institution addresses the numerous topics involved with research animals and compliance.

So – what are the federal regulations?

The ***Animal Welfare Act*** (AWA) was established in 1966 under the U.S. Department of Agriculture and covers the care and use of warm-blooded animals. It requires that the institution register with the USDA every three years and involves at least once annually unannounced inspections by the USDA of facilities and programs for all registered institutions. The AWA was brought about originally to protect pets that were being stolen and sold on the "black market."

The Health Research Extension Act of 1985 brought about the regulations that we as administrators are likely the MOST familiar with - the ***Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals***. Any institution that receives PHS funding is required to follow this policy (http://grants.nih.gov/grants/olaw). PHS Policy expands upon the requirements of the Animal Welfare Act. The Act also brought about the notion of institutions being responsible for monitoring their own compliance and requires each institution engaging in animal research to have its own IACUC to oversee organizational compliance. Each IACUC must have at least five members, including a veterinarian, a practicing scientist experienced in working with animals, a non-scientific member (lawyer, clergy, etc.), and one member completely unaffiliated with the institution.

For institutions receiving any PHS funding, the IACUC needs to report to the Office of Laboratory Animal Welfare (OLAW) on issues of animal compliance. OLAW is a wonderful source of information for expanding your knowledge on animal compliance – in fact, my "refresher" was watching OLAW's webinar entitled "Research Involving Animals". I highly recommend this webinar for all administrators, as it is very informative and touches base on all pertinent topics that a research administrator should be aware of when guiding their faculty on the basic issues of compliance. OLAW's website also offers much more in depth training for researchers and their staff.

Comparing the Animal Welfare Act and PHS Policy		
	USDA Regulations / Animal Welfare Act	PHS Policy
Species Covered	Warm-blooded animals except mice, rats & birds	All live vertebrate animals
Oversight	Unannounced inspections by USDA; Self-monitoring and reporting by IACUC	Self-monitoring and reporting by IACUC
Sanctions	Fines, revocation of USDA registration, imprisonment	Restriction of withdrawal of grant funding
Policy References	Animal Welfare Act and USDA policies	"PHS Policy on the Humane Care and Use of Laboratory Animals" and "Guide for the Care and Use of Laboratory Animals"

PHS policy adheres to the *Guide for the Care and Use of Laboratory Animals* (National Academies Press) – the "Bible," if you will, for animal researchers, available for online for free. Though we as administrators would not likely read through the whole thing, or even understand it, it bears mentioning.

What are your institutional policies? Who do you go to at YOUR institution for guidance?

While most investigators may never ask you a question regarding animals and compliance – there are those that may. In that case, it does not hurt to familiarize yourself with your IACUC offices and the people that can help your investigators with questions. Most institutions have their own set of policies and procedures which usually adhere to both the AWA and PHS policies. So what should you familiarize yourself with? Robert A. DeAngelis, Ph.D., Protocol Specialist & IACUC Administrator at the University of Pennsylvania, Office of Animal Welfare had suggested some topics below that Research Administrators may familiarize themselves with to provide guidance to their faculty (R. DeAngelis, personal communication, October 23, 2015):

- Know the process for submitting a protocol, including any tips or tricks and common errors.
- Know your institution's review process and general timing for how long a review takes (which may be different for protocols, amendments, annual reviews, etc).
- Who handles animal transfers? Who handles animal purchases? At both the University of Pittsburgh and the University of Pennsylvania, these are handled by separate departments. Knowing who to send your investigators to for what purpose is a great help.
- What about connecting funding? How do PIs add funding sources to protocols? How do they then choose what funding to use, if they can have more than one per protocol?
- Is there a congruency check done to make sure the grant and protocol are congruent? If so, who does that, and when (at the time of protocol submission, grant submission, JIT, etc.) Both the NIH and the American Heart Association require that the application is reviewed to make sure the proposed research is consistent with the protocol that was submitted to the IACUC to ensure that all processes have been reviewed and approved.
- Is there a safety office that is involved? What is their role in protocol approval, if any?

What are the most common sources of non-compliance?

Some of the most common sources of non-compliance recognized by OLAW include the following:

- Protocol approval lapses, whether an annual renewal as required or a "de novo" third year renewal.
- Personnel begin working with animals prior to completing required training and prior to being added to a protocol.
- Procedures deviate from those described in the protocol.
- Animals are taken from housing areas to use sites that are not listed in the protocol.

Straight from the IACUC office!

Pamela Lanford, PhD, Director of Animal Research Support & Manager, IACUC, at the University of Maryland offers a few pointers for research administrators (P. Lanford, personal communication, October 26, 2015):

- **Understand the timeline for submission, review and approval of new protocols and amendments**. It often takes a couple of months to get approval (sometimes much longer). Many institutions have a monthly meeting, and a submission deadline falls well in advance of the meeting.
- **IACUC protocols cannot be "expedited."** When submitting a grant application, please know that protocols will take the usual length of time to work through approval, regardless of JIT status on the award. (Research administrators can do a limited release of funds until the IACUC protocol is approved.)
- **Triennial renewals of a protocol must be consider de novo,** and may take as long to process and approve as a new protocol, so begin your renewal submission at least 60 days prior to expiration date.
- **If a protocol expires,** animals on that protocol may be transferred to a holding protocol (if your institution has one) or **could** be held without a protocol (but not indefinitely, and some institutions will not allow this). **In both instances, all research activities with animals must stop.** When placing animals onto a holding protocol, grant funds can continue to pay for basic animal care. If the animals are not placed onto a holding protocol, no PHS funds can be used to pay for their care.

New and Upcoming Changes in Animal Policy

National Science Foundation (NSF): Beginning October 2015, the NSF now requires grant recipients to follow the PHS policy, and report findings to OLAW.

National Institutes of Health (NIH): The new National Institutes of Health (NIH) policy on consideration of sex as a **biological variable** http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-102.html, once approved by the Office of Budget and Management, will require investigators to include accounting for sex as a biological variable in the 'research strategy' section of the application. The NIH has also simplified the requirements for the Vertebrate Animal section for grant applications http://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-006.html.

These policies will apply to **applications submitted on or after January 25, 2016**.

Why do you need to know this information?

Robert A. DeAngelis, Ph.D. summed the topic up quite nicely:
"Research is a privilege granted to us by society, not a right, and if the public thinks we are not treating animals as well as we can, they are going to demand we stop using them. The regulations and protocols help ensure that's the case and that we have documentation to prove it. Animal activists are constantly looking for slip-ups."

References

1. National Institutes of Health. (2015) Frequently Asked Questions, PHS Policy on Humane Care and Use of Laboratory Animals. Retrieved from http://grants.nih.gov/grants/olaw/faqs.htm on November 19, 2015.
2. National Institutes of Health. (2012) Research Involving Animals: NIH Regional Meeting - April 18, 2012. Retrieved from https://grants.nih.gov/grants/olaw/educational_resources/webinar_04202012.htm on November 19, 2015.
3. The National Academies Press. (2011) Guide for the Care and Use of Laboratory Animals. Retrieved from www.nap.edu/catalog/12910/guide-for-the-care-and-use-of-laboratory-animals-eighth on November 19, 2015.
4. Extramural Nexus. (2015) Animal Oversight Changes for Institutions Receiving National Science Foundation (NSF) Funding. Retrieved from http://nexus.od.nih.gov/all/2015/08/31/animal-oversight-changes-for-institutions-receiving-national-science-foundation-nsf-funding on November 19, 2015.
5. USDA/APHIS: www.aphis.usda.gov/wps/portal/aphis/ourfocus/animalwelfare

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Principal Investigators' Safety Page

This page provides one location where PIs and Lab Managers can find most of the safety requirements and information they need.

Principal Investigator/Lab Manager Requirements

- Summary of Expectations for Conducting Safe Research
- Laboratory Personnel Safety Checklist
- Safety and Environmental Management Requirements for Operating Laboratory Facilities at UMD
- Registration of Experiments Involving Recombinant DNA and/or Infectious Agents
- Possession, Use and Transfer of Select Agents and Toxins
- Lab Signage
- Lab Signage Request Form
- Procedures for Vacating a Laboratory
- Standard Operating Procedure Examples and Resources
- Supervisor's Safety Responsibilities
- Biological Agents that Require Oversight

Online Training Requirements (as applicable)

- Bloodborne Pathogens for Researchers Training
- Bloodborne Pathogens Refresher for Researchers Training
- Chemical Hygiene Training Program for Laboratory Workers
- Hazardous Waste Generator Training
- Laser Safety Training
- NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules
- Radiation Safety Training for use of Particle Accelerators
- Radiation Safety Training for use of Radioactive Materials
- Radiation Safety Training for use of X-Ray Devices
- Radiation Safety Refresher Training
- Radioactive Waste Generator Training
- Shipping Infectious Substances and Dry Ice Training - take the online general training, then contact the Biosafety Officer for specific training.
- Biosafety Practices Training
- Supervisor Training
- Working Safely With Laboratory Animals Training
- Universal Waste Training
- ESSR Training Schedule

Emergency Response

- Emergency Response Guide
- Chemical Spill Kits
- Workers' Compensation/First Report of Injury Forms
- University of Maryland Policy Concerning Fire Emergencies
- Fire On Campus

Safety Information

- Autoclave Safety
- Autoclaving Procedures
- Fact Sheets
- Formaldehyde Management Program
- Safe Handling and Use of Cryogenic Liquids Training
- Methylene Chloride Management Program
- Personal Protective Equipment
- Personal Protective Equipment Form
- Respiratory Protection
- Respirator Fit Test Scheduling
- Safety Data Sheets (SDSs)
- Table of Incompatible Chemicals

Waste Disposal

- Waste Disposal Guidelines
- Use and Disposal of Sharps
- Hazardous/Chemical Pickup and Removal Requests (online)
- Biological, Pathological or Medical Waste Removal Requests (online)
- Low-level Radioactive Waste Pickup and Removal Requests (online)
- How to Label Your Hazardous Waste

Guides/Manuals/Policies

- Laboratory Safety Guide
- UMD Biosafety Manual
- Bloodborne Pathogens Exposure Control Plan
- Campus Pollution Prevention and Waste Minimization Guidelines
- Chemical Hygiene Plan/Policy
- Hazardous and Regulated Waste Procedures Manual
- Laser Safety Plan/Policy
- Laboratory Relocation Guidelines
- Policy on Means of Egress
- Policy on Children and Unauthorized Personnel in Hazardous Environments

Contact Information

- ESSR Technical Contact Information
- Who Is Your Departmental Compliance Officer?

Other

- Backflow Prevention Devices
- Chemical Reactivity Worksheet

Research Conducted Under COI or the Appearance of COI Conditions

Dr. XXXXXX is listed as Principal Investigator representing XXXXX on a grant proposal to the XXXXXXX that have been identified as research involving a conflict of interest or the appearance of a conflict of interest. In this instance, Dr. XXXXX is representing the University of Maryland, College Park, however, he is the President, Director, and Chairman of the Board for XXXXXX and also a faculty member at the University of Maryland, College Park.

The University takes very seriously its role in ensuring that its research and scholarship is conducted with the highest integrity and is protected from influences which could lead to bias, or the appearance of bias, in the collection or interpretation of data, or publication of research results. The conflict of interest in this case cannot be eliminated with the usual procedures. Therefore, the following management plan will be implemented:

I, Dr. XXXXXX, the Associate Dean within the University of Maryland, College of XXXXXX have agreed to serve as the Oversight Official for "*STUDY TITLE*". I will provide oversight of COI issues by conducting annual reviews of project data, financial records, and any other necessary supporting documents. All aspects of the research will be under approved IRB protocols with informational or informed consent and the research will undergo independent expert, peer review under approved IRB protocols. Dr. XXXXX will continue to submit awards that identified Conflicts of Interest to external evaluators and/or documented peer review process, in addition to myself as Oversight Official for these awards.

Any concerns raised will be reported to the COI Committee for review, consideration, and potential subsequent recommendations.

It should be understood that the management plan implemented for this case is unique to this case and does not imply that a similar plan will apply in future conflict of interest cases. The COI Committee decides each case on its own merits which include, among other things, considerations of the nature of the research, the potential risk to the University, and the benefits to public welfare.

Oversight Official: Name: XXXXXXX

Sign: _____
Date: _____

Individuals with COI: Name: XXXXXXX

Sign: _____
Date: _____