

UM ASSURANCES

ORA CERTIFICATE CLASS #4
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1

Compliance: Why Do We Care?

Protect human and animal subjects, investigators and the institution

State and University policy requirements

Sponsor requirements

Compliance Oversight by the Division of Research is carried out by the Research Compliance Office and the Department of Environmental Safety

US Laws with potential criminal violations w/ severe penalties

2

Objectives

Human Subjects – protect human subjects in research by minimizing risks and informing them of their rights as participants

Animal Subjects – ensure that animals are not being mistreated

Biohazards/radioactive materials – protect workers from contamination/illness; protect public from potential terroristic acts

Export Compliance – protect staff and faculty from violations of US export laws

3

State Policy Requirements

Human Subjects – IV-2.10 University Of Maryland System Policy On Human Subjects Of Research

- <http://www.usmh.usmd.edu/Leadership/BoardOfRegents/Bylaws/SectionIV/IV210.html>

Animal Subjects – UMCP Policy on Animal Care and Use

- federal regulations for laboratory animals/Agriculture Guide

Biohazards/Radioactive Materials –

- VI-11.00(B) UMCP Policy On Occupational Exposure To Bloodborne Pathogens
<http://www.president.umd.edu/policies/vi1100b.html>
- VI-13.00(A) UMCP Policy on Occupational Exposure to Hazardous Chemicals in Laboratories
<http://www.president.umd.edu/policies/vi1300a.html>
- VI-17.00(A) University of Maryland Policy on Biosafety
<http://www.president.umd.edu/policies/vi1700a.html>

Policy on Classified and Proprietary Work IV-2.20

- <http://www.usmh.usmd.edu/regents/bylaws/SectionIV/IV220.html>

4

Sponsor Requirements

Human Subjects – DHHS/OHRP: The Common Rule (45CFR46); FDA (21CFR50/56)

Animal subjects – DHHS, Office of Laboratory Animal Welfare (OLAW)

Biohazards/radioactive materials – All OSHA, EPA, DOT, NRC regulations. Other local, state and federal regulations.

Export – DoD/DOE/NASA grants and contracts

5

Committees

Institutional Review Board (IRB)

- reviews projects involving human subjects

Institutional Animal Care and Use committee (IACUC)

- reviews projects involving animal subjects

Institutional Biosafety Committee (IBC) – ESSR administers this and other Environmental Safety Committees

- reviews projects involving biohazard materials, radioactive materials, hazardous chemicals

Export Compliance Committee

6

Agency Regulations: Responsible Conduct of Research (RCR)

NIH: requires participation in and successful completion of instruction in RCR by individuals supported by any NIH training/research education/fellowship/career award.

NSF: Requires RCR training for students and postdoctoral researchers

RCR Fulfillment:

- Workshops offered by the Division of Research
- Guidance: <http://www.umresearch.umd.edu/RCR/>
- CITI RCR modules customized for disciplinary areas
- www.citiprogram.org

7

Human Subject Research Protection -Basics-

JOSEPH M. SMITH
MANAGER, INSTITUTIONAL REVIEW BOARD
UNIVERSITY OF MARYLAND COLLEGE PARK

What is Human Subjects Research?

Human Subjects Research

Human Subject: A human subject is a living individual about whom an investigator obtains either:

- data through interaction or intervention with the individual
- private, identifiable information (medical record; student record, blood samples, etc.)

Research: A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

- The definition of “generalizable knowledge” can vary. Examples: publication, posters, adding to an existing body of knowledge.

Brief History Lesson

WHY DO WE HAVE RULES ABOUT HUMAN SUBJECTS RESEARCH?

Brief History Lesson

WWII: Nuremberg Code

- Voluntary Consent
- Experiments should yield fruitful results
- Avoid unnecessary risk
- Adequate resources and training to conduct study
- Participation is entirely voluntary

1964 Declaration of Helsinki

- Every participant must receive best known treatment

1974 National Research Act

- Formed in the aftermath of the Tuskegee Syphilis Study to develop guidelines for human subject research

Brief History Lesson (2)

Tuskegee Syphilis Study

- A clinical trial conducted between 1932 and 1972 in Tuskegee, Alabama by the U.S. Public Health Service. Investigators **recruited** 399 poor, mostly illiterate, African-American sharecroppers with syphilis for research related to the natural progression of the untreated disease
- **Advertised** treatment for “bad blood,” a local term used to describe several ailments, including syphilis, anemia, and fatigue. In exchange for participating, the men received free medical exams, free meals, and burial insurance.
- Researchers **failed to treat** patients appropriately after the 1940s validation of penicillin as a cure for the disease

Brief History Lesson (3)

Sexually Transmitted Diseases (STD) Inoculation Study (Guatemala: 1946-1948)

- Intent: to look for new ways to prevent STDs. Experiments involved infecting female commercial sex workers with gonorrhea or syphilis and then allowing them to have unprotected sex with soldiers, prison inmates and mental hospital patients. Some individuals were directly inoculated with gonorrhea or syphilis.
- About 1500 study subjects were involved. Once individuals were infected, most received treatment with injections of penicillin.
- The study subjects were not informed of the purpose of the study and did not provide consent.
- Ethical Violations: 1) use of study subjects who were members of highly vulnerable populations, 2) research without valid informed consent, and 3) deliberate exposure of subjects to known serious health threats.
- <http://youtu.be/WUmEWLkJOiA>

Belmont Report

1979 Belmont Report

- Identifies the **basic ethical principles** that should underlie the conduct of biomedical and behavioral research involving human subjects:
 - **Respect for Persons**
 - Individuals are autonomous (Voluntary Consent)
 - Protect those w/reduced autonomy (adequate protections)
 - **Beneficence**
 - Do not harm (Risk : benefit ratio)
 - Minimize potential risks
 - **Justice**
 - Distribute risks and benefits equally among those who may benefit. (Equitable subject selection)

Requirements/Assurances

WHAT IS THE RESEARCHER REQUIRED TO DO TO COMPLY WITH APPLICABLE LAWS AND POLICIES?

Federal Wide Assurance (FWA)

All human subjects research activities will be guided by a statement of principles governing the institution in the discharge of its responsibilities for protecting the rights and welfare of human subjects of research conducted at or sponsored by the institution.

These terms apply whenever the Institution becomes engaged in human subjects research conducted or supported by any U.S. federal department or agency that has adopted the Common Rule (45CFR46)

UMCP FWA #: 00005856

Engagement & Authorization Agreements

Engaged in Human Subject Research

- An institution becomes "engaged" in human subjects research when its agents (employees/faculty/staff):
 - (i) intervene or interact with living individuals for research purposes or,
 - (ii) obtain individually identifiable private information for research purposes

Authorization Agreements

- If two or more institutions will be engaged in human subjects research
- Allows one institution to be the IRB of Record for the life of the study
- Varies from institution to institution – be sure to check before beginning the process
- Benefits:
 - Reduces administrative burden
 - Helps to eliminate confusion
 - Institutional review occurs with appropriate expertise present

Funding Requirements

Grants Involving Human Subject Research

- Must submit a protocol through IRBNet to UMCP IRB
- A protocol may have more than one funding source
- Contact IRB Office for guidance if using human subjects.

Grants Not Involving Human Subject Research

- Do not require IRB Review
- If unsure, contact IRB to discuss
 - **Better to be safe than sorry!**
 - **There is no retroactive IRB Approval!**
- Complete Request for Human Subjects Research Determination Form for official documentation

Funding Requirements

Federal Funding

- Grant application must be uploaded with Initial Protocol Submission
- The information in the Grant must be consistent with what human subject research activities will be conducted at UMCP
- New or change in funding source after initial IRB Approval must be added to the protocol via an Amendment application

Preparing for the Application Process

WHAT DO I NEED TO KNOW WHEN SUBMITTING AN APPLICATION? REVIEW PATHS, TURNAROUND TIMES, WHO CAN BE A PI, TRAINING, CONTINUING REVIEW, ETC.

Institutional Review Board

The IRB is a committee designated by an institution to help assure the protection of the rights and welfare of human subjects.

- Guided by OHRP, FDA, State and Local Laws, Institutional Policies
- Membership includes: scientists, non-scientists, unaffiliated members

The IRB makes an independent determination whether to approve or disapprove the protocol based upon whether or not human subjects are adequately protected, which includes determination of a favorable risk : benefit analysis of the research.

The IRB approves the initiation of and continuing reviews of research involving human subjects.

Investigators are responsible for the conduct of the study and protection of human participants.

- Investigator may be student or faculty. If student, the faculty advisor must be on the project and sign.

http://youtu.be/5ohIA_xABw

Required CITI Training:

Register at: <https://www.citiprogram.org/>

Required for all Initial Applications:

- Social and Behavioral - Basic/Refresher Certificate
- OR**
- Biomedical Research - Basic/Refresher Certificate

**Both certificates are valid for 3 years. Refresher course must be taken if HSR is continuing.*

***All CITI Training is provided at no cost to you!*

Review Paths

EXEMPT (45CFR46.101) – 6 Categories

- Exempt from requirements of 45CFR46
- IRB makes this determination, not the PI
- PI can suggest an Exempt Category

EXPEDITED (45CFR46.110) – 9 Categories

- Does not mean "Fast"
- Minimal Risk transactions
- Amendments to Greater than Minimal Risk protocols can be Expedited

FULL BOARD

- Research presenting greater than minimal risk to participants

Protocol Review Considerations

Vulnerable Populations

- Are there appropriate protections in place for the group or groups you are recruiting?
 - Prisoners
 - Children
 - Pregnant woman and Fetus
 - Cognitively impaired
 - Students

HIPAA - Health Insurance Portability and Accountability Act

- Is PHI involved (designated record set)?
- Plans to protect PHI
- Authorization to collect PHI? (HIPAA Authorization)
- Who will have access to identifiers?
- Will the data be coded?
- Where will the data be stored?

Timeline for Review

Initial Protocol Review [Expedited] – Two to Three weeks

- Expedited projects are granted approval for one year.
- Exempt projects are granted approval for three years.

Continuing Review [Expedited] – Two to Three weeks

- Required prior to expiration date if human subject's research will continue beyond initial approval.

Amendment [Expedited] – Two to Three weeks depending on the type and number of changes.

Full Board Transactions [All] – One month: Be sure to check the submission deadlines!

Timeline for Review

Quality of Protocol Applications

- Turnaround time likely to be shorter when protocol is written well and requires little to no modification
- Student may be PI, as long as Faculty Advisor is on the project and signs. FA bears responsibility for the quality of the application!

Continuing Review (Annual Renewal)

- To avoid Protocol Expiration or Administrative Closure, submit Continuing Reviews at least 45 days in advance of Expiration date.
- IRBNet will send you reminders!

Submitting an Application to the IRB

Complete Required Forms

- All the required documentation can be found in the Designer Page of IRBNet as well as the IRB website.

New Project Applications Require:

- Application Part 1
- Application Part 2
- Supplemental Project Documentation (Consent Forms, Interview Scripts, Questionnaires, etc.)
- Department Liaison's Signature
- Faculty Advisor's Signature
- Principal Investigator's Signature
- Linked CITI Training records for all investigators

Protocol Expiration

Expiration: w/o Continuing Review Submitted

- **All human subject research activity must cease.** New protocol application must be submitted if PI wishes to continue

Expiration: w/Continuing Review Submitted

- Human subject research activity must cease until submitted Continuing Review is IRB Approved
- Continuing Review applications submitted after Expiration will not be considered

Protecting Investigators

Case Example

Investigators – A Cautionary Tale

- One person will create 10 different accounts under different email addresses and then answer A, A, A, A, etc. right through the survey to rack up the cash
- Usually these are easy to catch when reviewing the survey results.
- Prepare ahead of time
 - Inform participants that suspected abuse and fraud will result in forfeiture of compensation
 - This must be done during the consent process
 - Strongly recommend this warning also be included on the advertisement
 - Build in a "check" question. "The answer to this question is D."

What Now?

Know Your Responsibilities

- Educate others
- Be Accountable (PI, Student Investigator, Research Staff)
- Utilize your resources
- Contact the IRB Office with any questions

Contact Information & Resources

UMD Research Compliance Office:
www.umresearch.umd.edu/RCO/

UMD IRB: www.umresearch.umd.edu/RCO/New/

IRBNet: www.irbnet.org

CITI Training: www.citiprogram.org

IRB Contact: irb@umd.edu or 301-405-0678

- Location: 1204 Marie Mount Hall


The Role of the IACUC in Biomedical and Agricultural Research

PAM LANFORD, PHD
DIRECTOR OF ANIMAL RESEARCH SUPPORT &
IACUC MANAGER

Why do we use animals for research?

Benefits

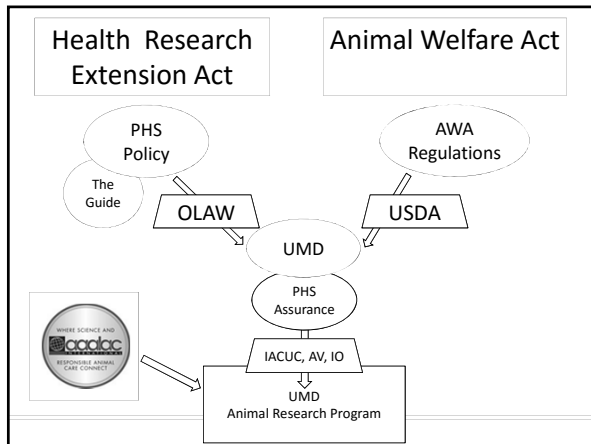
- Advancement of scientific knowledge
- Advancement of agricultural technique and sustainable agriculture
- Veterinary Medicine
- Human Medicine
 - HPV
 - Pompe's disease




Bottom line: Animal research has many concrete benefits to humans, animals and science in general.

Establishment of the IACUC

- Nuremberg Trials
- Animal Welfare Act, 1966
 - In response to outcry over use of dogs in research
 - Requirement for institutional oversight - 1985
- PHS Policy, 1985
 - Requires institutional oversight
 - Requires an assurance statement – describes how we “do business”





Bottom Line: Federal law requires research and testing be performed in animals prior to human clinical studies, and that rigorous, independent oversight of animal research be provided by the institution. Federal regulations flow down through the institution and the IACUC to the PI.

Institutional Oversight:
Institutional Animal Care and Use Committee

- Composition - scientists, nonscientists and nonaffiliated members, as required by federal regs.
- Review and approve proposed activities that use animals in research, teaching, or testing
- Twice a year:
 - inspect all facilities (on and off campus)
 - review program (IACUC processes, policies, etc)
 - Report to the Institutional Official
- Report to federal agencies

Other Functions of the IACUC

- Post-approval monitoring
- Investigation of adverse events and issues of noncompliance
 - Must report noncompliance to OLAW
 - May result in suspension of protocol
 - May result in stop funding
 - May or may not require repayment to NIH for funds expended.



Other Functions of the IACUC

- AAALAC accreditation site visit
- Works with depts to ensure proper maintenance, upgrades
- Must ensure proper Occupational Health program for all animal users.
- Must have the resources to ensure that the program is run in compliance with regs.

Bottom Line: The IACUC oversees animal research before, during, and after. It works to ensure compliance with federal regulations, maintain quality facilities and animal care, and provide occupational health monitoring and resources for all human workers.



What is a protocol?

- A document submitted to the IACUC describing all research, teaching and testing activities using animals
- Provides a series of justifications for the use of animals in the study
 - Why animals?
 - Why this many?
 - Why this species?
- Must endeavor to meet "The 3 Rs"
 - Reduce, Refine, Replace

Bottom Line: All research with animals must be fully described, ethically justifiable, and scientifically sound. Efforts must be made to use the minimum number of animals possible to get scientifically valid results, and to replace animal use wherever possible.



When should protocols be submitted?

Prior to start of activities where animals will be housed, held, and/or manipulated

- May not need a protocol if performing observation-only research (some field studies)

Prior to start of collaborations with colleagues or grad student work at outside institutions

- Documentation of outside IACUC approval must be submitted for grad work (e.g., at NIH) or for release subaward funds
- The UMD IACUC does not reapprove, but does examine outside documentation

Bottom Line: Protocols are required for most, but not all work with animals. Documentation of outside collaborations or graduate work should be submitted for administrative review. **When in doubt, call Pam**



Timing of Review Process

- New protocols (including renewals) must be submitted by 1st of the month
- IACUC meets on the 3rd or 4th Thursday of each month for Full Committee Review
- Follow up to committee review is often requested ("Mods required")
- Amendments accepted on a rolling basis, most approved via Designated Member Review – 5 days for committee members to call it to FCR
- Follow up to designated member review often requested

Bottom Line: Approvals take time – approx. 1.5 months for protocols & renewals; 2-3 weeks for amendments. **Allow plenty of time for a submission to be processed.**



PHS and IACUC Approval

- PHS policy requires that the research plan must first be reviewed and approved by the IACUC before funds can be awarded.
- IACUC approval may be put into the application as “pending” and then submitted “Just in Time.”
- ORA may request for a limited release of funding for non-animal related parts of the study until IACUC approval is received.
- Under no circumstances will the IACUC rush a decision to accommodate an award timeline.

Compliance Checks

Verification of IACUC approval prior to funding

PI must provide:

- A copy of the proposal
- The protocol number(s) and title(s) that the PI is using to cover this work
- If more than one protocol covers the proposed work, the PI should indicate which portions of the grant proposal pertain to the specific protocols



Bottom Line: Use of PHS funds is tied to IACUC approval. Award funds for animal research activities cannot be released until there is an approved protocol specific to the research described. Limited release for non-animal activities is possible, but the IACUC should not be pressured to approve for the purposes of grant award.

Important Approval Details

- Protocols are approved for 3 years
 - Given an internal # (e.g., R-15-13, T-15-24, etc.,)
- A de novo review is required for triennial renewals (like a brand new protocol)
- Amendments expire with the protocol
- If renewal is not approved prior to expiration date, all research must stop;
- Research activities performed without a protocol, must be reported and may result in repayment for funds used to support the research during the period of noncompliance



Bottom Line: All protocols must be given a new review every three years. If a protocol expires, and work continues, these activities must be reported to OLAW and the PI may be asked to repay funds spent for the period of time that work continued.

Protocol Submission via IRBnet

Encourage PIs and their staff to contact the IACUC office for help with protocol submission

Pam will do individual &/or group trainings on IRBnet, on request

IACUC office cannot:

- Upload documents for the PI
- Relock their submission package
- Sign off on a submission
- Be given "shared" status on a submission



Bottom Line: IACUC office staff can't do *everything* for the PI, but are happy to help PIs and/or their staff and have many resources available.



Obtaining Animals

Purchase of research animals must be through approved vendors or peer institutions

Documentation of the procurement must be provided to the Central Animal Resource Facility (CAPS form)

Approved vendors list is on the IACUC website

All new animals housed at UMD go through a quarantine period



Bottom Line: If placing an animal order for a PI, check that there is an approved protocol and be sure a CAPS form is being sent to the Attending Veterinarian/CARF.

Support for Research and Researchers

Our Bottom Line:

It is the objective of the IACUC and IACUC office to support researchers' efforts to

- Comply with federal law and regulation
- Implement effective research programs
- Perform high-quality, ground breaking science

Contacts & Information

IACUC office

- Pam Lanford planford@umd.edu X57295
- Renee Kahn rkahn002@umd.edu X54792
- IACUC office email: iacuc@umd.edu

Attending Veterinarian

- Doug Powell dpowell@umd.edu X54920

Use of Animals in Research (information):

<http://speakingofresearch.com>

<http://www.animalresearch.info/en/>


ASSURANCE OF HAZARDOUS PROCEDURES

Department of Environmental Safety
Sustainability and Risk (ESSR)

Office of Research Safety
3115 CHESAPEAKE BUILDING
(301) 405-3960
Glynnis Bowman CIH, CSP, CHMM
Senior Industrial Hygienist
gbowman@umd.edu

Hazardous Materials, Processes and Procedures

Biological materials (pathogenic)
 Select Agents
 Radioactive materials
 Radiation producing equipment
 Hazardous chemicals
 Toxic/Reactive gases
 Scientific diving/Boats



11/30/2015 ESSR 015-0015

What does ESSR do?

Environmental Safety assists PI's and Researchers with environmental and safety compliance

Radiation Safety Officer

- Radioisotopes
- Ionizing radiation producing devices
- Non-ionizing radiation producing devices

Biological Safety Officer

- Recombinant DNA
- Infectious agents
- Human or non-human primate blood/tissue/human cell culture

Chemical Hygiene Officer: Hazardous Chemicals
Environmental Compliance Manager
Diving Safety Officer: Scientific diving and boats

11/30/2015 ESSR 015-0015

Who manages the Environmental and Safety related assurances?


Biological:	IBC and ESSR
Radioactive:	RSC and ESSR
Chemicals/Gases:	ESSR
Diving/Boats:	ESSR
Hazardous Waste:	ESSR
Animals:	IACUC with ESSR support

11/30/2015 ESSR 015-0015

Why do assurances?

Federal and State agencies have specific requirements for conducting hazardous operations or using hazardous materials

- National Institutes of Health (NIH)
- Nuclear Regulatory Commission (NRC)
- Centers for Disease Control and Prevention
- Occupational Safety & Health Administration
- US Department of Agriculture
- US Army Medical Research & Material Command



11/30/2015 ESSR 015-0015

ESSR on the Routing Form

Research	Routing Form Question
Radioactive materials	22a
Ionizing radiation producing instruments	22b
Non-ionizing radiation producing instruments	22c
Infectious biological materials	23
Select agents	24
DURC	23 and/or 24
Highly toxic gases	25
Scientific Diving/Boats	26 and/or 27
Chemicals	28
Hazardous waste	No Specific Question on Routing Form for Items like These
Chemical release to the environment	
Analytical Equipment installation	
Infrastructure Modifications	

11/30/2015 ESSR 015-0015

Ionizing Radiation Use Oversight Regulations

Specific University Licenses & Registrations

Policies & Procedures
Radiation Safety Committee (Reports to the Provost)
Radiation Safety Officer

Authorized Users (PIs)

11/30/2015 ESSR 015-0015

Non-Ionizing Radiation

NON-IONIZING RADIATION IONIZING RADIATION

Radio Frequency Infrared radiation Ultra-violet radiation X-rays gamma rays

Power lines Mobile devices Radar

11/30/2015 ESR 015-0015

Biological Materials

- Recombinant DNA (rDNA)
 - IBC Approval #: _____ (Not needed to submit grant)
 - Always subject to NIH Guidelines
- Infectious Agents
- Blood, unfixed tissue, primary cell culture from humans or non-human primates
- Select Agents

11/30/2015 ESR 015-0015

Additional Considerations

- rDNA and infectious agents registration is now online
- Researcher only needs to register new rDNA experiments that are described in grant application
- Grant application may be submitted before IBC approval has been obtained
- Changes
 - “Intent to perform recombinant DNA experiments” form no longer used
 - “Assurance on Hazardous Procedures” form no longer used

11/30/2015 ESR 015-0015

Toxic & Reactive Gases

Building Code Control Requirements

- Exhaust Ventilation
- Gas Detection
- Alarm/Control

UM Chemical Hygiene Program

– Prior Approval



11/30/2015

ESSR 015-0015

Toxic & Reactive Gases



11/30/2015

ESSR 015-0015

Chemicals

All labs with hazardous chemicals must develop a Chemical Hygiene Plan:

- Standard Operating Procedures
- ESSRignated Areas
- Personal Protective Equipment
- Prior Approval Criteria
- Chemical Safety Data
- Copy to ESSR



Grant applications are not forwarded to ESSR (at this time)

11/30/2015

ESSR 015-0015

Scientific Diving and Boats

- Individuals conducting scientific diving under the auspices of UM must be registered with the Diving Safety Program through the DSO.
- Prior to operating any UM vessel, prospective operators must be checked out by the SBO and demonstrate skills in the operation of any size boat.
- For more information, 5-3979 or www.ESSR.umd.edu/risk_comm/diving/index.html



11/30/2015

ESSR 015-0015

Safety Concerns not Captured on the Routing Form

Inadequacy of existing laboratory infrastructure

- Ventilation modifications
- Insufficient electrical access

Acquisition of equipment that has not been rated by one of the National Testing Laboratories

11/30/2015

ESSR 015-0015

Environmental Impact

Some funding agencies require submission of an Environmental Impact certification

- US AMRMC: Certification of Environmental Compliance
- DOE ARPA: Environmental Impact Questionnaire

The routing form does not have a question specific to Environmental Impact



11/30/2015

ESSR 015-0015

Examples of Research Projects with Unexpected Constraints

Research lab in JM Patterson was slated for use in pharmaceutical research—but lacked sufficient air supply to support the ‘clean room’ requirements

→research had to be conducted at the sponsor’s facility

11/30/2015

ESR 015-0015

Example 2

Engineering research group acquired an instrument that was not tested by a NTL and was not ESSRigned for US power

→resulted in unexpected costs and 6 plus months delay.

11/30/2015

ESR 015-0015

Example 3

Researcher intended to use equipment that requires specialized ventilation in a lab without single pass air. 600 pound instrument was moved into the lab in advance of the ventilation evaluation

→cost of moving the instrument and delays related to designing and installation the appropriate hood and ducts.

11/30/2015

ESR 015-0015


All Environmental Health and Safety Considerations

TIP:
Verify ESSR involvement as early as possible in the research planning stages to ensure no delays in the release of funding or the start of work



11/30/2015 ESSR 015-0015

ANY QUESTIONS?



"You are completely free to carry out whatever research you want, so long as you come to these conclusions."

Additional Information for PIs:
<http://www.ESSR.umd.edu/ls/pi.html>

11/30/2015 ESSR 015-0015

Export Compliance Office



UNIVERSITY OF MARYLAND

www.umresearch.umd.edu/Export
1204 Marie Mount Hall
Adam Grant: 301-405-4212; export@umd.edu

81

WHAT IS "EXPORT COMPLIANCE"?

What is an "Export"?

- Physical Export: sending any material to foreign location (includes travel).
- Deemed Export: disclosing "controlled" technical data either written, oral, or visually to a non-US person ("US person" is defined as a citizen or permanent resident).



US Export Laws:



The University Mission:

II. Graduate Education and Research

The University of Maryland will continue to provide the highest quality graduate and professional education at all levels. The University strives to be recognized as a world center for the creation and dissemination of knowledge across all disciplines, addressing major societal issues and expanding the frontiers of knowledge that will place us among the very finest research universities in the nation and the world. We will enroll and educate students who excel in academic achievement and exhibit the promise of outstanding creativity and innovation, and whose diversity will contribute to the vigor, scope, and intellectual excitement of our programs.



US Department of State controls technologies developed for military applications or designed to military specifications under a set of laws referred to as the International Traffic in Arms Regulations (ITAR). Components and technologies designated "ITAR" have the highest-level of export control restrictions and generally cannot be "exported" to any non-US person without a license.

86



ITAR Stuff:



US Department of Commerce controls all other technology not under the jurisdiction of Department of State (above) or considered to be in the public domain. The more sensitive technology is designated with an Export Control Classification Number (ECCN) and requires an export license to export to many parts of the world. All other technology is designated "EAR99" and can be exported to most, but not all locations, without a license.





US Department of the Treasury controls financial transactions (including certain exports and services). Traveling researchers need to be aware of associated Treasury laws when visiting sanctioned countries.

- Office of Foreign Assets Control (OFAC) 31 CFR 500-599 - Administers and enforces economic and trade sanctions based on US foreign policy and national security goals against targeted foreign countries and regimes, terrorists, international narcotics traffickers, those engaged in activities related to the proliferation of weapons of mass destruction, and other threats to the national security, foreign policy or economy of the United States.

Current OFAC Sanctions Programs

- Balkans-Related Sanctions-02/07/2014
 - Belarus Sanctions-08/11/2011
 - Burma Sanctions-04/01/2014
 - Central African Republic Sanctions-07/07/2014
 - Cote d'Ivoire (Ivory Coast)-Related Sanctions-01/06/2011
 - Counter Narcotics Trafficking Sanctions-07/23/201
 - Counter Terrorism Sanctions-07/15/2014
 - Cuba Sanctions-07/30/2013
 - Democratic Republic of the Congo-Related Sanctions-07/08/2014
 - Iran Sanctions-07/21/2014
 - Iraq-Related Sanctions-05/27/2014
 - Lebanon-Related Sanctions-07/30/2010
 - Former Liberian Regime of Charles Taylor Sanctions-04/02/2013
 - Libya Sanctions-10/18/2012
 - Magnitsky Sanctions-05/20/2014
 - Non-Proliferation Sanctions-07/09/2014
 - North Korea Sanctions-06/20/2011
 - Rough Diamond Trade Controls-05/21/2008
 - Somalia Sanctions-07/05/2012
 - Sudan Sanctions-02/01/2012
 - South Sudan-related Sanctions-06/02/2014
 - Syria Sanctions-07/09/2014
 - Transnational Criminal Organizations-07/02/2014
 - Ukraine-related Sanctions-07/16/2014
 - Yemen-Related Sanctions-11/09/2012
 - Zimbabwe Sanctions-07/10/2014
- www.treasury.gov/resource-center/sanctions/Programs/Pages/Programs.aspx

91

What is Fundamental Research

...Fundamental research is defined to mean basic and applied research in science and engineering where the resulting information is ordinarily published and shared broadly within the scientific community, as distinguished from research the results of which are restricted for proprietary reasons or specific U.S. Government access and dissemination controls.

(22 CFR § 120.11 Publicly available)

92

What Isn't Fundamental Research

University research will not be considered fundamental research if:

- (i) The University or its researchers accept other restrictions on publication of scientific and technical information resulting from the project or activity, or
- (ii) The research is funded by the U.S. Government and specific access and dissemination controls protecting information resulting from the research are applicable.

93

Export Compliance Risks at the University:

- Deemed exports (highest risk in areas of applied technical research) DoD & NASA
- Contracts vs. Grants
- Foreign collaborations/visiting researchers
- Dealing with Sanctioned countries
- International Shipping
- International Travel



94



Why does it matter?



The Washington Post



95

What can you do?

96

Vigilance

Sponsor wants to restrict research results or add security requirements

Equipment vendor's terms indicate that the equipment is export controlled

PI to take hardware on international flight

97

Accurate reporting

Routing Form:

Refer to umresearch.umd.edu/Export/overview.html for more information about **Export Control**.

18. a. yes no Are any **export controls indicated** in the solicitation or in discussions with the sponsor, or does the research relate directly to a **military technology**?

18. b. yes no Does the scope of work involve **fabrication of a prototype** that meets given specifications or requirements?

18. c. yes no Will your project involve the **shipment of equipment outside of the US**?

18. d. yes no Will your project involve **collaboration with a foreign entity**?

If yes to any of the above, please provide additional documentation with the following information: full name of foreign collaborator(s), country or countries of citizenship, affiliation (e.g. employer). Use additional pages as necessary.

19. a. yes no Will this project require the use of another party's **proprietary** (restricted) information or materials?

19. b. yes no If yes to 36a, will such information be subject to a nondisclosure agreement or any other agreement authorizing a sponsor or other party to **withhold from publication** information provided to UM?

19. c. yes no Will this project involve any other **restrictions** on the ability of the PI, Co-PI and/or other UM researchers to publish the results of their research or information provided to them or UM?

19. d. yes no Will the researchers need to generate any data that will be considered **confidential or proprietary**?

If yes to any of the above, attach copies of any proposed NDA and/or any other agreement containing any restriction on publication or dissemination of proprietary information or research results.

98

Accurate reporting

Visit Request:

3. Will UMD release any proprietary or confidential information to the Foreign Person that has been identified by the Department, a research sponsor or any other party as export controlled information?

Yes No

[If the answer is "Yes," then an export license may be required. Please contact the Export Compliance Office at 301-405-4212 before proceeding further.]

[In this question, export controlled information means technology or technical data identified in the Commerce Control List ("CCL") of the Export Administration Regulations or the United States Munitions List ("USML") of the International Traffic in Arms Regulations.]

99

Restricted Party Screening

Sichuan University – Chengdu, China
Northwestern Polytechnic University – Xi'an, China
Imam Hossein University, Tehran, Iran

Government consolidated screening list:

http://export.gov/ecr/eg_main_023148.asp



Know when to ask

- Ship items internationally
- Travel or collaborations with Cuba, Iran, N. Korea, Syria, or Sudan
- Sponsor requests that research results not be published w/o review
- Sponsor restricts work to US-only participants
- Need to receive export controlled technical data
- Need to receive hardware that the sponsor or vendor has designated "ITAR"

101

ECO Services

www.umresearch.umd.edu/Export/overview.html

- Training
- Visit Requests
- Proposal Support
- Travel and Shipping Assistance
- High-tech Lab equipment
- Foreign appointments
- Export Licensing
- Technology Control Plans

102
