

Research Compliance Overview

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Focus of Discussion

- ▶ Research Compliance/Integrity Responsibilities
- ▶ Human subjects requirements (IRB)
- ▶ Animal subjects requirements (IACUC)
- ▶ Research Misconduct Requirements
- ▶ Conflict of Interest (COI) Requirements
- ▶ Responsible Conduct of Research
- ▶ Export Controls, US Economic Sanctions, Controlled Unclassified Information, and Secure Research

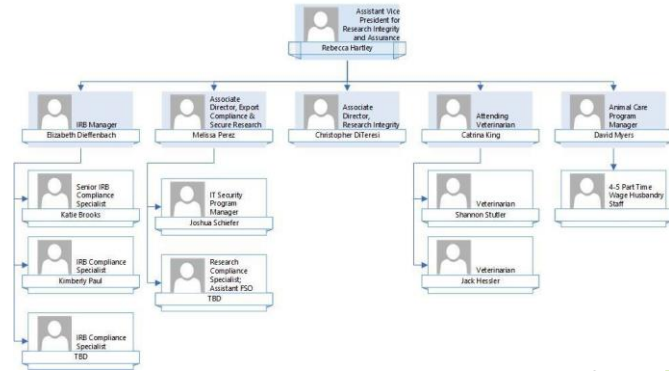
A plug...

If you want to know more about these topics - apply for Mason's Advanced Certificate in Research Integrity program.

Responsibilities

- ▶ Institutional - Who does that include?
- ▶ Researcher
- ▶ ORIA
- ▶ OSP
- ▶ SEERM - Safety, Emergency, & Enterprise Risk Management Group
- ▶ Colleges/Departments

ORIA Team at Mason



Human Subjects Protections



Human Subjects Protection History

- ▶ Nuremberg Code (1946)
- ▶ Declaration of Helsinki (1964)
- ▶ National Commission for the Protection of Research Subjects in Biomedical and Social Behavioral Research (1974)
- ▶ Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects (1979)
 - ▶ Respect for persons
 - ▶ Beneficence
 - ▶ Justice



Regulatory requirements

- ▶ Regulations
 - ▶ Federal
 - ▶ 45 CFR 46 - DHHS Policy for Protection of Human Subjects - Subpart A = the "Common Rule"
 - ▶ Heavily influenced by the Belmont Report
 - ▶ Adopted by 15 Federal departments and agencies
 - Subpart B - D = Additional protections for vulnerable populations
 - ▶ 21 CFR 50 - FDA Protection of Human Subjects = requirements for clinical investigations regulated by the FDA
 - ▶ Code of Virginia (32.1-162.16)

Institutional Requirements

- ▶ Because we accept funding from federal agencies Mason has a Federalwide Assurance (FWA)
- ▶ State Code specifies following the code or 45CFR46
- ▶ The institution is responsible for reviewing all human subjects research through use of and support for an Institutional Review Board (IRB).
- ▶ The institution is also responsible for ensuring compliance with all requirements in our FWA and the regulations and providing education.

Human Subjects Review

- ▶ The IRB Reviews Human Subjects Research as Defined by the
- ▶ What does this mean?
- ▶ How do we approach projects?



Step 1: Is it Research?

What is Research?

A systematic investigation **designed** to develop or contribute to **generalizable** knowledge (includes research development, testing, and evaluation)

This include biomedical, social, and behavioral research

Step 2: Does the Research Involve Human Subjects?

Human Subject = a living individual about whom an investigator conducting research obtains

- ▶ data through intervention or interaction with the individual, or
- ▶ identifiable private information

IRB Review

- ▶ The IRB only reviews projects that meet the definitions of BOTH research and human subjects
- ▶ The IRB is a peer review board consisting of at least 5 members of varying backgrounds who:
 - ▶ Are sufficiently qualified
 - ▶ Are not solely from one profession
 - ▶ Are diverse
- ▶ Additional IRB composition requirements:
 - ▶ At least one non-scientist
 - ▶ At least one non-affiliated member
 - ▶ Expertise on vulnerable populations
 - ▶ Outside consultants when needed

IRB Responsibilities

- ▶ Review and approve, require modifications, or disapprove all covered research
- ▶ Review informed consent practices and ensure compliance with regulations
- ▶ Notify investigators of concerns, questions, and decisions
- ▶ Conduct yearly (or more frequent) review of ongoing covered research

IRB Approval

- ▶ In order to approve a project the following must be met:
 - ▶ Risks to subjects are minimized
 - ▶ Risks are reasonable in relation to anticipated benefits
 - ▶ Selection of subjects is equitable
 - ▶ Informed consent is sought from each subject
 - ▶ Informed consent is appropriately documented
- ▶ In Addition - for certain projects:
 - ▶ Data collection is monitored to ensure subject safety
 - ▶ Privacy and confidentiality is protected
 - ▶ Additional safeguards are included for vulnerable populations

Special Protections for Vulnerable Populations

- ▶ Subpart B: Additional Protections for Pregnant Women, Human Fetuses and Neonates involved in Research
- ▶ Subpart C: Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects
- ▶ Subpart D: Additional Protections for Children Involved as Subjects in Research

Question

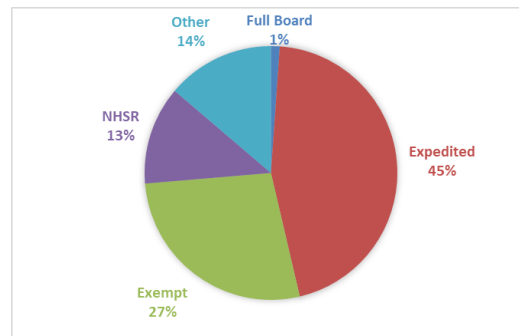
- ▶ You have likely heard that obtaining informed consent is important when working with human subjects, why is consent important and what might it include?

Answer

- ▶ Consent is important because it shows respect toward human subjects.
- ▶ Required Elements of Informed Consent

Numbers

RDIA and the IRB Processed 1785 submissions in FY2018 including 806 New Applications



IRB Contacts

- ▶ Bess Dieffenbach
Human Subjects Program Manager
Phone: 703-993-5593
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IRB@gmu.edu
- ▶ Katie Brooks
Senior IRB Compliance Specialist
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Fax: 703-993-9590
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- ▶ Kimberly Paul
IRB Compliance Specialist
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Animal Care and Use



Animal Use

- ▶ Law
 - ▶ USDA - Animal Welfare Act (certain species)
- ▶ Policy
 - ▶ Public Health Service (Office of Laboratory Animal Welfare - OLAW) - all species at institutions that accept PHS funding
- ▶ Guidance
 - ▶ Guide for the Care and Use of Laboratory Animals (not really “guidance” because it is adopted by both USDA & OLAW). Similar to the rDNA “guide”

Oversight

- ▶ NIH/OLAW - assurance + annual reports
- ▶ USDA - registration + annual reports
- ▶ Accreditation
 - ▶ AAALAC - Association for the Accreditation and Assessment of Laboratory Animal Science International

IACUC

- ▶ Institutional Animal Care and Use Committee
- ▶ Members must be qualified through experience & expertise to provide oversight for the animal programs, facilities & procedures.
- ▶ Minimum of 5 members
 - ▶ Veterinarian
 - ▶ Practicing scientist experienced in animal research
 - ▶ Non-affiliated member
 - ▶ Non-scientist

IACUC

- ▶ Reviews all research involving **vertebrate** animals
- ▶ Approves for up to 3 years with annual continuing reviews
- ▶ Reviews facilities and program every 6 months

Question

- ▶ From many perspectives, using animals in research involves a more cumbersome review and oversight process than human subjects research. Why might this be the case?

Answer

- ▶ Animals cannot provide informed consent and their care, not just the research, is directly under the control of the institution (for laboratory based research)

Animal Care and Use Contact

- ▶ David Myers
Manager, Animal Care Program
Phone: 703-993-6118
Fax: 703-993-9590
IACUC@gmu.edu

Common to both committees

- ▶ The following standards are common to both IRBs and IACUCs

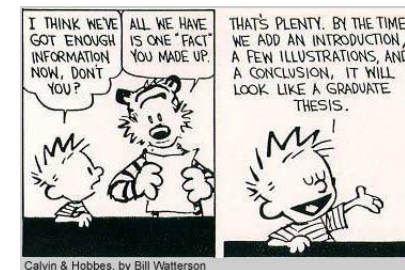
Records

- ▶ Copies of all protocols, evaluations, consent documents (HS), continuing reviews, progress reports, and unanticipated problems reported
- ▶ Meeting minutes
- ▶ IRB/IACUC-PI Correspondence
- ▶ Committee membership & credentials
- ▶ Written procedures

Additional information

- ▶ All investigators interacting with human or animal subjects must complete training prior to initiation of that work
- ▶ Noncompliance with protocols is evaluated in the context of risk to subjects. If there are serious unanticipated problems or negligence/intentional harm the institution would need to report to the appropriate agency. Suspensions must also be reported.

Research Misconduct



Research Misconduct

- ▶ On December 6, 2000, the OSTP in the White House published the Federal Research Misconduct Policy which required all federal agencies or departments supporting intramural or extramural research to implement within one year.
- ▶ The following agencies or departments have done so: DHHS, DOD, DOL, DOT, VA, EPA, NASA, NEH, NSF, and the Smithsonian Institution.
- ▶ From <https://ori.hhs.gov/federal-policies>

Research Misconduct

- ▶ Definitions:
- ▶ *Research misconduct is defined as fabrication, falsification, or plagiarism ("FFP") in proposing, performing, or reviewing research, or in reporting research results.*
 - ▶ *Fabrication is making up data or results and recording or reporting them.*
 - ▶ *Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.*
 - ▶ *Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit. Research misconduct does not include honest error or differences of opinion.*

Finding of Research Misconduct

- ▶ *A finding of research misconduct requires that:*
 - *There be a significant departure from accepted practices of the relevant research community; and*
 - *The misconduct be committed intentionally, or knowingly, or recklessly; and*
 - *The allegation be proven by a preponderance of evidence.*

Requirements for institutions

Agencies and research institutions are partners who share responsibility for the research process. Federal agencies have ultimate oversight authority for Federally funded research, but research institutions bear primary responsibility for prevention and detection of research misconduct and for the inquiry, investigation, and adjudication of research misconduct alleged to have occurred in association with their own institution.

Research Misconduct

- ▶ Agencies rely on research institution to perform review, inquiry, investigation, and adjudication whenever possible.
- ▶ Initial review generally is performed by Research Integrity Officer (RIO) - is the allegation credible and specific? Is it FFP?
- ▶ Inquiry - determines whether the allegation has substance and if an investigation is warranted. (Peer Based Evaluation)
- ▶ Investigation - the formal development of a factual record, and the examination of that record leading to dismissal of the case or to a recommendation for a finding of research misconduct or other appropriate remedies. (Peer Based Evaluation)

Research Misconduct

- ▶ Adjudication - recommendations are reviewed and appropriate corrective actions determined.
- ▶ Agency follow-up to institutional action. Reviews report from institution, takes additional oversight/investigation steps if needed, and levies penalties.

Research Misconduct Cases

- ▶ https://ori.hhs.gov/case_summary

What would you do?

- ▶ A graduate student comes to you in confidence and tells you that her faculty PI wants to put her name on a paper but she never participated in the research. What would you do?

Research Misconduct Contact

- ▶ Research Integrity Officer (RIO)
- ▶ Rebecca Hartley
Assistant VP
- ▶ Office of Research Integrity & Assurance
Phone: 703-993-2308
Email: rhartle1@gmu.edu or RIO@gmu.edu

Financial Conflicts of Interest



What is an FCOI?

- ▶ An outside financial interest that compromises, or has the appearance of compromising, the professional judgment of a researcher when designing, conducting, or reporting research

Policy 4001

- ▶ State and federal law require that all employees fully disclose “Personal Interests” that present a Conflict of Interest or commitment with one’s University responsibilities.
- ▶ A Conflict of Interest is a situation in which a Personal Interest may compromise or bias an employee’s professional judgment and objectivity when performing research or making decisions on behalf of the University.
- ▶ -Applies to all officers and employees of the university
- ▶ -Generally an officer or employee may not have a “personal interest in a contract” with the University other than his or her own employment contract.
- ▶ -A “Personal Interest” is a financial benefit or liability accruing to the employee or member of his or her immediate family. This includes an ownership interest in the business that exceeds 3% of total equity, or income from the business that exceeds \$5,000 annually.
- ▶ Having a potential conflict does NOT mean someone has done something improper.

Immediate family

- ▶ For purposes of conflicts where an employee's "Immediate family" works for a company or has an ownership interest in a company doing business with Mason that exceeds state limitations, "Immediate Family" means:
 - ▶ (i) a spouse and
 - ▶ (ii) any child who resides in the same household as the officer or employee and who is a dependent of the officer or employee.
- ▶ Note that this is different from the employment conflict, where the definition of "related to them by family or Marriage, or an individual sharing the same household" is much broader.

Exceptions

- ▶ The prohibition may be waived in certain circumstances, generally related to the transparency of the interest and the employee's lack of involvement in both the business' and the university's contracting processes, and, for contracts for research and development or the commercialization of intellectual property, the employee's disclosure of his or her interest and the university
- ▶ President's approval ("waiver") of the potential conflict must occur before the contract is executed.
- ▶ Waivers of conflicts of interests are available to employees, but not officers, of the University.

FCOI NIH Requirements

- Applies to each institution that is applying for, or that receives, NIH research funding (excluding Phase I SBIR/STTR).
- Applies to all Investigators - the PD/PI and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the NIH, or proposed for such funding.
- Includes subgrantees, contractors, consortium participants, collaborators, and consultants.

What is an FCOI?

- ▶ Financial Conflict of Interest (FCOI): means an Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of the NIH-funded research.

Investigator Duties - NIH

- ▶ Disclose all SFIs:
 - Prior to submission of a proposal;
 - Within 30 days of obtaining a new SFI;
 - Updated at least annually

Institutional Responsibilities - NIH

- Compliant policy (made publicly available via a website)
- Review SFI disclosures and determine if any SFIs pose an FCOI
- Manage FCOIs
- Submit initial and annual reports to NIH for all FCOIs
- Retrospective reviews when required
- Public disclosure of FCOIs

Training - NIH

- Training prior to expenditure of funds and at least every 4 years. Also when:
 - Institutional FCOI policies change in a manner that affects Investigator requirements
 - An Investigator is new to an institution
 - An Institution finds that an Investigator is not in compliance with the Institution's FCOI policy or management plan

Public Disclosure of Information -NIH

- Public disclosure of information upon request:
 - name,
 - title/role,
 - name of entity in which SFI is held,
 - nature of SFI, and
 - approximate dollar value

Funding Agencies other than NIH

- ▶ Have requirements for institution to have FCOI policy
 - Do not require reporting to agency if FCOI is managed,
 - Do not require training,
 - Do not require public disclosure
- THIS IS AN EVOLVING AREA, and may change significantly in the next year.

At Mason

- ▶ Policy 4001
- ▶ Disclosure system
- ▶ 4429 individuals submitted 4644 annual disclosures. Of these, 170 individuals disclosed 288 Significant Financial Interests in 2019.
- ▶ 329 Project Disclosures were submitted by 94 investigators. Of these, 270 Project Disclosures by 74 different investigators were reviewed by the Conflict of Interest Committee.
- ▶ Nineteen COI Waivers and five COI Management Plans were approved in 2019.

Question

- ▶ You support a PI who has an NIH funded project. He casually mentions that his wife is the project lead at the small business responsible for a subaward on the project. You don't recall seeing a request for a COI waiver or management plan. Is this a problem?

Answer

- ▶ In the scenario described above the PI would most likely need a waiver and a management plan.

FCOI Contacts

Christopher DiTeresi

Associate Director, Research Integrity
Office of Research Integrity & Assurance
Phone: 703-993-6409
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Elizabeth Woodley

University Policy Manager and FOIA Compliance Officer
Compliance Diversity and Ethics
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Responsible Conduct of Research



Responsible Conduct of Research

- ▶ The practice of scientific investigation with integrity. It involves the awareness and application of established professional norms and ethical principles in the performance of all activities related to scientific **research**.
- ▶ NIH, NOT-OD-10-019 - Requirement for Instruction in the Responsible Conduct of Research: “the awareness and application of established professional norms and ethical principles in the performance of all activities related to scientific research”
- ▶ Basis for compliance across subject matter areas

Requirements

- ▶ NIH policy requires participation in and successful completion of instruction in responsible conduct of research by individuals supported by any NIH training/research education/fellowship/career award. It is expected that course attendance is monitored and that a certificate or documentation of participation is available upon course completion. (In person)
- ▶ Section 7009 of the America COMPETES Act specifies NSF requirements: The Director shall require that each institution that applies for financial assistance from the Foundation for science and engineering research or education describe in its grant proposal a plan to provide appropriate training and oversight in the responsible and ethical conduct of research to undergraduate students, graduate students, and postdoctoral researchers participating in the proposed research project. (CITI)

Mason's training plan

- ▶ RDIA facilitates a faculty-led 8-hour face to face training program in the Responsible Conduct of Research.
- ▶ Online training in RCR is available through citiprogram.org.
- ▶ Advanced certificate in Research Integrity for research administrations. (2 years +)
- ▶ Outreach to units
- ▶ EHS laboratory safety training
- ▶ Customized training w/r/t animal subjects, human subjects, export compliance

RCR Contact

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Export Controls, Sanctions Compliance, and Secure Research



Major Government Players

3 primary federal agencies that **currently** oversee and enforce export controls and economic sanctions:

- **State Department:** International Traffic in Arms Regulations (ITAR) - Governs military, weapons, and space related technologies
- **Commerce Department:** Export Administration Regulations (EAR) - Governs technologies with dual uses (those with both military and commercial applications or strictly commercial applications)
- **Treasury Department:** Office of Foreign Assets Control (OFAC) - Governs transactions with countries subject to embargo, boycott, or trade sanctions

Sanctioned Countries

- ▶ The United States currently maintains broad-based economic embargoes against:

- ❑ Crimea region of Ukraine
- ❑ Cuba
- ❑ Iran
- ❑ North Korea
- ❑ Syria

Getting it Wrong

Failing to comply with U. S. export control laws can result in severe penalties on Institutions and Individuals, including personal or institutional debarment from federal contracting.

ITAR: (Individual and Entity)

Criminal: \$1.1M and/or 10 Years in prison

Civil Fines: \$1.1M and Forfeitures

EAR and OFAC (Individual and Entity):

Criminal: \$1.1M or 5X value of export and/or 20 years in prison

Civil Fines: \$285K per violation or 2x the value of the transaction, whichever is greater

The cost of an investigation in institutional, personal and financial terms is always significant, even if formal penalties are not imposed.

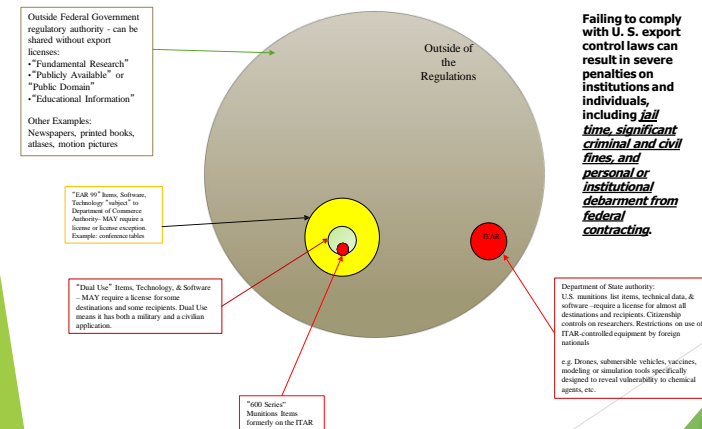
Treatment of University Research

Fortunately, the vast majority of RESEARCH conducted at universities is exempt from export controls under three exclusions found separately in the ITAR and the EAR:

- ❑ Public domain/publicly available exclusions
- ❑ Educational information exclusions
- ❑ Fundamental research exclusions

Although most university research is exempt from export controls under these exclusions, Mason must meet the specific definitions found in the relevant regulations. Unlike some universities, Mason does accept research which is subject to export controls.

US Export Controls at Mason



Examples of Common Export Scenarios

- ❑ Sponsored research that:
 - Restricts research publication rights or limits participation by foreign nationals or
 - Provides researchers with export-controlled information, items or technology, or other controlled unclassified information
- ❑ Traveling or conducting research outside the United States
- ❑ Shipping or carrying items, technology or software outside of the United States
- ❑ Collaborative research with foreign colleagues
- ❑ Providing services (e.g., consulting or training) to foreign nationals

There are additional complications if these activities involve sanctioned countries or individuals from sanctioned countries.

It is important to stay in the fundamental research sphere if possible, because dealing with export controlled technical data can be very complicated.

So, what do we do about this?

- ❑ Determine if the research is subject to export controls.
- ❑ Evaluate contract for "troublesome clauses."
- ❑ Negotiate fundamental research designation wherever possible.
- ❑ Narrow scope of covered export control material if not possible to obtain a fundamental research designation.
- ❑ Properly protect controlled technical data we receive with an appropriate technology control plan.

Example: Shipping Items Abroad

► **The Issue:** You wish to send an atmospheric testing device and a related antenna and cable to a foreign colleague.

► **Problem:** Can I ship the materials?

► **Solution:**

- Work with RDIA to:
 - ▶ Determine the item's export classification
 - ▶ Determine whether the shipment requires an export license or other export clearance documents
 - ▶ Ensure appropriate records are kept.

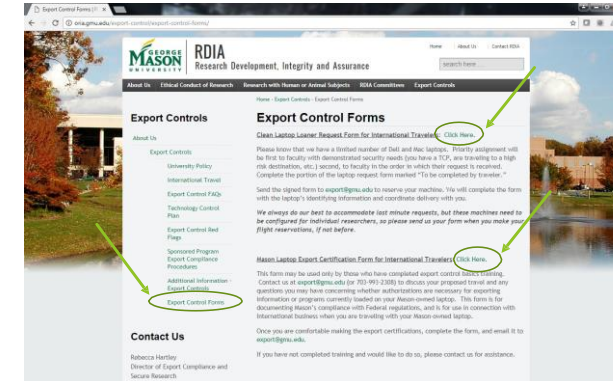
Economic Embargoes

- ❑ The United States currently maintains broad-based economic embargoes against: Crimea region of Ukraine, Cuba, Iran, North Korea, and Syria
- ❑ These embargoes are not identical, but generally restrict ALL TRANSACTIONS with these countries/areas
- ❑ For example, a US person cannot, without a general or specific license, sell pencils to Iran or travel to Cuba.
- ❑ Personal items can be taken, as can publically available information (like publications and text books) for use in the sanctioned country.
- ❑ Mason Policies:
 - ▶ Travel policy requires RDIA approval prior to Mason related travel to any sanctioned country
 - ▶ Mason laptops can't be taken to a sanctioned country unless a general or specific license applies
 - ▶ VPN access is not permitted from sanctioned countries

Example: Presenting in Iran

- **The Issue:** You have been asked by a distinguished professor at an Iranian university to speak about your research, using the presentation materials you used at a conference last month. Can you present your paper?
- **Problem: You need a license.** Presenting your paper in Iran exactly as you did at the former conference would be an illegal performance of services, as would answering questions about the materials. You would also need a license to attend the conference even if you were not a presenter.
- **Solution:** Work with ORIA to determine whether your presentation would make a good candidate for licensure. Do so WELL in advance of your trip.

International Travel Forms



Export Control Contacts

Determining when an export license is required can be challenging. Mason's ORIA office is here to help you navigate the regulations to ensure compliance with these laws.

Melissa Perez
Associate Director for Export Compliance & Secure Research

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Export@gmu.edu

Controlled Unclassified Information: New Era of Data Protection



Controlled Unclassified Information: E.O. 13556

- ▶ Executive Order 13556, "Controlled Unclassified Information", November 4, 2010
- ▶ President Obama issued this Executive Order because:
 - Confusing patchwork of agency-specific designations
 - Inconsistent marking requirements
 - Inconsistent safeguarding requirements
 - Unclear or unnecessarily restrictive dissemination policies
 - Practical impediments to authorized information sharing
 - Agency requirements often hidden from public view

CUI Regulations

- ▶ These regulations change the way many kinds of information is protected:
 - Before, sensitive information was required to be protected, and organizations often had broad discretion on how to provide that protection
 - NIST 800-171 controls now apply to CUI shared by the Federal government with a non-federal entity
 - Apply within the US as well as outside of the US (no "export" required to trigger the controls)

CUI at Mason: Where is this stuff hiding?

Sponsored and Non-sponsored Research

- ▶ Contracts with government agencies
- ▶ Subcontracts with "prime" contractors
- ▶ Other written agreements, including grants, licenses, data use agreements, and similar arrangements that involve Mason receiving CUI from the government or producing CUI for the government.

Eventually, "enterprise" locations such as financial aid, police department, student health, FERPA records

BUT THE IMPLEMENTING REGULATIONS ARE STILL NOT ISSUED FOR MOST AREAS.

CDI/CUI: How must it be protected?

- ▶ NIST SP 800-171 – IT Security Controls



Covered Defense Information: How do we cope?

Same way as for potential export controlled projects:

- ❑ Determine if the research is subject to CUI controls.
- ❑ Evaluate contract for "troublesome clauses."
- ❑ Negotiate fundamental research designation wherever possible.
- ❑ Narrow scope of CUI material if not possible to obtain a fundamental research designation.
- ❑ Properly protect CUI we receive or produce with an appropriate technology control plan and associated IT system security plan.

Questions?