
Non-Fiscal Research Compliance
for Research Administrators
RSH204
RAFT FOUNDATIONS

RSH204 Non-Fiscal Compliance

Compliance means being in accordance with established guidelines or specifications. When considering compliance in relation to research, it's important that work is done "the right way" to ensure the highest level of professionalism, accountability, trust and responsibility is maintained at UF.

This course covers the basics of non-fiscal compliance in the areas of human subject research, animal research, biological research, conflict of interest and export controls.

At the end of this course, you will be able to:

- Describe research compliance and what makes staying in compliance difficult
- Explain the history behind major compliance regulations
- Describe the purpose of IRB, IACUC, and IBC
- Discuss Conflict of Interest issues and Export Controls processes

To pass this course, you must obtain at least **80%** on the final assessment.

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Module 1: What is Research Compliance?

What is Research Compliance?

Click each question mark to reveal definition.

Research

The systematic investigation into and study of materials and sources in order to establish facts and reach new conclusions.

Compliance

State of being in accordance with established guidelines or specifications.

Research Compliance

The systematic investigation into and study of materials and sources in order to establish facts and reach new conclusions in accordance with established guidelines or specifications.

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Module 1: What is Research Compliance?

But what does research compliance *really* mean?

- Research compliance is knowing what the right thing is and doing it.
- It's doing the right thing even when no one is looking.
- It's incorporated into the everyday work of your PIs and lab staff.
- It's integral to professionalism, accountability, trust and responsibility.
- Without it, research would come to a halt at UF.

It's your job to help your colleagues that are involved in research adhere to research compliance guidelines.

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Module 1: What is Research Compliance?

Ok, research compliance seems simple enough. Why do my colleagues need help?

Simple in concept, but difficult in practice.

Take a few minutes to think like a PI. What might a PI say about having to comply with research compliance expectations? Click the boxes below to see a few examples.

- Not enough time, money, resources, etc.
- These rules don't make sense
- Too much paperwork
- Too many regulations
- I'm here to do research, not paperwork
- Can't understand the regulations/ too complex

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Module 1: What is Research Compliance?

Remember!

Remaining compliant takes effort, desire, and information. Compliance doesn't happen by accident and that's why your PIs and colleagues need your help.

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Module 1: What is Research Compliance?

Read the following case study and determine what you would do.

The relationship between two Co-PIs who have been funded on grants and worked together for the past 10 years has deteriorated. You, the poor RA, are caught in the middle. They make demands and counter-demands on you (buy this, don't let him buy that). The grant is ending, and reports and final deliverables are due. Furthermore, each PI is trying to sabotage the other's renewal attempts.

What would you do?

Click for Expert Answer

Ideally the best initial way to address issues is to discuss them directly with the faculty. In this case you could let each faculty member know you are receiving conflicting directions and that you need consistent directions to properly close out the award. Engage the Department Chair if needed to rectify the situation. At any point you can consult with applicable Compliance Offices to ensure activities are compliant or for advice on how to handle a challenging research-related situation.

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Module 1: What is Research Compliance?

You've read the memo to the right. You know that one of your PIs is doing an outreach extension project with high schools in the area that involves taking 20-30 small drones to the high schools and teaching the students how to fly these drones.

What would you do?

From: Human Resource Services [mailto:INFOGATOR-L@LISTS.UFL.EDU] **On Behalf Of** -HRS Human Resource Services
Sent: Tuesday, January 05, 2016 9:42 AM
To: INFOGATOR-L@LISTS.UFL.EDU
Subject: New interim procedures for unmanned aircraft systems (drones)

To: UF Faculty, Staff and Students
From: Curtis Reynolds, Vice President for Business Affairs

Effective immediately, the University of Florida has implemented interim procedures for the use of unmanned aircraft systems (UAS), or drones.

In short, any UF employee or student who wants to operate a drone as part of their university employment or a university program must first receive a Certificate of Waiver or Authorization from the Federal Aviation Administration. Further information is available at the Research Compliance website.

Full details are available online at http://www.ehs.ufl.edu/programs/rm/uas_procedures/.

Click for Expert Answer

The first thing you should do is reach out to the PI and make sure they are aware of requirements. Ask if the PI has obtained the proper approvals. If not, offer to help facilitate the approvals – such as get the forms, find out who the PI needs to talk to, identify requirements, etc. If the PI does not have approval and insists on conducting the activity without it, appropriate next steps would include alerting the Department Chair and the applicable Compliance Office.

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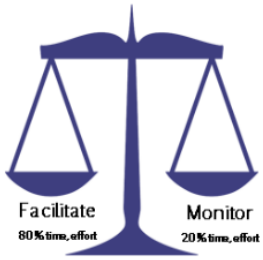
Module 1: What is Research Compliance?

In regards to research compliance, your role is to help facilitate adherence and monitor performance within your normal duties. If you identify a potential issue, verify details with the PI and check with compliance offices if there is really an issue. Click each pan on the scale to learn more.



You can always call the UF Compliance Hotline and remain anonymous
1-877-556-5356
https://www.reportlineweb.com/Welcome.aspx?Client=UF

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Module 1: What is Research Compliance?

Compliance expectations can effect research at both the Proposal and Award stages.

Proposal Stage	Award Stage
Most sponsors do not require compliance approvals (IRB, IACUC, IBC) to be in place prior to submission of the proposal. Some sponsors require disclosure of financial interests and proposal stage. All proposals including UFIRST require proper identification of the scope of work and answers to whether or not human or animal work is planned at any point throughout the project. National success ratios for many federal programs range about 25%. If the sponsor doesn't require having approvals in place prior to proposal submission, UF does not either.	Compliance expectations really kick in after funding is received to do the research. Compliance breaches will cause a "hard stop" to the research activity. No more funding released until the compliance requirements are met. For example, if the IACUC or IRB approval lapses or if the study is suspended, funding will be suspended until approval is re-obtained or the suspension lifted.

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Module 2: Compliance Programs

There are many important compliance programs depending on the nature of research being conducted.
Click bubbles to see a brief description of each.

IRB (Human Subject Research)

Before any employee works with human subjects, their tissue or their data at the University of Florida (UF), the Institutional Review Board (IRB) requires registration, review and approval.

IBC (rDNA Research)

Before working with recombinant DNA, BSL-3 pathogens and USDA/HHS Select Agents at the University of Florida (UF), the Institutional Biosafety Committee (IBC) requires registration, review and approval. Recombinant DNA includes work involving synthetic nucleic acid molecules (DNA and RNA).

Export Controls

Export controls are US laws that regulate the distribution to foreign persons and foreign countries of strategically important commodities, services and information for reasons of foreign policy and national security.

IACUC (Animal Research)

Before working with vertebrate animals, animal tissue or aniimal cadavers in research at the University of Florida (UF), the Institutional Animal Care and Use Committee (IACUC) requires registration, review and approval.

COI (Conflict of Interest)

A conflict of interest (COI) occurs when a person serves or represents two distinct entities or persons and must choose between two conflicting interests or loyalties. A University employee has a conflict when his/her outside activity or financial interest could potentially interfere with their professional obligations to the University.

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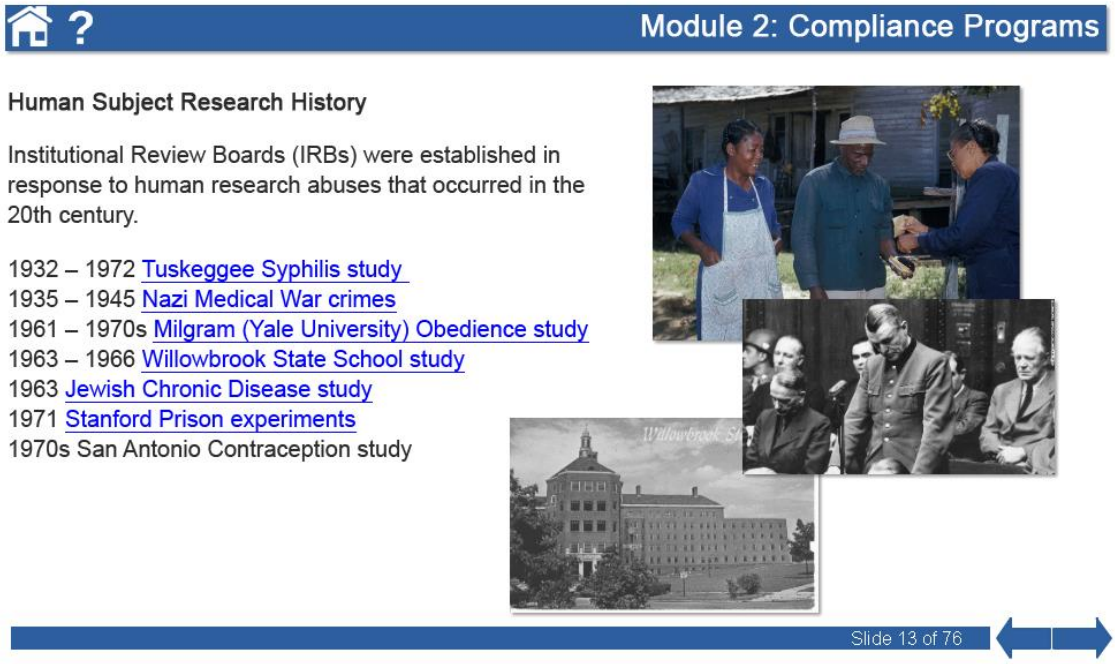

Tuskeggee Syphilis study - https://www.cdc.gov/tuskegee/timeline.htm

Nazi Medical War crimes - https://en.wikipedia.org/wiki/Nazi_human_experimentation

Milgram (Yale University) Obedience study - https://www.simplypsychology.org/milgram.html

Willowbrook State School study - https://science.education.nih.gov/supplements/webversions/bioethics/guide/pdf/Master_5-4.pdf

Jewish Chronic Disease study - https://nypost.com/2013/12/28/nycs-forgotten-cancer-scandal/

Stanford Prison experiments - https://www.simplypsychology.org/zimbardo.html

Module 2: Compliance Programs

The seminal event leading to US regulations was the U.S. Public Health Service Syphilis Study at Tuskegee. This study started in 1932 and was intended to observe the natural history of untreated syphilis. 600 African-American males were enrolled but were told they were being treated for "bad blood". These subjects were never consented to be in research and were never offered treatment with penicillin after its discovery.

The study gained public attention in 1972 after the research was leaked to the press and highlighted several significant issues:

- lack of informed consent
- inability to withdraw from the research
- risks of the research were born by a single segment of the population for the benefit of everyone
- death was a potential outcome

Module 2: Compliance Programs

As a result of this and other unethical research, the US government commissioned the Belmont Report, promulgated federal regulations to conduct research, and created the Office for Protection from Research Risks (now the of Office of Human Research Protections).

In 1974 the National Research Act established the federal policy for the protection of human subjects 45 CFR 46, Subpart A. This policy is also known as "the Common Rule".

Between 1975 and 2019, the policy has been amended several times.

1975 – added Subpart B - to provide special protection to pregnant women and fetuses
1978 – added Subpart C – to provide special protections for prisoners
1983 – added Subpart D – to provide special protections for children
2009 – added Subpart E – to require IRB registration
2019 – significantly revised Subpart A

Module 2: Compliance Programs

Human Subject Research at UF

- UF IRBs protect the rights and welfare of humans participating in research
- Local requirements require research involving humans must be submitted to and approved by a UF IRB prior to the initiation of any kind of research work. Work includes surveys or obtaining/ analyzing blood/tissue/data (even if unidentified) collections of any kind
- Researchers must complete mandatory training before they can submit research

There are 3 IRBs at UF:

- IRB-01 reviews all types of research
- IRB-02 reviews behavioral, social, and educational IRB that does not involve PHI/HIPAA
- WIRB reviews industry sponsored, FDA-regulated, multi-site drug and device clinical trials

If a protocol expires, (1) all research must stop until protocol is reapproved, and (2) project funds are shut down.

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Module 2: Compliance Programs

Due to the importance of maintaining protocol approval from the IRB, PIs receive multiple email reminders from the IRB and the Office of Research.

If you, as a Research Administrator, would like to be copied on these emails that go to the PIs in your department, contact the IRB office at (352) 273-9600 or ufirb-l@lists.ufl.edu.

Note that gaining and maintaining IRB approval takes time and extra work, especially for international research or research relying on non-UF IRBs, so budget your time appropriately.

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Module 2: Compliance Programs

There are a number of variables that can affect the IRB's ability to review and approve research. Particularly complex/novel research as well as poorly prepared submissions can require more time to reconcile and approve.

The following three areas typically require more/different work and *researchers should budget additional time for obtaining approval*:

- **International research:** researchers must not only comply with US requirements, but also any requirements in the foreign country. Other compliance units (Export Control, Privacy, IT security) may also have additional requirements.
- **Single IRB:** relying on an outside IRB or having a UF IRB oversee researchers from another institution introduces different work/issues and must be negotiated with the IRB as early in the proposal/award stage as possible so our researchers understand the additional/different responsibilities.
- **Exception From Informed Consent (EFIC):** starting in 2019 UF is engaging in EFIC emergency research. There are significant additional requirements for the IRB and researchers must receive institutional approval before the IRB will review EFIC research.

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Module 2: Compliance Programs

Read the following case study and determine what you would do.

You are processing an invoice for a receipt of a human tissue sample for a PI from your unit. However, you are aware of the PI's research and you know it does not involve humans or human tissue. Thus, you review his awards to look for IRB approval. You do not see any.

What would you do?

Click for Expert Answer

First, discuss the situation with the PI. Maybe the PI has approval via another faculty member's IRB protocol. If not, help facilitate obtaining IRB approval. If the PI refuses to pursue IRB approval, you can contact the IRB to confirm your understanding and then how to proceed. You could also choose to engage the Department Chair.

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Module 2: Compliance Programs

IRB Contact Information

IRB-01
Phone: 352-273-9600
Listserv: ufirb-l@lists.ufl.edu

IRB-02
Phone: 352-392-0433

General IRB website: http://irb.ufl.edu

Reporting noncompliance: http://irb.ufl.edu/index/noncompliance.html

UF Compliance Hotline at (877) 556-5356 or by completing the online form at https://www.reportlineweb.com/Welcome.aspx?Client=UF

Module 2: Compliance Programs

Animal Research History

Similar to human research, Institutional Animal Care and Use Committees (IACUCs) derived from the Animal Welfare Act of 1966 after a Sports Illustrated magazine article highlighted the poor state of animal welfare in the US.

The article focused on a pet dog, named Pepper, who was stolen from her owners in Pennsylvania to be used in an animal testing facility.

Soon after, a Life magazine article came out again highlighting the deplorable housing conditions at dog farm facilities.

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Module 2: Compliance Programs

The Animal Welfare Act of 1966 is the only federal law that regulates the treatment of animals in research and exhibition. It has since been amended 8 times with ever increasing regulatory requirements.

- Broadened scope of animals covered
- Applicable to all sources of funding (federal and non-federal)
- Animals must be registered and licensed
- Zoos, breeders and exhibitors are included
- Not dependent on “crossing state lines”
- Institutional oversight committees are required

Every institution that uses animals for federally funded laboratory research must have an IACUC. Each local IACUC reviews research protocols and conducts evaluations of the institution’s animal care and use, which includes the results of inspections of facilities that are required by law.

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Module 2: Compliance Programs

IACUC Contact Information

Phone: 352-273-9535
Listserv: iacuc@research.ufl.edu
Website: http://iacuc.ufl.edu
Call the IACUC for any questions/directions on training.

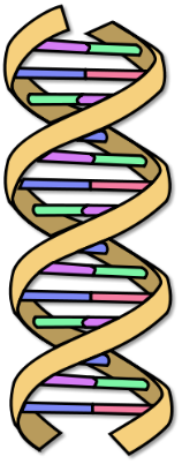
Suspected Mistreatment: http://iacuc.ufl.edu/mistreatment.html

UF Compliance Hotline at (877) 556-5356 or by completing the online form at:
https://www.reportlineweb.com/Welcome.aspx?Client=UF

Module 2: Compliance Programs

rDNA Research History

rDNA stands for recombinant DNA. This is an artificially made DNA strand that is formed by the combination of two or more gene sequences. rDNA is possible because DNA molecules from all organisms share the same chemical structure.



1953 – Drs. Watson and Crick discover the double-helix structure of DNA

1973 – Drs. Gilber and Sanger developed the technology for cleaving DNA which laid the groundwork for rDNA development

Module 2: Compliance Programs

rDNA Research History

1974 – Dr. Paul Berg, the first scientist to create a molecule containing DNA from two different species, voluntarily halted his research over biological safety concerns of the new technology and he, along with 10 other scientists, wrote a letter to the journal Science calling for an international meeting of scientists to discuss the appropriate ways to handle the potential biohazards of rDNA.

1975 – Asilomar Conference was held and guidelines were established for safe rDNA experiments. Due to concerns, scientists worldwide voluntarily halted experiments using rDNA until the guidelines were adopted and implemented.

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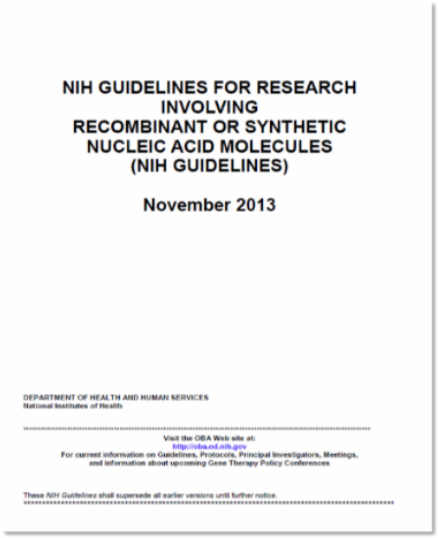
Module 2: Compliance Programs

The National Institutes of Health (NIH) adopted the Asilomar guidelines as the NIH Guidelines for Research Involving Recombinant DNA. Although only guidelines, and not regulations, compliance with the NIH Guidelines is mandatory for every institution that receives NIH funding for research involving rDNA.

A couple of the guidelines state that all rDNA research must be registered with the Institutional Biosafety Committee (IBC). The IBC is to oversee the use of Select Agents and any work that would be considered Dual Use Research of Concern (DURC).


NIH GUIDELINES FOR RESEARCH INVOLVING RECOMBINANT OR SYNTHETIC NUCLEIC ACID MOLECULES (NIH GUIDELINES)

November 2013

DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health

Visit the OBA Web site at:
http://oba.od.nih.gov
For current information on Guidelines, Protocols, Principal Investigators, Meetings, and information about upcoming Gene Therapy Policy Conferences

These NIH Guidelines shall supersede all earlier versions until further notice.

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Module 2: Compliance Programs

rDNA & Biologics at UF

Biologics = products derived from living organisms and includes recombinant protein, tissues, genes, blood components, blood, and vaccines, rDNA, and select agents.

- The IBC establishes, monitors, and enforces policies and procedures for working with rDNA and synthetic nucleic acids
- The IBC also oversees use of Select Agents and DURC
- The IBC oversees safety, not validity of science
- Research involving rDNA, select agents, synthetic nucleic acids or DURC must be submitted to and approved by the IBC prior to initiation of research work

Environmental Health & Safety oversees other, non-research, work with biologics, chemicals, radioactive materials, DEA-related, OSHA diving, etc

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Module 2: Compliance Programs

IBC and EH&S Contact Information

UF Institutional Biosafety Committee

IBC
Phone: 352-392-1591
Website: http://ibc.research.ufl.edu/

UF Environmental Health & Safety
Safety In The Workplace

EH&S
Phone: 352-392-1591
Email Directory: http://www.ehs.ufl.edu/about/directory
Website: http://www.ehs.ufl.edu/programs
Emergencies: http://www.ehs.ufl.edu/emergencies

UF Compliance Hotline at (877) 556-5356 or by completing the online form at:
https://www.reportlineweb.com/Welcome.aspx?Client=UF

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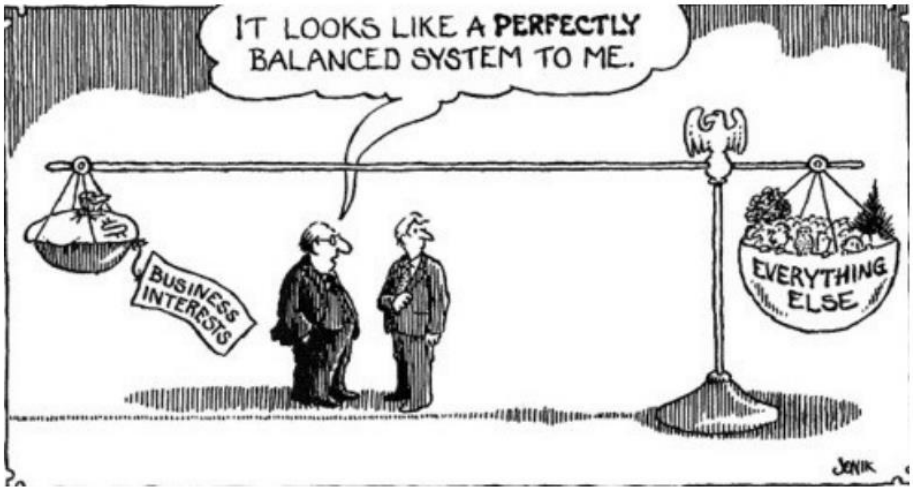
Module 3: Conflict of Interest



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Module 3: Conflict of Interest

What does Conflict of Interest (COI) mean?

One definition of Conflict of Interest is...

A conflict of interest is a set of circumstances that creates a risk that professional judgement or actions regarding a primary interest will be unduly influenced by a secondary interest.

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Module 3: Conflict of Interest

There are many types of conflict:

- **Research conflicts (personal or institutional)** – Dr. Smith serves on the Board of Directors of a company while participating in clinical research on the company's technology.
- **HSC conflicts (MDs)** – Dr. Doe publicly spoke against the CDC's 2016 opioid prescription guidelines stating the decision was based on weak science and were too restrictive while being part owner of an opioid manufacturer.
- **Purchasing conflicts** – Ms. Johnson participates in institutional purchasing decisions about products made by a company in which she holds stock.
- **Use of UF equipment, personnel, resources** – Dr. Williams has his grad student mow his lawn once a week over the summer during business hours as part of her grad work duties.

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Module 3: Conflict of Interest

There are many types of conflict (continued):

- **Academic conflicts** – Mr. Miller accepts a gift from a textbook vendor that has submitted a bid to supply his college.
- **Publishing conflicts** – a Publisher, The Journal of Good Reviews, hires the wife of an author as a reviewer of his submission.
- **Time conflicts** – Mrs. Wilson conducts meetings with a paying client of the consulting business she works on the side during the working hours of her primary job.

The Office of Research only concerns itself with conflicts that involve research.

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Module 3: Conflict of Interest

Which of the following situations are an example of a conflict of interest?

Associate Dean's wife has a catering company. You find that recently all of his department's catering events have been using this particular company. Is this a conflict?	Yes	No	This is a purchasing conflict. Assoc. Dean may be influencing decision for Dept. to use his wife's catering company. An exception would have to be granted to allow this to occur and that is unlikely since there are other catering companies that can be used.
PI has his own company but does all company administrative work in his UF office (phone calls, computer use, copier, scanner, stationary etc.) Is this a conflict?	Yes	No	This is a conflict. Use of UF equipment and resources for non-UF functions.
PI has dry cleaning business that demands most of his time and attention. He is rarely at work. Is this a conflict?	Yes	No	This is a time conflict. Doing outside work rather than doing one's primary job at UF.

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Module 3: Conflict of Interest

Conflict of Interest History

2006 - Dr. Alan Schatzberg, Chair of Psychiatry at Stanford University

- Dr. Schatzberg was the PI on a $600K National Institutes of Mental Health (NIMH) study to do research on abortion pill RU-486 to treat depression.
- Dr. Schatzberg founded an outside company, Corcept Therapeutics to develop (had patent) and market RU-486 for depression.
- He disclosed to Stanford an $100K investment in Corcept, but his actual investment was over $6 million.

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Module 3: Conflict of Interest

Conflict of Interest History

2008 - Dr. Joseph Biederman, Harvard child psychiatrist

- Dr. Biederman was a leading investigator in research that led to 40-fold increase in use of powerful anti-psychotic drugs for bipolar disorder in children.
- Dr. Biederman did not report he received $1.6 million in consulting fees from various pharmaceutical companies between 2000-2007 to the university.

2008 - Dr. Charles Nemeroff, Emory psychiatrist

- Dr. Nemeroff was the PI on a $3.9 million National Institutes of Health (NIH) grant to study 5 GlaxoSmithKline drugs for treatment of depression.
- Dr. Nemeroff did not report the $2.8 million he received in consulting fees from Glaxo between 2006-2007. He signed a contract with Emory saying he would accept no more than $10K from any one company.

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Module 3: Conflict of Interest

There are two sides to every COI story.

All doctors mentioned in this section are top-of-the-line in their fields. Many patient testimonials "I would not be here if not for Dr. xxx".

Let's say your mother has a fatal heart condition. There is only one expert who does a risky surgery that can potentially save her.

This Dr. honestly discloses he has equity in a company whose stent he uses for surgery.

Would you allow him to operate on your mother?

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Module 3: Conflict of Interest

COI Regulations

1995 – first COI regulations established by the Public Health Service (PHS) and the National Science Foundation (NSF).

2000s – USAMRMC/CDMRP funded studies have regulatory requirements to disclose and manage COI. The Congressionally Directed Medical Research Programs (CDMRP) and the United States Army Medical Research and Materiel Command (USAMRMC) is required with each grant application where UF will be the recipient or a sub-recipient of funding from the United States Army Medical Research and Materiel Command (USAMRMA) or from the Congressionally Directed Medical Research Program (CDMRP).

2009-2010 – regulations were reviewed by PHS and NSF.

Module 3: Conflict of Interest

Research Conflict at UF

- For PHS/NSF funded proposals, all PIs and key personnel must "disclose" their Financial Conflict of Interest (FCOI) at time of proposal submission.
  - If the FCOI is related to the research work, the COI has to be appropriately managed at UF and reported to PHS/NSF.
- Regulations promulgated to promote objectivity and remove bias in research due to increasing interactions of researchers with private industry, start-ups, etc.
- Regulations are designed to make sure that a PI has no outside financial interests related to his/her research project that would unduly influence design, conduct or reporting of the research.
- Thus all PIs and key personnel have to "disclose" their Significant Financial Interest (SFI) at time of proposal submission to PHS/NSF.

Module 3: Conflict of Interest

Read the following case studies and determine what you would do.

Dr. Stent, a professor of Cardiology, invents a new heart valve. UF patents this valve and licenses the technology to SuperCardio Inc. The company gives Dr. Stent and UF 20% of the stock each. It also asks Dr. Stent to serve on the scientific advisory board.

Is there a conflict? Is this allowed?

Click for Expert Answer

This is a potential conflict that must be disclosed and assessed.

More details about Dr. Stent and her work at UF will be needed for the PI, Chair, Dean and Office of Research to determine if it is allowable and how it will be managed.

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Module 3: Conflict of Interest

Read the following case studies and determine what you would do.

Dr. Stent, a professor of Cardiology, invents a new heart valve. UF patents this valve and licenses the technology to SuperCardio Inc. The company gives Dr. Stent and UF 20% of the stock each. It also asks Dr. Stent to serve on the scientific advisory board. ***SuperCardio Inc. also funds Dr. Stent's research at the university to develop the heart valve further.***

Is there a conflict? Is this allowed?

Click for Expert Answer

Yes, there is a conflict given the following: license, stock, company relationship, + research.

This must be assessed by the Office of Research and approved by the Vice President of Research and others. Cases like this one (technology is licensed by UF and company wants to fund research) are not always approved.

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Module 3: Conflict of Interest

Read the following case studies and determine what you would do.

Dr. Stent, a professor of Cardiology, invents a new heart valve. UF patents this valve and licenses the technology to SuperCardio Inc. The company gives Dr. Stent and UF 20% of the stock each. It also asks Dr. Stent to serve on the scientific advisory board. SuperCardio Inc. also funds Dr. Stent's research at the university to develop the heart valve further. ***SuperCardio Inc. gets an Investigation New Drug approval (IND) from the FDA and now want Dr. Stent to conduct a Phase 1 clinical trial at the university.***

Is there a conflict? Is this allowed?

Click for Expert Answer

Yes, since Dr. Stent owns stock in the company and has a role at the company.

This must be assessed by the Office of Research and approved by the Vice President of Research and others. Management plans can often be put into place to allow this level of conflict.

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Module 3: Conflict of Interest

Read the following case studies and determine what you would do.

Dr. Stent, a professor of cardiology, invents a new heart valve. UF patents this valve and SuperCardio Inc. licenses the technology. SuperCardio Inc. gives Dr. Stent and UF 20% of the stock each. It also asks Dr. Stent to serve on the scientific advisory board. SuperCardio Inc. also funds Dr. Stent's research at the university to develop the heart valve further. SuperCardio Inc. gets an IND from the FDA and now want Dr. Stent to conduct a Phase 1 clinical trial at the university. ***Dr. Stent also does other cardiovascular research on blood pressure mechanisms. This work is funded by the NIH.***

Is there a conflict? Is this allowed?

Click for Expert Answer

Relative to doing the NIH funded research on blood pressure, there is no conflict provided SuperCardio Inc. is not involved in this project. It is allowed for the NIH funded research. In summary, you can see how small details can affect if there is a conflict or not. Given the significance of conflicts and the complexity in assessing them, we highly recommend consulting the Office of Research Conflict of Interest program.

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Module 4: Export Controls

Export Controls are laws that control and restrict the release of:

- Equipment
- Chemical and biological materials
- Information
- Technical data
- Software
- Source code
- Services to foreign persons or countries
- Items or commodities

These laws are administered by the US Department of State (ITAR), the Department of Commerce (EAR), and the Office of Foreign Assets Control (OFAC).

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US Department of State (ITAR) - https://www.pmddtc.state.gov/ddtc_public

Department of Commerce (EAR) - https://www.bis.doc.gov/index.php/regulations/export-administration-regulations-ear

Office of Foreign Assets Control (OFAC) - https://www.treasury.gov/about/organizational-structure/offices/pages/office-of-foreign-assets-control.aspx

Module 4: Export Controls

Controlled Technologies

Items, information and software related to the following areas may be controlled.

Missiles, Rockets, Bombs	Materials Technology	Remote Sensing, Imaging, Reconnaissance
Navigation Systems	Space Related Technology	Astronomical Instrument Design
Circuits (MMIC, HEMT, Radiation Hardened)	Robotics	Autonomous Vehicles
Telecommunications / Networking	Sensors and Sensor Technology	Nuclear Technology
Optics	Laser and Directed Energy Systems	Information Security/Encryption
Infrared Technology	Armor	Radar

Items and information specifically listed on the United States Munitions List (USML) or the Commerce Control List (CCL) are always controlled.

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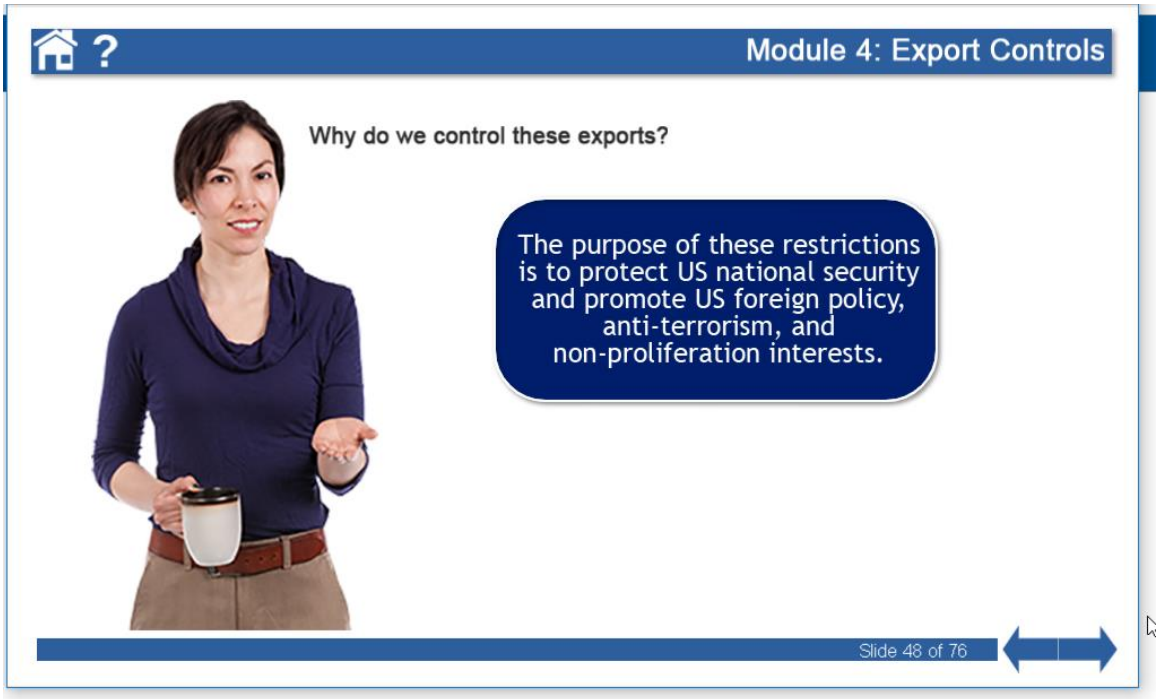
United States Munitions List (USML) - https://www.ecfr.gov/cgi-bin/text-idx?SID=86008bdffd1fb2e79cc5df41a180750a&node=22:1.0.1.13.58&rgn=div5

Commerce Control List (CCL) - https://www.bis.doc.gov/index.php/regulations/commerce-control-list-ccl



Module 4: Export Controls

Exports are typically thought to go "outside "of the U.S. However, these laws also affect transactions that occur "inside" the US. These are called Deemed Exports.

A deemed export is the release of any controlled item or technology within the confines of the United States to a foreign national.

That transaction is "deemed" to be an export and therefore subject to certain U.S. Government export control regulations. The export is considered to be released to the individual's country of citizenshi

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Module 4: Export Controls

Deemed exports are potential risks for the university.

Deemed exports can occur through visual inspection, fax, email, verbal conversations, or lab tours of controlled space.

Penalties for violation(s) of export control regulations and laws can be assessed.

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Module 4: Export Controls

Penalties

Potential violations for export controls can result in penalties and fines of large amounts or even imprisonment. Penalties can be assessed to the individual, UF, or both.

Potential Violations

Potential violations should be immediately reported to DRCGS or through the UF compliance hotline at (877) 556-5356. DRCGS is here to assist with review of potential violations and solving issues going forward.

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Module 4: Export Controls

Comprehensively Embargoed Countries

Comprehensively sanctioned countries, including the following, and require additional measures to be in place prior to proceeding with any transaction.

- Sudan
- Syria
- Cuba
- North Korea
- Iran
- Crimea region of the Ukraine

If you see any of these countries mentioned anywhere in a proposal or award, STOP immediately and call the Division of Research Compliance and Global Support (DRCGS).

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Module 4: Export Controls

Comprehensively Embargoed Countries

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Module 4: Export Controls

While Cuba is comprehensively sanctioned, some travel and transactions to Cuba are authorized via the regulations. These authorizations are called general licenses.

Most UF personnel can travel to Cuba for educational travel, professional research and professional meetings. It is important to note that while travel is authorized, the export and import of physical items may still require additional steps, especially when for use on UF-business purposes.

When contemplating travel or activities with Cuba, it is best to reach out to DRCGS at an early stage. In addition, registration is required with the UF International Center (UFIC).

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Module 4: Export Controls

The Review Process. Click each button to learn more.

What
Is the item or information on federal lists?

What is being exported? Is it on the USML or CCL list?
If so, a license may be required for export.
If you are unsure if the item is designated as controlled, reach out to DRCGS.

Where
Can this item or information be shared with this location?

Where is the item or information going? Is the location an embargoed or high-risk country?
If so, a license may be required warranting additional review.

Who
Is the recipient a denied entity or person?

Who is receiving the item or information? Is this person on the Restricted Parties List?
If so, consult DRCGS immediately prior to proceeding.

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Module 4: Export Controls

Restricted Party Screening

The US Government has multiple lists of individuals, organizations and companies that have been identified as parties the US cannot engage in certain activities with, including export.

UF uses the Visual Compliance tool for Restricted Party Screening. Visual Compliance is an internet-based software which performs screening of all government lists in one process.

All international partners and entities that faculty are engaging with or traveling to should be screened. Contact the DRCGS for assistance with this.

NOTE: With few exceptions, the University of Florida does not host visitors, enter into contracts or other agreements, do business, or engage in any activity with entities listed on the on a US Government restricted party list.

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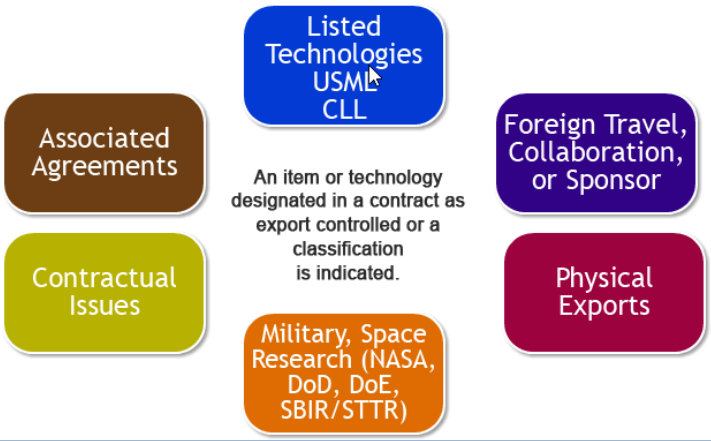
Module 4: Export Controls

Use this red flags list to review the research you administer when checking for export control restrictions. Click each oval to learn more.



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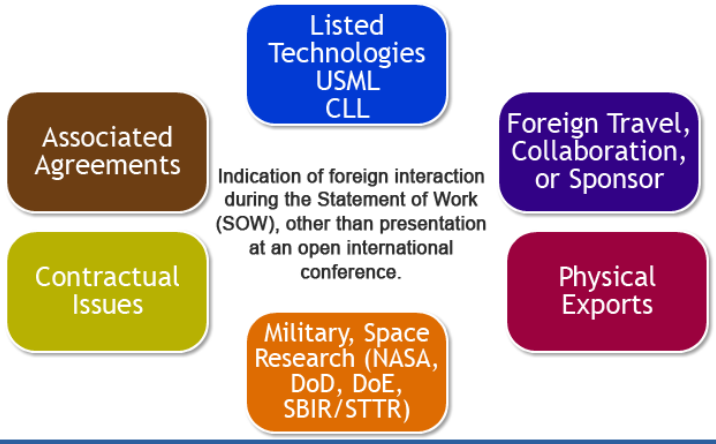
Module 4: Export Controls

Use this red flags list to review the research you administer when checking for export control restrictions. Click each oval to learn more.



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Module 4: Export Controls

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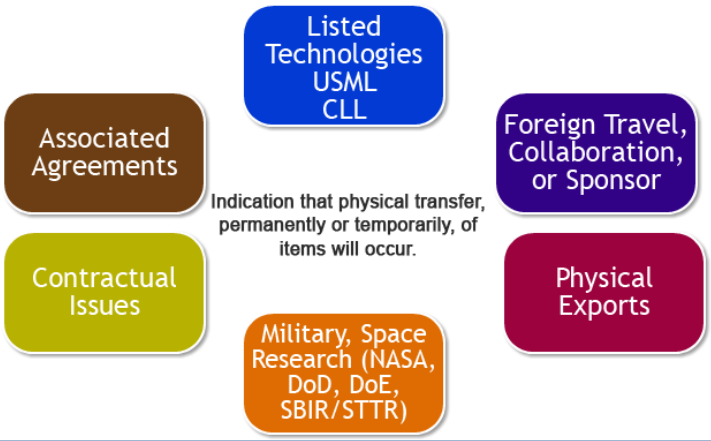

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Module 4: Export Controls

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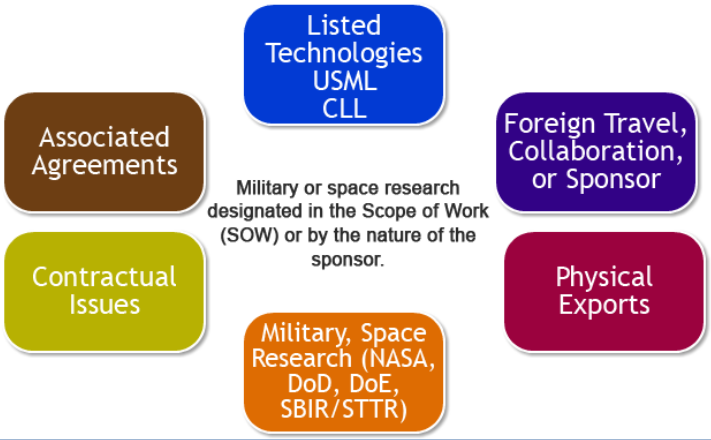

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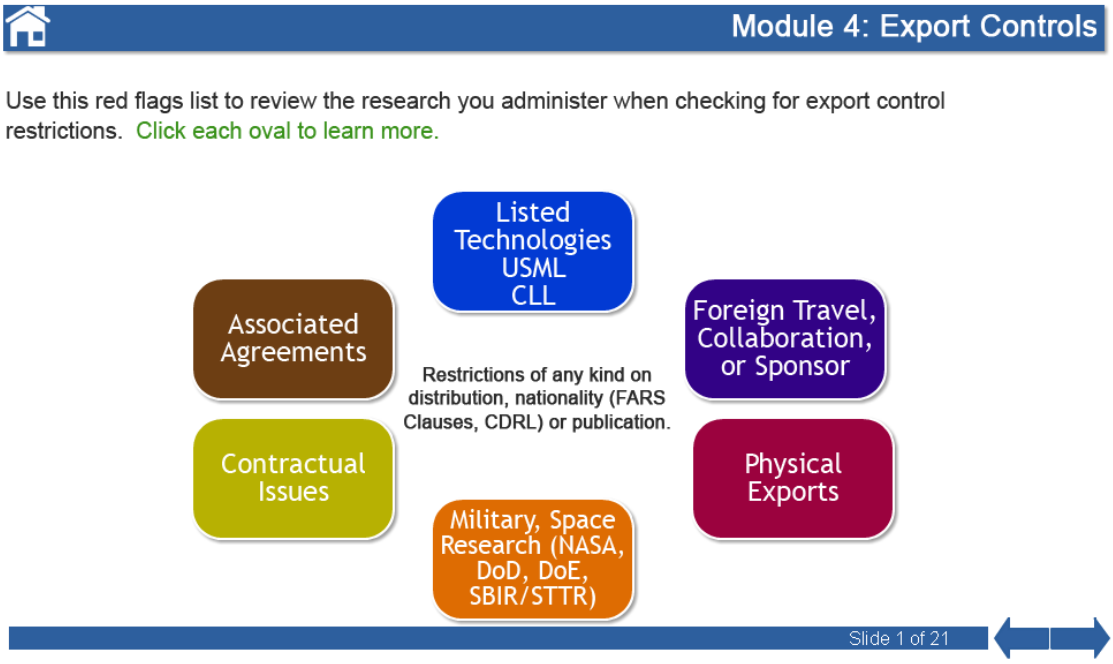

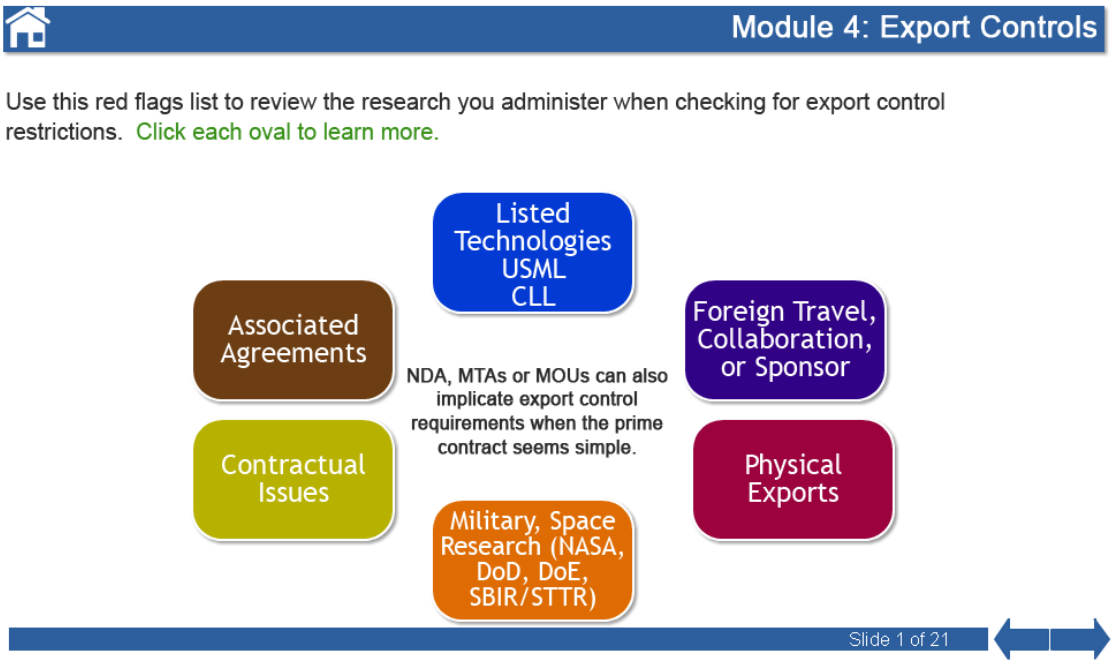

Module 4: Export Controls

Exclusions

There are several common exclusions which remove university activities from the application of export control restrictions. As long as the below conditions are met in full, the results of the research are not subject to the ITAR or EAR.

Fundamental Research = basic or applied research conducted at an accredited institution of higher learning in the US where results are ordinarily published and shared broadly within the scientific community.

Education Information = Information concerning general scientific, mathematic or engineering principles commonly taught in schools, colleges or universities.

Public Domain = Information which is published and generally accessible or available to the public and thus not considered controlled under the ITAR or the EAR.

If/when in doubt, always contact the DRCGS.

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Module 4: Export Controls

DRCGS Contact Information

For Export Control, Global Support or General Compliance
Phone: 352-392-9174
Email: exportcontrol@research.ufl.edu
Website: https://research.ufl.edu/compliance.html
Address: 219 Grinter Hall

UF Compliance Hotline at (877) 556-5356 or by completing the online form at:
https://www.reportlineweb.com/Welcome.aspx?Client=UF

Additional Resources:
Export Control Manual

Export Control training is available through by logging into my.ufl.edu. Navigate through Main Menu > Self-Service > CITI Training. For detailed information, contact DRCGS.

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Module 4: Export Controls

How UFIRST Helps

UFIRST

For sponsored research, UFIRST facilitates helping you identify and manage all of these areas:

1. DSP reviews for PI indication of humans or animals and ensures a protocol that references the funding is in place prior to set up.
2. UFIRST asks all PI's at time of award if there are any biologics and automatically emails EH&S to ensure that the use is registered.
3. For FCOI when the sponsor follows PHS, NSF or CDMRP policy, DSP requires each key person to submit an SFI disclosure prior to submitting the proposal. For non-PHS/NSF/CDMRP proposals, UFIRST requires each key person to verify any interests at time of agreement negotiation or award setup.

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Module 4: Export Controls

How UFIRST Helps

UFIRST

For sponsored research, UFIRST facilitates helping you identify and manage all of these areas:

4. For Export Control, UFIRST asks the PI a series of questions about the location and technical nature of the work and DSP reviews the award for conditions that take UF out of the fundamental research exemption.

Again, remember!

Remaining compliant takes effort, desire, and information. Compliance doesn't happen by accident and that's why your PIs and colleagues need your help.

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