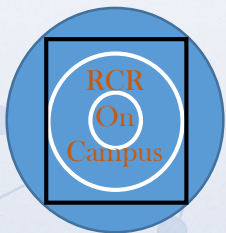


RCR Summer Seminar Series

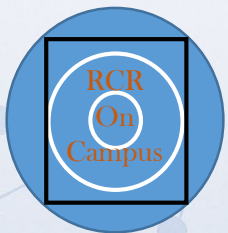
Special Topic:
Material Transfer Agreements &
International Shipping

Carter Post & William Bucha
UF Research Integrity, Security & Compliance

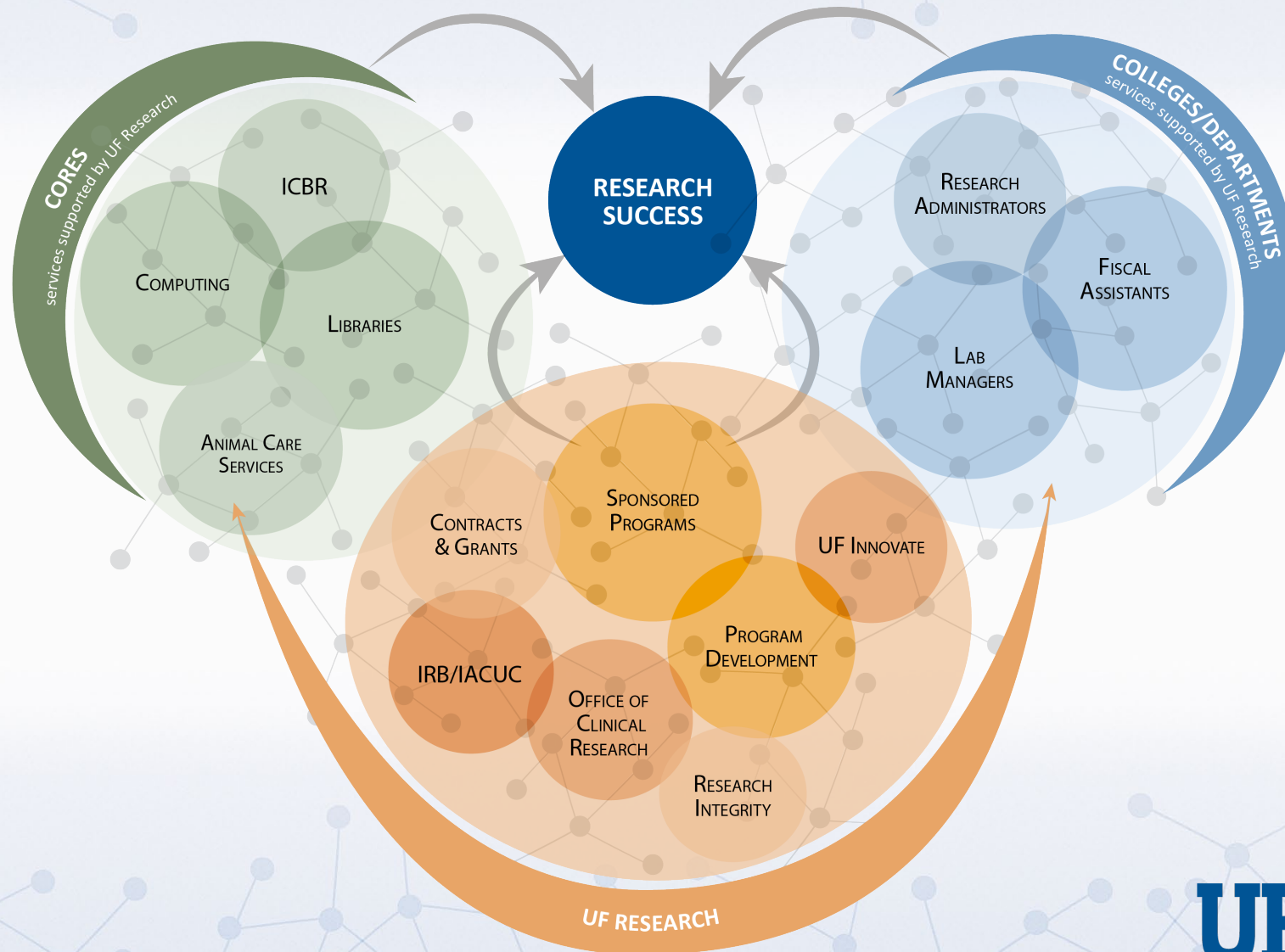


Reminders

- You must log in with UFL email in order to receive certificate credit
- Please take the survey after the class—we value your feedback
- In order to allow for free flow of ideas and questions, we will **not** record the session
- Slides and other materials will be sent to attendees after the class



UF Research Enterprise



Introduction

Marsha Pesch

Associate Director
Export Control Officer
UF Research Integrity

Carter Post

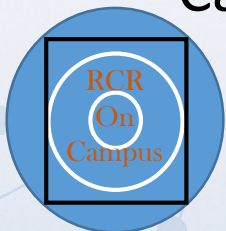
Export Compliance Specialist, III
UF Research Integrity

William E. Bucha, Jr., JD

Export Compliance Specialist, III
UF Research Integrity

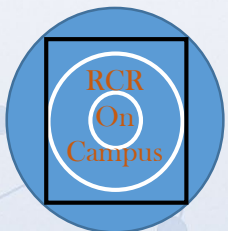


Call UF RISC at **352-392-9174** or email us at exportcontrol@research.ufl.edu



Agenda

- Export Controls for Researchers in Brief
- Export Control Requirements for International Shipments
- Breakout Rooms: Shipping Scenarios
- Material Transfer Agreements (MTAs)
- International Shipments of Biological Materials & Animals
- Additional Resources
- Q&A



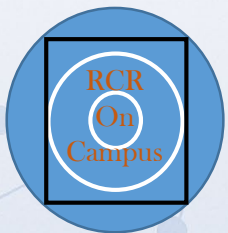
Who Regulates Export Controls?

- **U.S. Department of Commerce, Bureau of Industry and Security (BIS)**
 - **Export Administration Regulations (EAR)** Controls commercial, dual-use, and less sensitive military items
 - Controlled items are either described on the **Commerce Control List (CCL)** with an Export Control Classification Number (ECCN) or designated “EAR99”
- **U.S. Department of State, Directorate of Defense Trade Controls (DDTC)**
 - **International Traffic in Arms Regulations (ITAR)** Controls military items
 - Controlled items are described on the **U.S. Munitions List (USML)**
- **U.S. Department of the Treasury, Office of Foreign Assets Control (OFAC)**
 - Administers and enforces **economic and trade sanctions**
 - Comprehensively Sanctioned: **Cuba, Iran, North Korea, Syria, Crimea Region of the Ukraine**
- Note: Other agencies also have a role in limited circumstances, *e.g.*, NRC, NOA, DOE.



What is an International Shipment?

- The transfer of equipment, materials, or technology out of the U.S.
 - Examples
 - Shipping items purchased by UF funds to an international destination (i.e. via FedEx or UPS)
 - “Hand-carrying” a UF-owned laptop on a flight to an international destination
 - Requesting a Material Transfer Agreement with the UF OTL to ship a licensed material to an international collaborator
- *Before shipping internationally, please contact UF RISC for an Export Control review. Some shipments may require an export license or registration.*



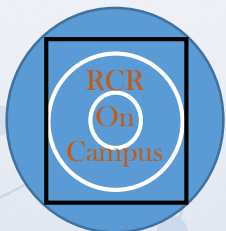
Shipping/Hand-Carry Checklist

- **What is being shipped?**

- UF-owned capital asset or attractive property with a UF Decal # (i.e. a UF owned laptop).
 - Foreign Travel Request in the myAssets portal, which will notify UF RISC for a review.
- Commercial item purchased from a manufacturer or vendor.
 - Contact UF RISC for classification and export review. Please provide as much detail as possible (i.e. Manufacturer, Model/Part #, Purchase Price, etc.)?
- Custom item designed and built by UF researchers.
 - Contact UF RISC for classification and export review.

- **Where is the final international destination?**

- China, Crimea Region of Ukraine, Cuba, Iran, North Korea, Russia, Syria, Venezuela are countries of concern, which require extensive review from UF RISC. Please contact our office prior to any engagement with these countries.



Shipping/Hand-Carry Checklist continued

- **Who is receiving the shipment?**

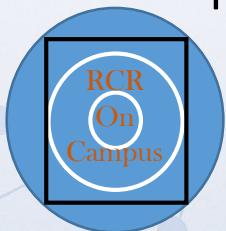
- Who is the receiving party and are they the intended user of the shipped item.
 - Restricted Party Screening – Visual Compliance.
 - Individual receiving the shipment
 - Associated Entity
 - End User of item
 - UF Travel Hand-Carry – UF traveler maintaining “effective control” of item

- **Why is the item being shipped?**

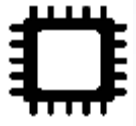
- What is the end use of the item and is the end use permissible without a License
 - Fundamental Research and Education. Fundamental research exemption does not include physical items.
 - Military, Government support, other prohibited uses

- **How long will the item remain abroad?**

- More or less than 364 days



High Risk Physical Items and Technologies



- Electronics



- Computers



- UAVs



- Energy Systems



- Software



- Optics



- Controlled Biologicals



- Marine



- Materials



- Radar



Restricted Party Screening

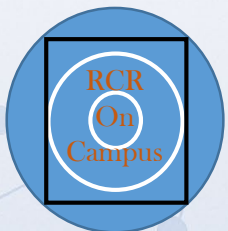
- **Restricted Party Lists**

- Entity List (BIS, Dept. of Commerce)
- Unverified List (BIS, Dept. of Commerce)
- Arms Embargoes List (Dept. of State)
- Specially Designated Nationals List (OFAC, Dept. of Treasury)

- **Visual Compliance Screening**

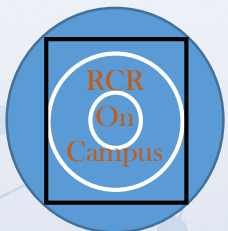
- Restricted Party Screening
- All U.S. Restricted Lists
- International Authorities Consulted

- *With few exceptions, the University of Florida will not host visitors, enter into contracts or other agreements, do business, or engage in any activity with entities listed on a U.S. government restricted party lists.*



Other Shipping Considerations

- **Electronic Export Information (EEI) Filing**
 - Automated Export System (AES)
 - Census Bureau
 - Greater than 364 days
 - License Required/Received
 - Value over \$2,500
 - Countries of concern
 - Facilitated by UF RISC or Designated Shipping Company
- **International Import Regulations**
 - ATA Carnet
 - Carnets facilitate temporary imports into foreign countries and re-importation into the U.S. By presenting an ATA Carnet document to foreign customs, you pass duty free and import tax free into a carnet country for up to one year. ATA Carnets also serve as the U.S. Certificate of Registration of goods (CBP 4455) upon re-importation.
 - College/Department Responsibility



Shipping/Hand-Carry Best Practices



Ask questions before you ship

Remember that every export is also an import at the international destination



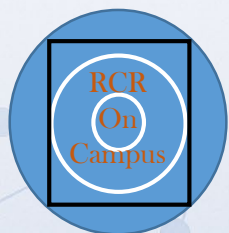
Retain records of rationale for shipping decisions

Be aware of red flags, such as shipping items to unknown persons that don't have a need for that item



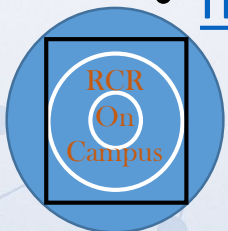
Use online screening tools: UF subscribes to Visual Compliance

Be aware that compliance related to shipping hazardous materials & dangerous goods is separate from issues related to export controls



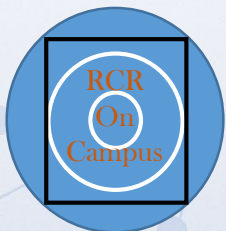
UF Shipping/Hand-Carry Reminders

- Contact UF RISC (exportcontrol@research.ufl.edu) prior to any international shipment. Please provide sufficient time and as much information as possible for an export control review.
- Travel Authorizations for UF travelers
 - my.UFL.edu
- UFIC Registration for all UF persons traveling abroad on UF business
 - <https://internationalcenter.ufl.edu/travel/online-travel-registration>
- Asset Management Registration for foreign travel and shipping UF-owned items
 - <https://myassets.fa.ufl.edu/ext/#/fta>



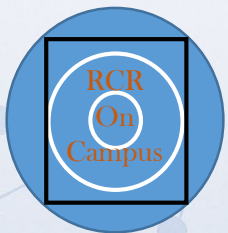
Breakout Room Scenarios

- For each shipping scenario, please discuss:
 - What necessary information is present?
 - What additional information is needed?
 - What are the next steps needed prior to shipping?
 - What UF authorizations and registrations need to be completed?
 - Which foreign entities need to be screened?
 - What needs to be supplied to UF RISC for an export control review?



Scenario #1

UF Professor, Dr. Tebow, is planning traveling to London for one week to conduct research with his collaborator, Dr. Leak, at the University of London. Dr. Tebow is bringing his UF-owned laptop (UF Decal #000000154114) on the trip, which has a value of \$1,000 and will remain in his “effective control” at all times.



Scenario #1

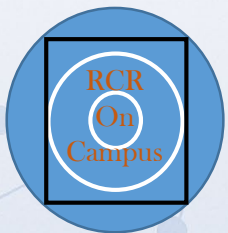
UF Professor, Dr. Tebow, is planning traveling to London for one week to conduct research with his collaborator, Dr. Leak, at the University of London. Dr. Tebow is bringing his UF-owned laptop (UF Decal #000000154114) on the trip, which has a value of \$1,000 and will remain in his “effective control” at all times.

Travel Authorization, UFIC Registration, Foreign Travel Request in myAssets Portal, conduct Restricted Party Screening of Dr. Leak and University of London. UF RISC will review FTR in myAssets Portal.



Scenario #2

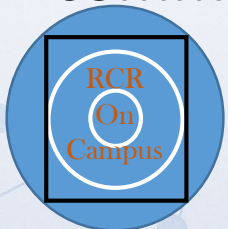
UF Professor, Dr. Wambach, is planning to ship lab supplies to her collaborator Dr. Barnhill, who is running a research lab at the University of Sao Paulo in Brazil. Dr. Wambach purchased \$5,000 worth of laboratory supplies and is currently boxing them up in her office in Turlington. To help in the shipping process, Dr. Wambach created a spreadsheet detailing each lab supply's manufacturer, part number, brief description, price and quantity.



Scenario #2

UF Professor, Dr. Wambach, is planning to ship lab supplies to her collaborator Dr. Barnhill, who is running a research lab at the University of Sao Paulo in Brazil. Dr. Wambach purchased \$5,000 worth of laboratory supplies and is currently boxing them up in her office in Turlington. To help in the shipping process, Dr. Wambach created a spreadsheet detailing each lab supply's manufacturer, part number, brief description, price and quantity.

Restricted Party Screening of Dr. Barnhill and University of Sao Paulo, send spreadsheet of lab supply to UF RISC, ASAP. UF RISC will conduct export control review, determine if a license or an EEI filing is necessary, and communicate results for review to Dr. Wambach and staff.



Scenario #3

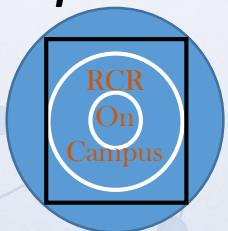
UF Professor, Dr. McMurtry, is planning to take her custom-built Unmanned Ariel Vehicle (UAV) on an extended trip to Russia to perform a field research with collaborators at the University of Moscow. The UAV contains components that require a license to export to Russia.



Scenario #3

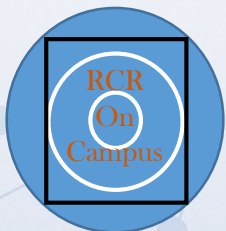
UF Professor, Dr. McMurtry, is planning to take her custom-built Unmanned Ariel Vehicle (UAV) on an extended trip to Russia to perform a field research with collaborators at the University of Moscow. The UAV contains components that require a license to export to Russia.

Travel Authorization, UFIC registration, Restricted Party Screening of collaborators and University of Moscow. Contact UF RISC ASAP for export control review. Since Russia is a Country of Concern and the UAV is a high risk, custom-built item, the review may take an extended period of time.



Material Transfer Agreements (MTAs)

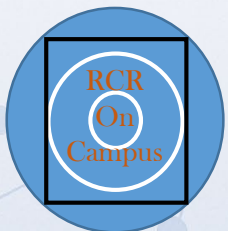
- MTAs document the transfer of material between the university and third parties and specify the rights, obligations, and restrictions concerning:
 - Ownership and Intellectual Property
 - Publication
 - Distribution and Commercialization
 - Permitted Uses
 - Liability, and
 - Regulatory Compliance/Commitments
- **Contact: Penelope M. Gianelli, J.D.**, MTA Coordinator, UF Innovate
 - **Email:** penelopegianelli@ufl.edu
 - **Phone:** 352-294-0990



Do I Need An MTA?

You are **required to use a Material Transfer Agreement (MTA)** that meets the legal and policy requirements of UF if:

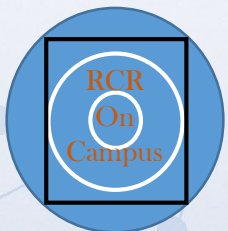
- You are *sending or receiving* materials, **and**
- These materials are *not* already covered by another agreement.



Do I Need An MTA?

Not required for sending out de-identified human sample(s) for research, if:

1. Sample(s) is not apart of an existing or planned invention disclosure to UF Innovate; **OR**
2. Sample(s) is not protected under an issued or pending patent application; **OR**
3. Sample(s) has not been licensed to an entity outside UF; **OR**
4. Sample(s) is not part of a contract with distribution restrictions.



MTA Export Review

- **Recipient/Sender Information**

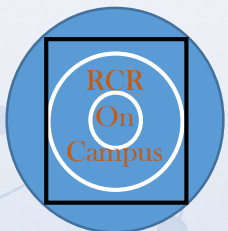
- Entity Legal Name (e.g. “Kings College London,” “Keio University,” “Love A Child,” etc.).
- Address & Location.
- Authorized Signatory Official.
- Recipient Principal Investigator.
- Contact Person, if different than PI.

- **Material Description**

- Should include a brief description, or specific title of what is being sent:
 - e.g. *Modified AAV plasmids for the purpose of treating Parkinson’s.*
- Should also include a specific citation for any material that is contained in a research publication.
- **NOTE: If the material includes any pathogen or infectious disease, this should be indicated in the material description.**

- **Recipient’s Intended Use Of Material**

- The purpose of the material should indicate the following:
 - The intended use or research involving the material – this can be an abstract or similar content.
 - Indication on application in human studies.
 - Indication on use in commercially funded research.
 - Duration of use for the material.



Shipping Biological Material – Export Control Concerns



<https://www.ehs.ufl.edu/programs/bio/>

- Certain biological materials that are listed on either the United States Munitions List (USML) or Commerce Control List (CCL) require a license from the appropriate U.S. governing agency **prior to leaving the United States.**
- **Examples of biological materials listed on the CCL:** Cholera toxin, Ebola virus, E. coli (EHEC), Pseudorabies virus, Salmonella typhi, and Vibrio cholera.¹
- Genetically Modified Organisms (GMOs) that contain both export controlled material and non-export controlled material can still be listed on the CCL and will still require a license.
 - **Example:**
 - Foot and mouth disease virus (ECCN 1C351) combined **with**
 - Human Adenovirus 5 (EAR99/no license required) →
 - Genetically modified human adenovirus 5 – FMDV (ECCN 1C353; 1C991 once formulated into a vaccine).



1. https://www.ehs.ufl.edu/programs/bio/shipping/export_control/

Shipping Biological Material – Case Study: Princeton Samples (2021)



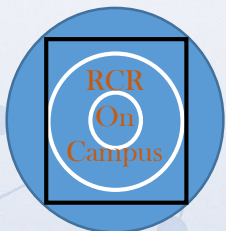
<https://www.ehs.ufl.edu/programs/bio/>

• WHAT HAPPENED?

- February 1, 2021, BIS announced a settlement with Princeton University over alleged exported animal pathogens and genetic elements of animal pathogens without required export licenses to researchers in the U.K., Canada, Australia, Europe, South Korea, India, Singapore, and China.¹
 - The items were classified under ECCN 1C351, 1C352 or 1C353, controlled for Chemical and Biological Weapons reasons, and valued in total at approximately \$27,000.^{1,2}

• WHAT WAS THE RESULT?

- BIS imposed a penalty of \$54,000,
- BIS mandated two audits of Princeton's export compliance program, and
- BIS further mandated submission to BIS of two reports detailing enhancements to Princeton's export control processes.²



1. https://www.wiggin.com/wp-content/uploads/2021/02/WD21-Advisory-Biologics-Researchers-and-Suppliers-Beware_v1.pdf
2. <https://efoia.bis.doc.gov/index.php/documents/export-violations/export-violations-2021/1287-e2642/file>

Shipping Biological Material – Environmental Health & Safety (EH&S) Concerns



<https://www.ehs.ufl.edu/programs/bio/>

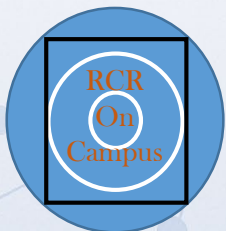
For shipping purposes, many biological materials fall into the category of “dangerous goods”

- Articles or substances which are capable of posing a risk to health, safety, property or the environment & which are shown in the list of dangerous goods in the Regulations or which are classified according to these Regulations. See *49 CFR Parts 100-185 & IATA 1.0*.
- **Examples:** Biological Toxins, Infectious Substances, Diagnostic Specimens, Biomedical Waste, Cultures, and Genetically Modified Organisms.

In order to ship biological materials, it is required that you must first have a Shipping and Transport of Biological Materials Training Certificate from UF Bio Safety Office in Environmental Health & Safety.

- Training is valid for 2 years and is a federal requirement.
- To Register: Email bsa@ehs.ufl.edu and provide your First Name, Last Name, and UFID number.
- In addition, safe transport of items within facilities and around campus is also required. These topics are covered in the “Shipping and Transport of Biological Materials” training.

****Note:** You must contact UF Biological Safety prior to any shipping of material under Category A¹. For more information, please contact EH&S at bsa@ehs.ufl.edu.



1. <https://www.iata.org/contentassets/b08040a138dc4442a4f066e6fb99fe2a/dgr-62-en-3.6.2.pdf>

Shipping Biological Material – Animal Care Services (ACS)



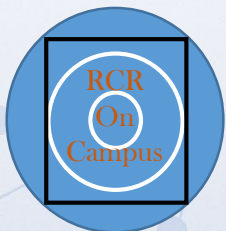
<https://www.ehs.ufl.edu/programs/bio/>

- **Before any animals can be exported to another institution (e.g. rodents), ACS will provide the following to the Receiving Institution for review:**
 - animal information,
 - facility information, and
 - the last 12 months of health reports
- **Once this information has been approved by the Receiving Institution, shipment will be coordinated by ACS and the Receiving Institution.**
- **The ACS Import/Export Coordinator can be reached at ACS-ImportExport@acs.ufl.edu or 352-273-8322.**



Additional Resources

- UF RISC Website: <https://research.ufl.edu/compliance.html>
- UF International Center - Travel: <https://internationalcenter.ufl.edu/travel/>
- UF Asset Management – Foreign Travel or Shipment Request: <https://www.fa.ufl.edu/directive-categories/foreign-travel-requests-and-off-site-certifications/>
- UF Innovate – MTAs: <https://innovate.research.ufl.edu/tech-licensing/innovators/mta/>
- UF EH&S – Shipping and Transport of Biologicals: <https://www.ehs.ufl.edu/programs/bio/shipping/>



Q&A



Thank you!

- Please take the survey at:

https://ufl.qualtrics.com/jfe/form/SV_1WVLQUcrykr7YFM

