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Research Compliance Newsletter Fall 2022

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Research Compliance Newsletter

Fall 2022

From the [Office of Research Compliance](#),
part of the [Office of the Vice President for Research and Dean of the Graduate School](#)

In this issue:

- Spotlight: International Research
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Spotlight: International Research

Research in all fields can often have international components. Examples could include international travel or field work, importing or exporting equipment or samples, collaborating with researchers from other countries, hosting visiting scholars, and more.

When there is any international element in research, it is critical to be aware that extra due diligence is required so you can initiate the appropriate reviews *early* to avoid delays to your project or activity, or noncompliance, which can carry serious consequences.

International Human Subjects Research

ORC has recently published [new guidance on international human subjects research](#). When conducting research with



participants outside the US, additional review and documentation will be necessary, if required, from the international site and country and the UMaine Office of Research Compliance and IRB. The principal investigator (PI) should start this process *as soon as possible*.

International Travel

In addition to abiding by the Office of the Vice President for Research and Dean of the Graduate School's [Research Travel Guidelines & Procedures](#) and [UMS travel guidelines](#), travelers are required to coordinate with the following offices, as applicable, to ensure appropriate travel and fieldwork procedures are followed and any necessary approvals are in place *prior* to international travel:

- Working with [UMS Safety Management](#) to develop and implement a Fieldwork Safety Plan. Please see: [Fieldwork Safety Training Guide](#) (requires @maine.edu account to view).
- Working with [UMS Risk Management](#) to ensure the appropriate insurance coverage is in place.
- Working with [export compliance staff](#) in the [Office of Research Compliance](#) to determine if any export licenses, or documented use of an exception, is required for the export (even temporary) of University equipment, computers, or supplies.
 - You may receive an inquiry from ORC after your international travel has been entered into Concur, but if you know in advance that you will be exporting materials (particularly a large number of items), please request a review by emailing us at um.export@maine.edu.

Export Control

U.S. export control regulations govern what research instruments, materials, software and technology that we, as a U.S. institution, can export (transfer) out of the country by any means, and what sensitive items and technology we can share with foreign nationals (e.g., individuals who are not U.S. citizens, do not have a Green Card, or otherwise do not fall into a federal protected category) who are studying, researching, working in, or visiting our facilities. These regulations also inform what research and business partners we engage with, such that we must avoid U.S. government-restricted or prohibited entities (entities of concern from a national security, export control, or embargoed-country perspective).

Export controls can impact University activities on-campus and abroad, including:

- International travel, fieldwork & conferences
- International shipping
- International financial transactions
- Hosting a foreign visitor/scholar
- Foreign national participation in research activities
- International collaboration (*both informal and those with agreements such as MOU and research agreements*)
- Using 3rd party proprietary information/restricted materials
- Teaching courses abroad or online

For more information, visit Export Compliance on our website. Please request reviews for any of the above activities by emailing us at um.export@maine.edu.

Other questions about international research?

If you have any questions about international research, please [reach out to the Office of Research Compliance](#) and we can help find the best path towards compliance.

New Information Sheets about Research Compliance



ORC has recently published a brand new [Introduction to UMaine Research Compliance Info Sheet \(PDF\)](#) to help guide faculty and staff who are new to UMaine or new to research compliance.

For those who are already more familiar with UMaine and ORC, we also offer the (recently redesigned) [Research Compliance Reference Sheet \(PDF\)](#) as a convenient overview and quick reference guide to the compliance areas covered by ORC.

We invite you to please review these two newly updated resources and share them widely with colleagues!

Training Requirements for PIs and Personnel

Staying up to date on training is a key element of research compliance and safety. **Principal Investigators (PIs) have the critical responsibility to ensure that they and all of their personnel (including undergraduate students) complete and remain up to date on all required training.** PIs must also maintain documentation of training completions for themselves and personnel (such as training completion certificates).

Financial Conflict of Interest (FCOI)

*All University employees and students who serve as **investigators** on proposals submitted to external sponsors are required to complete [Financial Conflict of Interest training on CITI](#) every four years.*

The [definition of "investigator"](#) covers not only PIs, but also potentially post docs, staff, grad students, or even undergraduate students, etc., depending on their role(s) in the research. PIs should carefully review this and ensure the necessary personnel complete the required FCOI training.

Responsible Conduct of Research (RCR)

*Undergraduate students, graduate students, postdoctoral researchers, and (in some cases) faculty and all staff participating in **NSF, NIH, or USDA-NIFA sponsored research** are required to complete *Responsible Conduct of Research (RCR)* training every four years.*

RCR training requirements vary by sponsor, and format of the required RCR training depends on the participant (whether faculty/staff, graduate student, undergraduate student); see [RCR Training Requirements](#) for details. PIs are responsible for ensuring that appropriate training occurs early in the first year each subject person receives NSF, NIH, or USDA-NIFA support, and for promptly submitting certification of that training to ORA.

Subject Area Training



Depending on the area of research, certain online CITI trainings are **required for researchers**, and many must be renewed periodically (typically every 4 years).

Researchers are only required to take the training(s) for their applicable area(s) of research compliance. The pages below offer guidance on who is required to take each training.

- [Animal Care Training](#)
- [Biosafety Training](#)
- [Export Control Training](#)
- [Human Subjects Training](#)

We encourage researchers to review the [Instructions for CITI Training \(PDF\)](#) for their specific research areas, and log into their individual CITI account to see when previously completed trainings must be renewed.

FYI for Human Subjects Researchers about Proposed FDA Changes: [FDA Takes Steps to Further Harmonize Clinical Research Regulations with HHS Common Rule](#)

New & Updated Compliance Resources

The [ORC website](#) is frequently updated with resources and information to help make gaining and maintaining compliance as easy as possible. We invite you to explore some of the new and recently updated resources that have been added to our site.

- [Research Compliance Reference Sheet \(PDF\)](#) (updated)
- [Introduction to UMaine Research Compliance Info Sheet \(PDF\)](#)

Biosafety

- [IBC Registration Form \(Word\)](#) (updated)

Export Controls

- [U.S. Sanctions and Export Controls on Russia](#)

Human Subjects

- [Guidance for Using Social Media for Research Purposes](#)
- [Informed Consent Guidance](#)
- [Informed Consent Checklist \(PDF\)](#) (updated)
- [International Human Subjects Guidance](#)
- [Online Survey Research Guidance \(PDF\)](#)
- [Sample Consent Anonymous Survey \(Word\)](#) (updated)

Research Security

- [Research Security & Foreign Influence](#) (updated)
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Research Compliance in the News

- [NIH Fails to Enforce Rules for Reporting Clinical Trial Results](#) - The Scientist, August 18, 2022
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- [Mexico Scientist Gets 4 Years for Spying for Russia in Miami](#) - AP, June 22, 2022
- [Feds Sue Operator of Dog Breeding Facility, Seize Beagles](#) - AP, May 20, 2022
- [China-US Climate Collaboration Ended Due to Security Concerns](#) - The Scientist, April 12, 2022
- [A Jury Finds a Kansas Scholar Guilty of Fraud and Hiding Ties to China](#) - NPR, April 7, 2022
- [Amid the Terror of War, Efforts to Keep Science Alive in Ukraine](#) - The Scientist, March 28, 2022
- [Universities Must Reject Fossil Fuel Cash for Climate Research, Say Academics](#) - The Guardian, March 21, 2022
- [Oust the Mouse: A Plan to Reduce Mammal Use in Drug Development](#) - The Scientist, March 15, 2022
- [UK Universities Brace for Impact of Sanctions Against Russia](#) - The Guardian, March 4, 2022
- [CRISPR Patent Ruling Favors Broad Institute](#) - The Scientist, March 1, 2022
- [The NIH is 'Largely Finished' Moving its Former Research Chimps to a Sanctuary](#) - NPR, January 27, 2022

ORC Website

Research Compliance Reference Sheet (PDF)

Joining or Leaving UMaine?

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