RG:13

Sponsored International Research Collaboration

I. PURPOSE

Lincoln Memorial University places high importance on fostering global ties and believes that the free interchange of ideas among researchers and students worldwide is essential to preparing the University's students for an interconnected world. However, to guarantee federal regulation compliance, protect the intellectual property of University employees and students, and ease administrative obligations that may result from sponsored foreign cooperation, proper identification and approval of sponsored international research collaboration is required.

II. POLICY STATEMENT

To meet compliance with federal, non-federal, and international regulations and expectations, Lincoln Memorial University will compile and review information about its sponsored international research activities to provide effective and compliant administration.

Training

Individuals who desire to participate in sponsored international research must complete CITI training modules "Undue Foreign Influence: Risks and Mitigations" and "Export Compliance."

Human/Animal Participants

Conducting research involving human and animal participants in foreign countries requires adhering to ethical standards that are both U.S.-based (IRB, IACUC, HIPPA, Code of Federal Regulations) and internationally recognized (Declaration of Helsinki, International Conference on Harmonization – Good Clinical Practice E6). Additionally, special attention may need to be given to the rights and well-being of international participants within diverse cultural environments and local regulatory frameworks. The entity with the stricter standard must be adhered to for research to occur. The PI's IRB/ICAUC application MUST note if research and/or research subjects will be outside of the United States.

Export Control

PIs/PDs who wish to engage in sponsored international collaborations should be familiar with export control regulations. Exports can apply to technology, information, instruction, software, bioagents, and toxins among other goods. While some research projects fall under public domain, others may necessitate licenses. The PI/PD must contact ORGSP as soon as it is known that any exports will be exchanged as a part of the international research agreement so that it can be checked against the export determination matrix by the Export Control Subcommittee.

Biological/Chemical Transfers

The exchange of biological and chemical transfers across international lines includes export law and potentially uniform biological material transfer agreements. The process to initiate these agreements should include research administration from the ORGSP and the collaborating institution's research administrators.

Data Management

Some federal funding agencies require that data management plans be submitted with collaborative projects. So that PI's/PD's sponsored international project meets both funding requirements and federal and international law, the PI/PD must contact the ORGSP when initiating a data management plan and/or Data Use Agreement.

Foreign Exchange Rates

The PI/PD must consult the ORGSP as they formulate project budgets – the office will assist in identifying exchange rates and establishing payment timelines and expectations. All award agreements must state the award amount in the United States Dollar (USD).

Contract/Agreement Language

Before a project or submission with an international partner begins, the ORGSP and LMU Office of the General Counsel must review any document and ensure that the agreement is issued in English. Final authorization of any foreign agreement is designated to the President of Lincoln Memorial University.

Prohibited Collaboration

PIs/PDs should not engage in research collaborations with foreign entities identified by the <u>United States Secretary of State's list of the "Country of Particular Concern List," "Special Watch List Countries," and "Entities of Particular Concern."</u>
Likewise, collaboration with persons or institutions in sanctioned entities is

III. DEFINITIONS

prohibited.

Country/Entities of Particular Concern: a designation given by the United States Secretary of State to a country that has engaged in or tolerated severe violations of religious freedom.

Export: The US government defines an export as the transfer or disclosure of an item outside of the United States, or the transfer of a controlled item or information within the US to a foreign national. This includes physical movement of items across the border, as well as oral, written, electronic, or visual disclosure. The term "export" can also apply to services performed for the benefit of a foreign person.

International Research Collaboration: the act of partnering with different organizations in academia, government, or the private sector in nations and territories outside of the United States, working together across countries in scientific or engineering investigations.

Sponsored Research: a type of research activity that is funded by an external organization, such as a government agency, private sponsor, or non-profit organization. Under this policy, LMU might act as a recipient of sponsored research or a provider.

IV. AUDIENCE

Faculty, staff, and students of Lincoln Memorial University who seek to enter into international agreements involving sponsored research.

V. COMPLIANCE

Failure to follow this policy can result in loss of grant funding, the ability to apply for future grant opportunities through the University, and/or disciplinary action up to and including termination of employment by the Executive Vice President for Academic Affairs.

VI. ROLES AND RESPONSIBILITIES

PI/PD: The Primary Investigator/Project Director assumes responsibility for notifying the ORGSP and any necessary compliance committee and/or subcommittee (IACUC, IRB, IBCSC, ECAS) if they are engaging in a sponsored international research project.

Dean/Chair: Ensures that graduate students, postdoctoral fellows, other postgraduate trainees, faculty, staff, and undergraduate students within a program/school/college are aware of the Sponsored International Research Collaboration policy.

IACUC, IRB, IBCSC, ESAC: Reviews research proposals and ensures researchers have met training requirements and compliance before an international sponsored research project is approved.

Office of Research, Grants, and Sponsored Projects: Provides access to training through the Collaborative Institutional Training Initiative (CITI). Assures PIs/PDs who notify the Office about sponsored international research projects have completed CITI training, properly notified the appropriate compliance committees, works with the PI/PD on reviewing and approving international agreements and budgets, collaborates with the LMU Office of General Counsel in reviewing international agreements, and submits any such agreements to the Executive Vice President for Academic Affairs and ultimately the President of the University for final approval.

Office of the General Counsel: Addresses questions related to international compliance. Reviews international agreements along with the ORGSP.

Executive Vice President for Academic Affairs: Reviews sponsored internal research agreements and determines whether the application will move to the President of the University.

President of the University: Authorizing authority for all international agreements.

VII. APPLICABLE STATUTES, REGULATIONS, AND RELATED POLICIES

Code of Federal Regulations

IX. PROCEDURE

- 1.) PI/PD completes CITI training on "Undue Foreign Influence: Risks and Mitigations" and "Export Compliance."
- 2.) PI/PD notifies the ORGSP of its intent to collaborate on a sponsored research project with an international entity.
- 3.) The PI/PD with the assistance of the ORGSP ensures that the proper compliance committee(s)/subcommittee is notified of the sponsored research collaboration.
- 4.) The compliance committee(s)/subcommittee initiates review of the project and shares its determinations of whether the project can move forward with the PI/PD and the ORGSP.
- 5.) The ORGSP works with the PI/PD to review agreements and ensures any agreement is in English and currency is in USD.
- 6.) The ORGSP submits the reviewed agreements to the LMU Office of Legal Counsel for further review.
- 7.) If an agreement is approved, it moves on to the Executive Vice President for Academic Affairs and then the President of the University for official authorization.
- 8.) Following any authorized agreement, the ORGSP and Office of the General Counsel assist the PI/PD with the creation of data management plans, export agreements, and/or other related matters.

X. CONTACT INFORMATION

For more information regarding this policy, please contact the Office of Research, Grants, and Sponsored Programs.

XI. DOCUMENT HISTORY

Effective: 10-16-2024

> CITI Training