



Exempt Research Performed in International Settings

Office of Research
Policy Number: 4.2.1

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I. Policy Summary

Federal regulations do not require research determined by the NJIT Institutional Review Board (IRB) to be exempt from further review (exempt research) to undergo review at the foreign site where the research will be performed. However, NJIT requires that all research performed by its faculty, staff, and students meet the highest ethical standards. Therefore, NJIT researchers performing research in an international setting must exercise due diligence with regard to respecting the host culture.

II. Policy Purpose

The purpose of this policy is to ensure that NJIT researchers performing exempt research in an international context exercise due diligence with regard to respecting the host culture (where the research will be performed).

III. Policy Scope and Applicability

This policy is in effect for all units of NJIT and applies to all protocols submitted to the IRB that are deemed by the IRB to be exempt from further review and that will take place in a non-US context.

IV. Definitions

Institutional Review Board (IRB): An administrative university committee charged with the evaluation of human subject research in accordance with federal regulations and institutional policies. The committee reports to the senior vice provost for research, but acts autonomously. IRB committee members and chairs serve on the basis of three-year renewable appointments.

IRB Administrator: A staff member tasked with assisting the chair(s) of the IRB with management of all administrative processes related to maintaining IRB workflow and processes. This person is tasked with assisting and training the NJIT community on IRB processes. The current IRB administrator is the assistant director of research compliance and integrity.

International Research: Research performed in a non-US country or region.

V. Policy Statement

Researchers performing research in international settings must respect the host culture. Respecting the host culture entails an awareness of, and compliance with, all local customs, standards, laws, and regulations. In addition, researchers must make their research objectives clear to local research subjects and must remain aware of any concerns of or risks to local individuals, groups, or communities, which may go beyond those normally encountered in a US context.

Researchers performing research in an international setting must exercise due diligence with regard to respecting the host culture. Exercising due diligence will require researchers to demonstrate an awareness

of, and compliance with, all local customs, standards, laws, and regulations, and respect for any concerns or risks that may go beyond those normally encountered in a US context.

VI. Procedures

All IRB protocols are submitted via our online grant management system, Streamlyne. Eligible individuals have login access to the system to input their protocol details. Problems with access or questions on system functionality should be addressed to the IRB administrator.

Adequate documentation demonstrating due diligence will be determined by the IRB co-chairs on a case by case basis. The assistant director of research compliance is responsible for maintaining records of all such documentation.

VII. Roles & Responsibilities

The IRB is an autonomous university committee with the authority to approve or disapprove protocols involving human subject research as defined by 45 CFR 46.

The IRB administrator is responsible for assisting PIs and co-investigators with the process of protocol submission and assists the committee chair(s) in organizing all IRB-related workflow and processes.

PIs and their co-investigators are responsible for submitting and completing protocols via Streamlyne for consideration by the IRB.

VIII. Authority and Responsibility

The senior vice provost for research has institutional authority for the matters addressed in this policy. Questions related to this policy are to be directed to the co-chairs of the NJIT IRB.

Related Policies and Regulations

4.2 Human Subjects Research