# Human Subjects Research

**Office of Research**
**Policy Number: 4.2**

*Effective Date:* Fall 2020
*Last Update:* Summer 2023

## I. Policy Summary

Research involving human subjects at NJIT requires oversight by the NJIT Institutional Review Board (IRB). Federal guidelines govern NJIT IRB protocols, membership and required training.

## II. Policy Purpose

This policy describes the ways NJIT guarantees that research involving human subjects is upheld to high ethical standards and that research projects preserve the autonomy of people who volunteer to be subjects.

## III. Policy Scope and Applicability

This policy is in effect for all units of NJIT and applies to all research involving human subjects and to all protocols submitted to the NJIT IRB.

## IV. Definitions

United States Department of Health and Human Services (45 CFR 46)

Research is defined as "a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge." (§.102[l])

A human subject is "a living individual about whom an investigator (whether professional or student) conducting research:

i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens." (§.102[e][1])

## V. Policy Statement

Under a Federal-wide assurance with the United States Department of Health and Human Services, all research involving human subjects performed by NJIT faculty, staff, and students either on-campus or off-campus, including at other institutions, must be reviewed and approved prior to initiation by the NJIT Institutional Review Board (IRB).

The NJIT IRB follows all regulations as outlined in 45 CFR 46.

## VI. Procedures

All current administrative procedures relating to human subjects research can be found on the NJIT Research Compliance website.

All IRB protocols are submitted via the NJIT 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.

Once the Institutional Review Board (IRB) has reviewed a protocol and approved for the procedures and subjects described in the protocol:

All research must be conducted in accordance with the procedures outlined in the approved protocol.

The protocol is approved until the expiration date listed in the approval letter and must be reviewed for renewal on an annual basis for as long as the research remains active. The PI must submit a request for Continuing Review at least 30 days prior to the expiration date. If the study's approval expires, investigators must stop all research activities immediately (including data analysis) and contact the IRB Office for guidance.

The principal investigator is responsible to:

- Conduct the research in a manner consistent with the requirements of the IRB and federal regulations 45 CFR 46.
- Obtain informed consent and research privacy authorizations using the currently approved forms and retain all original, signed forms, if applicable.
- Request approval from the IRB prior to implementing any/all modifications.
- Promptly report to the IRB any unanticipated problems involving risks to subjects or others and serious and unexpected adverse events.
- Maintain accurate and complete study records.
- Report all Non-Compliance issues or complaints regarding the project promptly to the IRB.

All research records must be retained for a minimum of three (3) years after the conclusion of the project. Once the project is complete, the PI must submit a Request to Close to the IRB.

## 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 HHS Revised Common Rule 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 irb@njit.edu.

**Related Policies and Regulations**

Office for Human Research Protections (OHRP) 45 CFR 46.