# IRB Guidance on the use of human subjects in educational settings

Office of Research	Effective Date: 13 April 2021
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# I. Policy Summary

ΝΙΙΤ

Classroom and educational activities at NJIT may involve assignments that include the use of research methods (such as questionnaires, interviews, or surveys) that involve interaction with living individuals. It is the responsibility of the class instructor or faculty advisor to determine whether the assignment or activity requires the approval of the Institutional Review Board (IRB) which governs human subjects research at the university.

#### II. Policy Purpose

This guidance is intended to help instructors make the determination whether an assignment or activity requires IRB approval. If there is any doubt or an instructor would like confirmation of their determination, they can contact the IRB co-chairs at irb@njit.edu.

# III. Policy Scope and Applicability

This policy is in effect for all units of NJIT.

#### IV. Definitions

For IRB purposes, research is defined in 45 CFR 46.102(l): "Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes."

# V. Policy Statement

All human subject research must be approved by NJIT's IRB. Certain educational activities resemble human subject research, but do not meet the regulatory definition of research as defined in 45 CFR 46.102(1). This guidance is aimed to help instructors determine if their educational activities meet this definition or not.

In determining whether IRB approval is necessary, this is the key question for instructors and advisors: **Is the classroom activity or assignment designed to develop or contribute to generalizable knowledge?** 

1. If the activity is not designed to contribute to generalizable knowledge, but rather to provide instruction or pedagogy concerning research methods, the activity is not considered research for regulatory purposes. There may be a research question driving the collection of data, but there is no intent for the collected data to lead to new knowledge (e.g., there may be too few individuals involved to reach any generalizable conclusion).

So, a class assignment that is intended to give students experience with and teach them how to conduct a survey, distribute a questionnaire, or interview individuals, would not constitute research. Likewise, classroom presentations of the results of such surveys, questionnaires or interviews, where the intent is to teach how to present research results, would also not qualify as research.

While these activities are not research, it is expected that they will be carried out ethically. Instructors using such activities are expected to explain the potential risks involved with human subjects' research to the students, and they should take care to eliminate potential harm from these educational activities. For example, unless a necessary part of the pedagogy, care should be taken to avoid questioning that might prove harmful to subjects (such as data about the use of drugs, physical or sexual abuse, sexual activity, or illegal activity).

Individuals that are asked to take part in these activities should be told that the projects are part of an educational activity to fulfill a course requirement and that all identifiable data collected will not be made public. It is the instructor's responsibility to make sure that the data collection is done in a way such that the individuals providing the data cannot be directly or indirectly identified.

# VI. Procedures

After the instructor makes a determination according to the guidelines in Section V., one of the following should occur:

1. If it is determined that the activity does not meet the definition of research discussed above, then no further interaction with the IRB is necessary for this activity to commence.

# <u>OR</u>

2. If the activity is designed to contribute to generalizable knowledge, then it is research as defined by 45 CFR 46.102(l) and requires IRB approval. The instructor or advisor must assume overall responsibility for such projects and ensure compliance with the approved IRB protocol.

# <u>OR</u>

3. If the activity is not designed to contribute to generalizable knowledge, but the instructor or student determines after starting or completing the activity that it has provided evidence for pursuing a research project, the resulting study would require IRB approval. This might happen, for example, if in doing a class assignment a correlation between two kinds of data is observed and the student or instructor decides it is worth pursuing a research study of that correlation.

#### VII. Roles & Responsibilities

It is the responsibility of the class instructor or faculty advisor to determine whether the assignment or activity requires the approval of the Institutional Review Board (IRB). In turn, the IRB will provide guidance and approval for any protocols submitted to it regarding human subjects' research at the university.

#### VIII. Authority and Responsibility

The Institutional Review Board has institutional authority for the matters addressed in this policy. Questions related to this policy are to be directed to the IRB chair(s) at irb@njit.edu.

### **Related Policies and Regulations**

4.2 <u>Human Subjects Research</u>
4.2.1 <u>Exempt Research Performed in International Settings</u>
4.2.2 <u>Principal Investigators for IRB Protocols</u>