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|  | **SUNY Downstate Medical Center****University Hospital of Brooklyn****College of Medicine****College of Health Related Professions****College of Nursing****School of Graduate Studies****Graduate Program in Public Health** | Students, Residents, Fellows, Employees, or Volunteers as Research Participants |
| For more information on recruiting and enrolling students, residents, fellows, employees, or volunteers as research participants, please the IRB at 718-613-8480 or IRB@downstate.edu  |

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# Introduction

This document provides guidance about research that enrolls students, residents, fellows, employees, or volunteers as research participants or research that involves information about them. The primary concerns are 1) whether investigators have sufficiently minimized coercion or undue influence, 2) whether the research participant’s privacy is adequately protected, and 3) whether the research is following any additional applicable federal regulations or NYC Department of Education IRB requirements.

This guidance represents the IRB’s current thinking on this topic; however, the use of the word “must” in this document means the concept is a Downstate policy or regulatory requirement.

The use of the word *“should”* in this document means the concept can be treated as guidance or something is recommended or suggested, but not required. An investigator may use an alternative approach if the approach satisfies regulatory requirements.

# Definitions

## Undue Influence

Undue influence refers to any situation or act of persuasion that overcomes the free will and judgment of another. This could occur when a person in a position of authority persuades his or her subordinate to a decision. The persuasion may be due to the unequal relationship between the two individuals and the influencing individual can gain an advantage in the situation.

*Example*: A program director insinuates that residents who participate in a research project will be viewed in a positive light. The program director then flatters and tricks a resident into participating in a study, despite the resident’s reservations for becoming a research participant.

## Coercion

Coercion refers to a situation in which an individual in a position of authority uses force, intimidation, or authority to compel another individual toward an action.

*Example*: A gym instructor requires all track students to be in research study that involves urine drug screening. The students must volunteer to be in the study in order to remain on the track team.

# Research Considerations

## Risks

In general, the IRB should only approve research involving students, residents, fellows, employees, or volunteers that presents no more than minimal risks to research participants. However, the IRB may review and approve research with higher levels of risk on a case-by-case basis, particularly if there is any prospect of direct benefit to the research participants.

## Recruitment

As a rule, the IRB disapproves of recruiting students, residents, fellows, employees, or volunteers as a targeted population, merely for the sake of convenience or because they are easily available to the research team. The PI must provide adequate justification if targeting these individuals.

Students, residents, fellows, employees, or volunteers should be recruited through general announcements, mass e-mails, bulletin board postings, advertisements, information booths, rather than direct individual solicitations.

When these individuals are assigned to work with a particular PI or work in a particular laboratory, they should NOT be directly recruited for participation in any study conducted by the PI they are working with or the laboratory they are working in; however, they may, on their own, volunteer to participate.

Investigators may recruit students in a classroom as long as the investigators on the study are not the classroom instructor.

If an investigator is recruiting from a course or work unit, the investigator must obtain prior approval from instructor or supervisor before recruiting participants or conducting the research.

## Incentives

Students may be rewarded though incentives (e.g., extra credit); however, a major ethical concern is whether they are unduly coerced or influenced to take part in a study.

If extra credit incentives are offered, there must be an equal opportunity for all students to participate and if a student wishes to decline participation in the research they MUST be given an alternative to earning equivalent extra credit that is comparable in terms of time, effort and educational benefit. These alternatives must have prior IRB approval. Some acceptable alternatives to research participation include, but are not limited to the following:

* Attend workshops, symposia, or discussions on topics related to the research;
* Observe the research process. For example, a student could observe data collection rather than provide data;
* Work in research labs;
* View a video about research or read a short research report and answer questions or write a summary of the video or report;
* Participate in data collection for non-research purposes. For example, a student could act as a participant in a course-related research project or other course-related training where data are not collected for purposes of generalizable knowledge and, therefore, falls outside of the definition of research; or
* Complete an assigned number of CITI modules.

Research participant pools may be established for future recruitment and enrollment efforts for students, residents, fellows, employees, or volunteers; however, individuals in the pools have not yet provided their legally effective informed consent to participate in a research project until their informed consent is obtained to participate in an IRB approved study. Furthermore, such individuals are free to decline participation in any research.

Students, residents, fellows, employees, or volunteers must not be penalized for refusing to participate in research.

Investigators cannot require research participation as a condition of education or employment.

## Data Collection

Instructors should not use class grades, assignments, evaluations, student records in the research without the express written consent from the students, unless consent can be waived.

Use of employee data should not be used in the research without the express written consent from the employees, unless consent can be waived.

Data collection for these individuals should be conducted by a third party, rather than an instructor or supervisor.

## Consent

The following guidance is provided for obtaining consent for a study involving students, residents, fellows, employees, or volunteers:

* If the research meets the criteria for an exemption or a waiver of the requirements of informed consent, an information sheet should be given to the research participants. The information sheet should include a brief introduction to the study summarizing the risks and benefits, as well as the assertion that participation is considered voluntary must be included.
* The consent process should be conducted by a third party, rather than an instructor or supervisor of the research participant.
* The research participant should be provided with the name and contact information of a neutral third party to contact should they feel coerced at any time during the process. This may be the IRB or Office of Student Affairs or Deans Office or Human Resources.
* Parental permission must be obtained for student participant in research when the student has not reached the age of 18, unless the IRB grants a waiver of informed consent.
* The informed consent document and process shall include all general requirements needed for IRB approval. In specific there must be a full disclosure of information about risks and the limitations as to what can be kept confidential must be disclosed.

## Additional Privacy Protections

When research is conducted within a classroom setting or work setting, the instructor or supervisor should be blinded to the identity of the research participants. Student data should not be analyzed until after grades are posted.

Surveys involving students, residents, fellows, employees, or volunteers should be collected in an anonymous fashion. Paper surveys should be placed in a locked drop box, once they are completed by the research participant.

# Research Conducted in the Kindergarten to 12th Grade Setting

The following guidance applies to research involving students when conducted in the Kindergarten to 12th grade setting.

## Research Supported by the US Department of Education

Research supported by the US Department of Education (DoED) is subject to additional requirements. For more information, see: <http://www2.ed.gov/about/offices/list/ocfo/humansub.html>

### Family Educational Rights and Privacy Act (FERPA)

The Family Educational Rights and Privacy Act (FERPA) is a federal law that protects the privacy of personally identifiable information contained within a student’s educational record. FERPA applies to all schools (K-12 including postsecondary institutions) that receive funds under various programs from the U.S. Department of Education. Generally, investigators may not access classroom performance evaluations, grades, or information in a student’s records without prior written permission from a parent or authorized legal representative, regardless of the access an investigator may have in his/her academic role. An investigator who is also an employee in the school system should be aware that he or she may have access to student records as an employee, but does not have the same access as a researcher.

For more information see:

<http://www2.ed.gov/policy/gen/guid/fpco/index.html>

### Protection of Pupil Rights Amendment (PPRA)

The Protection of Pupil Rights Amendment (PPRA) outlines additional protections and requirements that apply to surveys of students which reveal protected information of a sensitive nature.

The PPRA governs the administration to students of a survey, analysis, or evaluation that concerns one or more of the following eight protected areas:

* political affiliations or beliefs of the student or the student’s parent;
* mental or psychological problems of the student or the student’s family;
* sex behavior or attitudes;
* illegal, anti-social, self-incriminating, or demeaning behavior;
* critical appraisals of other individuals with whom respondents have close family relationships;
* legally recognized privileged or analogous relationships, such as those of lawyers, physicians, and ministers;
* religious practices, affiliations, or beliefs of the student or student’s parent; or,
* income (other than that required by law to determine eligibility for participation in a program or for receiving financial assistance under such program)

For more information see: <http://www2.ed.gov/policy/gen/guid/fpco/index.html>

## Children’s Online Privacy Protection Act (COPPA)

The Children’s Online Privacy Protection Act (COPPA) imposes certain requirements on operators of websites or online services directed to children under 13 years of age, and on operators of other websites or online services that have actual knowledge that they are collecting personal information online from a child under 13 years of age.

Verifiable parental consent is required when using websites or online services for research about children under 13 years of age, unless excluded based on specific criteria outlined within the regulations.

For more information see: <https://www.ftc.gov/enforcement/rules/rulemaking-regulatory-reform-proceedings/childrens-online-privacy-protection-rule>

## NYC Public Schools

Research involving NYC public schools must also be approved by the NYC Department of Education. For more information see: <http://schools.nyc.gov/Accountability/data/DataRequests.htm>

# Investigator Responsibilities

Through the IRB application and approval process, a principal investigator must demonstrate adequate methods to minimize coercion or undue influence and risks to privacy and confidentiality and include plans for additional protections to protect students, residents, fellows, employees, or volunteers.

Investigators who recruit students, residents, or fellows must:

1. Ensure students fully understand they do not need to participate in the research and their lack of participation will not affect their grade or academic standing
2. Ensure students fully understand they may withdraw at any time without consequences.
3. Avoid using class time to recruit or enroll students in research.

Investigators who recruit employees or volunteers must:

1. Ensure employees and volunteers fully understand they do not need to participate in the research and their lack of participation will not affect their employment or performance evaluations.
2. Ensure employees and volunteers fully understand they may withdraw at any time without consequences.

# IRB Application Materials

If the research study involves the recruitment of students, residents, fellows, employees, or volunteers, the IRB application Materials should describe the following:

* Adequate protections to minimize coercion and undue influence.
* Adequate protections to minimize any risks to privacy and confidentiality.
* Provisions to allow such individuals to volunteer to participate on their own, without being directly recruited by investigators, when they are assigned to work with or in a particular investigator, laboratory, or work unit.
* Provisions in the informed consent process to avoid creating the perception that participation in the research by these individuals will favorably influence the participant’s professional or academic career.
* Provisions in the informed consent process to stress to these individuals their performance evaluations, job advancement, or grades will not be influenced by participation or lack of participation in the research study.

# References

* Conducting Research with Employees or Students as Participants. Maimonides Medical Center IRB/Research Committee Guidance (2012)
* Family Educational Rights and Privacy Act Regulations (FERPA): 34 CFR Part 99: <http://www2.ed.gov/policy/gen/reg/ferpa/index.html?exp=6>
* J Chiropr Educ. 2007 Spring; 21(1): 28–31. Methods, Interest, and Incentives. Lee R. Goldenberg, DC, Edward F. Owens, Jr., MS, DC,, and Joel G. Pickar, DC, PhD. Available: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2384177/>
* NYC Department of Education IRB: <http://schools.nyc.gov/Accountability/data/DataRequests.htm>
* OHRP Letter: Student Subject Pools and Use of Penalties for Students Who Fail to Show up for Scheduled Research Appointments (January 8, 2010): [https://www.hhs.gov/ohrp/regulations-and-policy/guidance/january-08-2010-student-subject-pools-and-use-of-penalties/index.html#](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/january-08-2010-student-subject-pools-and-use-of-penalties/index.html)
* Oregon State University IRB Guidance: <http://research.oregonstate.edu/irb/policies-and-guidance-investigators/guidance/recruitment-students-and-employees-research>
* Recruiting and Enrolling OHSU Students as Research Subjects: <http://www.ohsu.edu/xd/about/services/integrity/policies/upload/IRB-Policy_Recruiting-and-Enrolling-OHSU-Students-as-Research-Participants.pdf>
* University of Kentucky: IRB Guidance for Enrolling K-12 Students as Research Subjects: <https://www.research.uky.edu/ori/ORIForms/79-K-12-Students-as-Subjects-guidance.pdf>
* Students as Research Subjects- University of Colorado Boulder: <http://www.colorado.edu/innovate/sites/default/files/attached-files/Students%20as%20Research%20Subjects-%20How%20to%20Avoid%20Undue%20Influence%20and%20Coercion.pdf>

# Authors

Angela Cartmell, PhD, CIP

Kevin L. Nellis, MS, CIP

# Review and Approval History

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IRB Steering Committee

Rebecca S. Twersky MD, MPH

Richard Coico, MS, Ph.D.

Shoshana Milstein, RHIA, CHP, CCS

 Phyllis Supino, EdD

 Stanley Friedman, MD

 Kathleen Powderly, Ph.D.
Nicole McNair, MS
Diann Johnson, MPH

F. Lisa Murtha, Esq.

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