New York City Department of Education
Institutional Review Board

Policy Guide

Created August 2023
Updated May 2024

Research and Policy Support Group
Office of Policy and Evaluation

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1. Overview

1.1 Purpose of this document

This Policy Guide documents policies governing research and evaluation in the New York City Department of Education (NYC DOE) in order to support research facilitation and oversight.

This guide:

- Clarifies the policies in place to protect the rights of students, staff, and families.
- Makes doing research in NYC public schools more accessible to researchers by providing explicit guidance on processes, requirements, and policies.
- Promotes transparency by describing internal administrative processes, documenting DOE research policies and requirements, and explaining considerations in the review process.
- Intends to make research in NYC public schools more relevant and beneficial to our students by explaining policies prioritizing research that brings direct value to the NYC DOE.

If you have any questions after reading this guide, please reach out to IRB@schools.nyc.gov.

1.2 Research Oversight Jurisdiction

The New York City Department of Education's Research Policy and Support Group (RPSG) oversees and facilitates human subjects research (HSR), non-HSR evaluation, and the use of administrative data for research and/or evaluation through the NYC DOE Institutional Review Board and the Data Request Committee.

1.2.1 NYC DOE Institutional Review Board -- Updated May 2024

In 1980, the New York City Department of Education established the Proposal Review Committee, now known as the Institutional Review Board (NYC DOE IRB), to review all requests to conduct data collection for research and evaluation in NYC public schools. Any studies being conducted in schools or with NYC public school students, staff, or affiliates must be reviewed and approved by the NYC DOE IRB to ensure they comply with DOE policies, protect the privacy of students, parents, and staff, and do not disrupt the work of students and staff.

The NYC DOE IRB must review and approve any studies within its jurisdiction. This jurisdiction includes, but is not limited to:

- Any study conducted by an external person/organization with NYC DOE students, families, school staff, non-school based staff, or staff of organizations contracted by the DOE (including CBOs, such as PreK providers)
- Any study conducted in a NYC DOE school or other physical or virtual site where DOE affiliates are involved
- Any study (including program evaluations or studies deemed not human subjects research) that involves students, is conducted by an external organization, and was not initiated on the DOE's behalf
- Any study that involves access to individual-level NYC DOE administrative data (students, staff, families) or aggregate-level administrative data not publicly available

- Any NYC DOE employee of office engaged in human subjects research as part of their employment
- Other research and evaluation work, as determined by the NYC DOE IRB

Many internal program evaluation, continuous improvement, and other activities occur in NYC public schools that are not technically considered human subjects research (HSR). However, in some cases the NYC DOE IRB may conduct a DOE Research Policy Review for non-HSR evaluations if certain conditions exist (including, a sensitive participant population, multi-agency involvement, data sharing outside of the DOE, involvement of students, involvement of an external party, or if the project was not initiated on the DOE's behalf). Please reach out to the IRB inbox (IRB@schools.nyc.gov) if you have questions about if your study needs to be reviewed by the IRB.

Research with charter and private schools typically does not fall within the jurisdiction of the NYC DOE IRB. However, if charter or private schools are also part of a study that includes traditional public schools, this should be stated in the IRB protocol submission.

DOE employees or affiliates who are conducting research to complete a graduate degree are considered external researchers and must receive approval from their institution's IRB before submitting to the DOE IRB. Even though the researcher is a DOE employee, they are not conducting their dissertation research on behalf of the DOE, so the study is considered external. Additionally, the DOE employee must still receive a determination from the Conflicts of Interest Board to conduct research in DOE schools (see here for more info on the COIB requirements).

Oversight role

- The NYC DOE IRB typically serves as the **IRB of Record** for studies conducted by NYC DOE employees conducting research as part of their official work responsibilities.
- The NYC DOE IRB may conduct a **DOE Research Policy Review** for collaborative or external studies approved by an external IRB but conducted with NYC DOE affiliates or in NYC DOE schools.
- Depending on the type of study and the extent to which DOE affiliates are engaged in the study, the DOE IRB may conduct different levels of review. See Types of Review for more information.

1.2.2 Do I need to submit to the NYC DOE IRB? -- Updated May 2024

Review the following table to determine if your study needs to be reviewed and approved by the NYC DOE IRB.

Do I need to submit my study to the NYC DOE IRB?

<table>
<tr><th></th><th>Must submit</th><th>Do not need to submit</th></tr>
<tr><td rowspan="4">Research</td><td>A research study, including but not limited to human subjects research, conducted by an external party in which activities (e.g. recruitment, screening, consent, data collection) occur in NYC DOE schools or virtual spaces, or in which potential subjects are included because of their status as a NYC DOE student, staff member, or family.</td><td>A research study in which no component, including but not limited to recruitment, consent, and data collection, occurs in NYC DOE schools or virtual spaces (e.g. Google Classroom) AND potential subjects' likelihood of inclusion in the study is in no way related to their status as a NYC DOE student, staff, or family.</td></tr>
<tr><td>Any NYC DOE employee or office engaged in human subjects research as part of their DOE job responsibilities.</td><td rowspan="3"></td></tr>
<tr><td>Any NYC DOE staff conducting research, including but not limited to human subjects research, within RFOC’s jurisdiction but outside of their official NYC DOE responsibilities, including staff who are completing a dissertation or other type of project for a higher education degree.</td></tr>
<tr><td>Other research, as determined by the RFOC.</td></tr>
<tr><td rowspan="4">Evaluation & Program Improvement</td><td>Program evaluations or data collection for program improvement, conducted by external organizations.</td><td rowspan="2">Program evaluations or data collection for program improvement, conducted internally (by a NYC DOE program team, office, or school), as part of individuals’ or teams’ DOE official responsibilities.</td></tr>
<tr><td>Any NYC DOE staff conducting program evaluation within RFOC’s jurisdiction but outside of their official NYC DOE responsibilities, including staff who are completing a dissertation or other type of project for a higher education degree.</td></tr>
<tr><td>Programmatic data collected for a program, and used for any purpose aside from directly serving current program participants. For example, data collected for programmatic implementation that you want to use to evaluate the program.</td><td rowspan="2">Programmatic data collected solely for the purpose of directly serving the recipients of a program (such as, collecting student assessments to determine the level of math intervention they should receive).</td></tr>
<tr><td>Other evaluation work, as determined by the RFOC.</td></tr>
</table>

Additional questions to consider:

- Has this project been reviewed by an external IRB already? If so, what was the determination?
    - If an external IRB reviewed your study as any category of minimal risk, Expedited, Exempt, or Full Board, you will need to submit to the NYC DOE IRB.
    - If an external IRB reviewed your study as "not research" or some other not applicable category, please email the IRB inbox (IRB@schools.nyc.gov) to determine if you need to submit.
- What data is being collected?
    - If you are collecting data from DOE staff about their thoughts, feelings, or opinions, you will likely have to submit to the NYC DOE IRB.
    - If you are collecting information from DOE central office staff about programmatic operations or job functions, this may not require NYC DOE IRB review.
- Will you be collecting any data from students or families?
    - If you are collecting any data from students or families, you will need to submit to the NYC DOE IRB.
- How will the results or findings be used and/or shared? Who is the intended audience for the findings? Do you plan to publish any of the findings?
    - If results will be published or shared with an external audience (such as academic journals, conferences, or funders), you will need to submit to the NYC DOE IRB.

Please note, submission to the NYC DOE IRB for review is required even if you have already received approval from your institutional IRB.

Studies are reviewed on a case-by-case basis, and studies that do not fall into the categories above may still need to be reviewed by the NYC DOE IRB. Please email IRB@schools.nyc.gov with questions.

1.3 Legal and Policy Regulations

[Coming soon.]

2. The NYC DOE Institutional Review Board (IRB)

2.1 Research and Research Ethics -- Updated May 2024

The NYC DOE IRB aligns with the basic ethical principles and guidelines for the protection of human subjects in research, defined in the Belmont Report.

Respect for Persons

- Respect the autonomy of individuals
    - Respect personal decisions, and provide necessary information to make decisions
    - Subjects enter into research voluntarily, and with adequate information
- Protect individuals with diminished autonomy (such as, children)
    - Ensure individuals take part in activities voluntarily, and with awareness of possible adverse consequences
    - Exclude individuals from activities that may harm them
    - Depends on the risk of harm and the likelihood of benefit

Beneficence

- The obligation to do no harm
- The obligation to maximize possible benefits and minimize possible harms

Justice

- Consider who bears the burden of research, and who benefits from the research
- Consider if some populations are systematically selected for research because of their easy availability, compromised position, or manipulability

The NYC DOE IRB follows the definitions as described in the Basic HHS Policy for Protection of Human Research Subjects (link), including:

- Human subject: 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.
- Intervention: Includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.
- Interaction: Includes communication or interpersonal contact between investigator and subject.
- Private information: Includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).
- Identifiable private information: Private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.
- Research: A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

2.2 The Board

[Coming soon.]

IRB Registration: The NYC DOE IRB is registered with the United States (US) Department of Health and Human Services (DHHS) Office for Human Research Protections (OHRP). The DOE IRB registration number is: IRB00011754 and IRB00012206.

Federal Wide Assurance: The DOE has filed a Federal Wide Assurance (FWA) with the US DHHS OHRP, which documents the DOE's commitment to comply with federal regulations for the protection of human subjects in research. The DOE FWA number is as follows: FWA00005811.

3. Types of Research and Reviews

This section details the different types of research and analysis that may be conducted in NYC public schools, and how proposals to conduct these types of research may be reviewed. However, before considering the different types of studies and review, it is important to understand how the DOE is engaged or not engaged in the study.

3.1 Engagement in research

To adhere to federal requirements for research oversight, and to determine what institution's IRB should serve as the IRB of Record for a research study, it is important to understand what entities are "engaged in research." Understanding this also helps determine if a study should be internal, collaborative, or external.

Federal guidance released in 2022 [link] recommends the following definition:

> *A party is "engaged in research" if it (or its employees, staff, or agents) has a key role in designing the research, conducting the research, analyzing and interpreting the results, or gaining informed consent from human subjects.*

To align with this guidance, the NYC DOE IRB defines engagement in research in the following way.

Defining "engaged in research"

The following definitions are a guide for how the NYC DOE IRB may consider engagement in research. However, every protocol is reviewed on a case-by-case basis.

The NYC DOE IRB distinguishes between "engaged" and "not engaged" in research by who has **operational and/or intellectual control over the research**, including who is designing the study, and who has the power to make decisions and judgement calls in the research implementation.

Someone would likely be considered "engaged in research" if they:

- Design any part of the research
- Recruit research participants, or track research subject participation (e.g., track consent form completion, follow up with potential participants)
- Conduct the research (e.g., conduct interviews or focus groups)
- Access or analyze individual-level or identifiable data collected through research activities
- Obtain informed consent from human subjects (e.g., explain the study, answer questions)
- Engage in interpretation of results, writing findings, or are cited as an author on any publication

Someone would likely be considered "not engaged" in research if they only:

- Provide feedback on research design, survey questions, etc.
- Provide relevant contextual information about NYC DOE operations
- Do not have access to any data collected as part of the research, but may advise on methodology (e.g., a methods advisor)

- Provide access to a research activity (e.g., put parent consent forms in students' backpacks, passively forward recruitment emails to school staff over whom they have no supervisory authority)
- Collect signed informed consent materials or provide factual information to potential participants (e.g., collect signed forms in a box to give to researchers, or direct participants to the researchers to answer questions about the study)

What if a DOE employee is "engaged in research"?
In cases where a DOE employee is engaged in research, they must be listed on the protocol as part of the research team, must obtain CITI certification, and their activities must be detailed in the protocol. If the study is being done by an external researcher and a DOE employee together, the study would likely be identified as collaborative, depending on the degree of engagement by the external researchers and the DOE employee. The IRB of Record and appropriate PI would be determined by the level of engagement of each person/institution engaged in the research. See the Types of Studies section for more info on collaborative, external, and internal studies.

Another option: The DOE Advisor
Sometimes a DOE employee works closely with the research team to provide feedback on the study and share information about DOE priorities. However, the DOE employee does not have operational or intellectual control of the research; they are not engaged in the research. In these cases, the DOE employee may be listed on the protocol as a "DOE Advisor" as part of the research team. Depending on their role, the DOE Advisor may not need CITI certification and the study may not need to be listed as collaborative. However, the DOE Advisor's involvement must be detailed in the protocol. The purpose of listing the DOE employee and describing their role is so the DOE IRB knows how any DOE employees are involved in the study (even if they are not formally "engaged in research"), and so the Board can make more informed decisions about how the study may benefit the DOE.

[Please note, the current application xform available in IRB Manager does not yet have a formal field for the DOE Advisor. Please instead include in the narrative description of the project.]

The "school coordinator"
[Coming soon.]

If the DOE is a Federal Funding Awardee
When the DOE is the primary awardee for federal research funding, this does not mean the DOE is automatically "engaged," since the DOE may contract research work out to sub-awardees. Federal guidance recommends determining "engagement" in research by who has control and decision-making power over the research. If the DOE serves as only a pass-through entity for funding, but has no operational and/or intellectual control over the research, they may not be considered "engaged."

Examples of the DOE being "engaged" or "not engaged" in research

	If a DOE affiliate does <u>any</u> of the following activities, they would be considered: **ENGAGED**	If a DOE affiliate <u>only</u> does the following activities, they would be considered: **NOT ENGAGED**
Authorship	Would be an author or co-author on the study in their DOE capacity	Is included in a paper's acknowledgements
Study design	Co-write research questions	Share feedback on what research questions and participant populations are of most interest to the DOE
Instrument design	Write survey protocol	Provide edits to question wording and technical terms that are particular to the DOE, to ensure understandability
Recruitment	Track student rosters to see who has returned consent forms and follow up with parents Select a random or representative sample of participants Recruitment procedures: • Use DOE channels (such as Principals Digest) • State that the DOE endorses the study • List a DOE affiliate on recruitment materials	Brainstorm ways to improve participation response rates Provide rosters to researchers through a FERPA exception Passively forward an email about the research to people they do not supervise
Consenting	Answer participant questions about the consent form	Pass out consent forms for students to backpack home Collect completed consent forms for researchers to retrieve Direct participants to the researchers to answer any questions
Data collection	Administer a 1-on-1 assessment with a child for research, outside of normal job responsibilities Access identifiable data collected through the research (e.g., a teacher inputs paper survey data into a database for researchers) Monitor and respond to subject distress	Administer a 1-on-1 assessment on a child as part of normal job responsibilities Collect completed paper surveys from parents who filled it out at home
Data analysis	Access data collected through research to advise on analysis methods, or conduct any data analysis	Advise on methods only, and do not access any research data
Sharing findings	Write, revise, or substantively change the meaning of findings that are included in any publications	Coordinate logistics and invitations for a presentation where researchers share findings with a school community

3.2 Types of Studies

After determining who is engaged in research, and to what extent they are engaged, you can determine what kind of study you plan to conduct. Studies may be Internal, Collaborative, or External. Determining the type of study relies on the NYC DOE IRB's definition of "engaged in research," and aligns with federal guidance on cooperative research and single IRB requirements.

3.2.1 Internal research

Internal studies are human subjects research conducted by NYC DOE staff or affiliates for the purposes of the DOE, where the DOE is the institution conducting the research. The NYC DOE IRB will serve as the IRB of Record for internal studies, and the DOE staff member or affiliate would be listed as the PI.

A study may be internal if:

- A DOE employee is conducting human subjects research as part of their work for the DOE.
- A DOE program team designs a human subjects research project, is the primary decision-maker, and hires an external research firm to implement a survey. In this case, the DOE affiliates are likely "engaged in research" and the hired research firm may not be formally "engaged." The DOE IRB would use the extent of each party's engagement to determine if the study is internal.

A study may <u>not</u> be internal if:

- A DOE employee is conducting human subjects research in order to complete a dissertation to fulfill the requirements of a graduate degree. This would likely be external, and the employee would be required to receive approval from their university IRB before submitting to the DOE IRB.
- A DOE program team hires an external research firm and collaborates with them to design and implement a human subjects research project, where both entities have decision-making power. This would likely be collaborative. In this case, both the DOE team and the external research firm are "engaged in research." The IRB of Record would likely be determined by each party's degree of engagement.

The DOE often conducts **internal evaluations** of program implementation for the purposes of continuous improvement. These are not considered human subjects research because they are intended for program improvement, and are not intended to contribute to generalizable knowledge. Since they are not human subjects research and they are conducted internally to the DOE, these projects typically do not need to be approved by the NYC DOE IRB. DOE staff conducting internal evaluations may still request guidance from the NYC DOE IRB, and are encouraged to reach out with questions about protecting subjects and data.

Please note, <u>external</u> evaluations that are not technically human subjects research may still need to be reviewed by the NYC DOE IRB. Please see section: "Activities that are not technically Human Subjects Research" for more information.

3.2.2 Collaborative research -- Updated May 2024

Collaborative studies, also known as cooperative or multi-site studies, are projects where more than one institution is "engaged in the research" **and one of those institutions is the NYC DOE** [please see above section on "Engagement" for a definition of engagement in research]. A study by two or more institutions working together, but not including the NYC DOE, would be considered an "External" study.

Collaborative studies may be composed of:

- A NYC DOE program team and an external research institution working together on a study
- The NYC DOE working with another city agency and a university on a study
- Some other collaboration, including the NYC DOE

IRB of Record

- In collaborative studies, the IRB of Record is typically determined by who is the PI, and how much each institution is engaged in the research. This is determined on a case-by-case basis.
- The NYC DOE IRB is typically the IRB of Record if:
    - A DOE staff member is the PI
    - DOE has hired a research organization to implement a research study that the DOE has already designed
- An external IRB is typically the IRB of Record if:
    - The external partner is the PI
    - The DOE is the prime awardee of research funding, and the external organization is a sub-awardee and holds operational and intellectual control over the research

Additional requirements for collaborative studies

- A collaborative study must have at least one DOE staff member listed as a member of the research team, and they must be CITI trained. The DOE staff member does not need to be the PI.
- Documentation of external review and approval for all collaborating institutions and researchers is required and must be attached to the protocol once obtained.
- It may be necessary to execute a reliance agreement between the NYC DOE IRB and the external IRB. Please reach out to IRB@schools.nyc.gov with questions about reliance agreements.

3.2.3 External research

External studies are projects conducted by universities, research institutions, or other organizations. External studies must be reviewed and approved by an external IRB before they can be submitted to the NYC DOE IRB. The external IRB would serve as the IRB of Record. In some cases, an external IRB may not fully approve a study until the DOE IRB has approved. In these cases, the external IRB can review and provide conditional approval contingent on approval from the NYC DOE IRB.

External studies may include:

- A research firm conducting a study on a curriculum being implemented in NYC schools. In this case, the external research firm would serve as the IRB of Record.
- A DOE employee who is also a PhD student and is conducting research to complete a dissertation. In this case, the university where the person is completing their PhD would serve as the IRB of Record.

Requirements for external studies

- Submissions of external research to the NYC DOE IRB must include:
    - Documentation of external IRB review and approval
    - The protocol application submitted to the external IRB
- The information, study design, and materials submitted to the DOE IRB must align with the research design and study materials that were approved by the external IRB, or any differences must be explained.
- For dissertation studies, we recommend that the PhD student serve as the PI. However, there may be cases where it is more appropriate for the faculty advisor to serve as the PI. This is up to the researcher to determine, and may depend on who is the primary decision-maker in the research, or who is bearing the primary responsibility for ensuring the protection of human subjects in the research. Please note, even if the faculty advisor is the PI, if the PhD student is a DOE employee, they must obtain a Conflicts of Interest determination.

Review process

- For studies where an external IRB has reviewed and approved as exempt or expedited, the NYC DOE IRB may conduct an expedited DOE Research Policy Review. However, the DOE IRB may bring a protocol to the full board for any reason, or if any of the following apply:
    - Research involves children
    - Protocol requests a waiver of documented informed consent
    - Protocol wants to video or audio record children
    - Interview, focus group, or survey instruments ask sensitive questions of children
    - Protocol wants to collect any medical or biometric data
- Please see below section on Types of Review for more information on how protocols are reviewed.

DOE involvement in external research

Sometimes DOE program teams support external research. To determine if a study should be listed as Collaborative or External, consider if the DOE is "engaged in research," as defined above.

DOE affiliates may be involved with external research and it would not constitute a collaborative study. This would depend on if the DOE affiliate is considered "engaged in research." If the DOE affiliate is not formally engaged based on the DOE definition, the study could likely be external. In this case, it may be appropriate to list a DOE staff member on the IRB protocol as a "DOE Advisor," and detail their involvement. Additionally, the presence of a DOE Advisor would not necessarily require the study to be collaborative. This is detailed more in the Engagement in Research section. Please note, if the DOE person is "engaged in research" at all, the study would likely become collaborative.

"Engaged in research" vs Research "on behalf of the DOE"

In some cases, the research will need to submit a Data Request for student-level data, and in order to qualify for a FERPA "studies" exception to access this data, the project will need a letter of support from a DOE staff member to confirm the study is being done "on behalf of the DOE." This letter of support and statement that the research is "on behalf of the DOE" does not necessarily mean a study is

collaborative. A study can still be external even if the DOE is interested in and supports the study. When a DOE affiliate becomes "engaged" in the research, you will need to consider if the study is collaborative.

3.2.4 Administrative Data Analysis

[Coming soon.]

See External Data Request FAQs.

3.2.5 Activities that are not technically Human Subjects Research

Program Evaluation, Continuous Improvement, etc.

Many internal program evaluation, continuous improvement, and other activities occur in NYC public schools that are not technically considered human subjects research. However, in some cases the NYC DOE IRB may conduct a DOE Research Policy Review for non-HSR evaluations if they involve students and are conducted by an external party who is not overseen by the DOE.

The non-HSR DOE Research Policy Review will consider alignment with DOE research policies.

Interviewing Central DOE Staff

If researchers are only requesting interviews with Central office staff about programmatic operations, then full IRB review may not be required. However, we ask that the researcher provide the following information to potential participants. These questions serve as a way for the interviewees to determine if they want to participate, and disclosing this information aligns with ethical research practices.

- Name(s) of individual(s) from whom you would like to collect data (e.g., interview, survey)
- Topics that will be covered in the interview/survey (please attach a study instrument, if available)
- Expected time commitment for the subject(s)
- A copy of an adult participant consent form (we can provide a template, if needed)
- A list of publications and/or other media outlets, if any, where you intend to distribute your findings
- How the district and/or the research subject(s) will be represented in any published work (identified by name, pseudonym, etc.)

Best Practices for internal non-HSR evaluation in the NYC DOE

For DOE staff conducting program evaluation, continuous improvement, or similar activities with students in NYC schools, keep in mind these best practices:

- Ensure participation is voluntary
- Request and obtain informed consent from participants
- Consider the burden (effort, time, risk) on participants
- Prevent coercion by making sure to not ask people to recruit anyone they supervise
- Follow the DOE's data security best practices [link coming soon]
- Do not compensate DOE employees for participation in evaluations
- Do not ask students sensitive questions

3.2.6 Research conducted by NYC DOE students -- Updated May 2024

Unfortunately, the NYC DOE IRB does not review research submissions from DOE students at this time.

Increasingly, NYC schools are offering courses in behavioral science research, providing students with the opportunity to design and carry out research projects. The NYC DOE IRB affirms the importance of students learning about the principles of behavioral science research and ethical treatment of human research subjects.

The responsibility for reviewing students' research projects, monitoring the development of research protocols, overseeing data collection processes, and ensuring data security and disposal, should reside with a school's research course instructors and/or a faculty research review committees/school-based IRB.

The DOE IRB has developed the basic guidelines to assist schools overseeing student research and data collection. These guidelines embody many of the federal regulations governing research with human subjects as well as policies and procedures that reflect the jurisdictional concerns of the NYC DOE. Please see guidelines in the Appendix 6.3.

Again, the provided guidelines are recommendations, and the NYC DOE IRB does not review or approve research conducted by NYC DOE students.

3.3 Types of Review

Depending on the type of study and the extent to which DOE affiliates are engaged in the research, the DOE IRB may conduct different levels of review.

3.3.1 NYC DOE IRB Review

When the NYC DOE IRB is the IRB of Record

When the NYC DOE IRB is the IRB of Record, it will conduct a full human subjects research ethics review of a study. This type of oversight usually applies to internal studies conducted by NYC DOE employees doing research as part of their official work responsibilities. Sometimes the NYC DOE IRB may serve as the IRB of Record in collaborative studies. Please reach out to the IRB inbox (IRB@schools.nyc.gov) if you are unsure if the NYC DOE IRB should be the IRB of Record.

Full Board Review

The NYC DOE IRB will likely conduct a full board review if the NYC DOE IRB is the IRB of Record for a study.

Expedited Review

The NYC DOE IRB may conduct an expedited review if the study falls into the expedited categories as detailed in §46.110.

Exempt Review

The NYC DOE IRB may determine a study is exempt according to federal regulations under §46.104, but will still review for alignment with DOE research policies through an NYC DOE Research Policy Review.

3.3.2 NYC DOE Research Policy Review

When the NYC DOE IRB is not the IRB of Record

For submissions that have been approved by an external IRB, and where NYC DOE IRB is not the IRB of Record, the NYC DOE IRB may conduct a DOE Research Policy Review. The DOE Research Policy Review is a review for compliance with specific DOE research policies. We rely on the IRB of Record to thoroughly review the study for compliance with human subjects protections, and require external approval/exemption before we conduct a DOE Research Policy Review.

This type of oversight typically applies to external or collaborative research studies, where an external IRB has already reviewed the study and is serving as the IRB of Record. This type of review is also used to review non-HSR evaluations involving students, conducted by an external organization, and not initiated on the DOE's behalf.

DOE Research Policy Review

The NYC DOE IRB typically reviews **all study submissions** for compliance with DOE research policies, irrespective of IRB determinations. The NYC DOE is a complicated environment for research due to the presence of children (a vulnerable category of research subjects), and the unique context and hierarchy of school buildings. As a result, the NYC DOE IRB requires compliance with additional policies in order to protect individuals' privacy and the work of the DOE. The NYC DOE Research Policy Review typically applies to all submissions to ensure compliance with DOE policies, which are detailed in the DOE Research Policies section.

DOE Research Policy Review can happen at different levels (which align with IRB "Full Board" and "Expedited" review levels for logistical ease):

Board Meeting Review

Similar to Full Board Review, almost all new study submissions will be reviewed at a bi-monthly NYC DOE IRB board meeting. Reviewers will read the submission, approve or identify required modifications in an Issues Letter, and determine the next level of review (board meeting or accelerated review).

A submission is more likely to go to board meeting review if it includes any of the following populations or procedures:

- Research involves students
- Research is greater than minimal risk
- Protocol requests a waiver of documented informed consent
- Protocol wants to video record anyone, or audio record children or classrooms
- Data collection procedures (interview, focus group, or survey protocols) ask sensitive questions of children
- Protocol wants to collect any medical or biometric data
- Protocol was previously rejected by the NYC DOE IRB

- Submission is a “Protocol Violation, Deviation, Adverse Event, or Unanticipated Problem”
- Protocol includes any other elements that may elevate the level of risk to potential participants in the DOE’s perspective
- An amendment significantly changes research procedures or level of risk

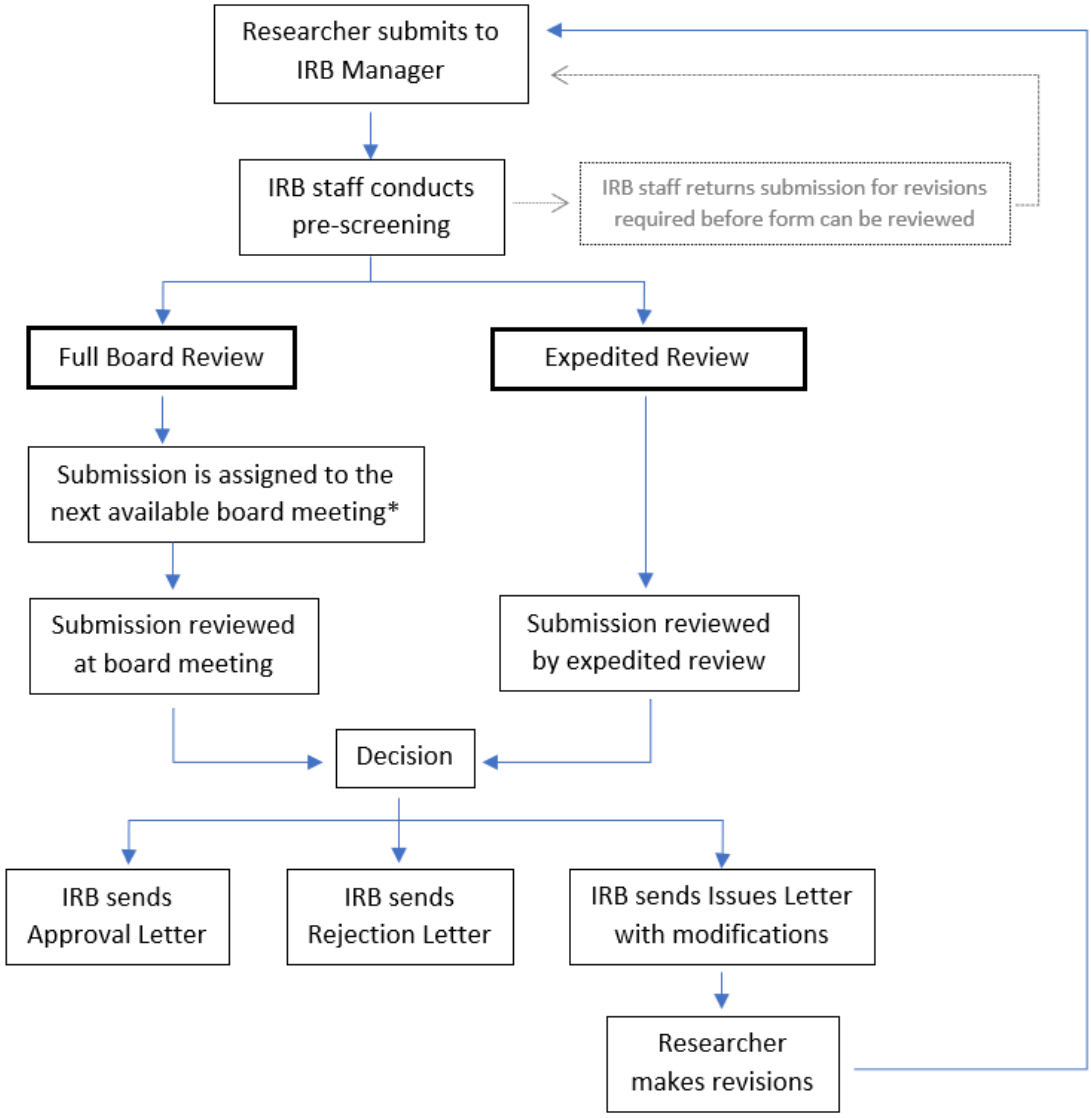
Accelerated DOE Research Policy Review

Similar to Expedited Review, the following types of submissions are likely to be reviewed as an accelerated review:

- Minor amendments (adding research staff, uploading translated materials, adding schools)
- Resubmissions, amendments, or continuations if the board meeting review determined the study qualifies for accelerated review

4. The NYC DOE IRB Process

4.1 Process Graphic



**Meetings are held twice per month and agendas are set 1-2 weeks before meeting date.*

4.2 Review Process Steps

Each submission to the NYC DOE IRB follows the following review process steps:

1. Researcher submits protocol form through IRB Manager.
2. IRB Staff conducts pre-review/screening and either returns form to PI for revisions, assigns to Full Board review (or DOE Research Policy Board Review), or assigns to Expedited review (or DOE Research Policy Accelerated Review).
3. Study is reviewed by the Full Board or by Expedited Review, and reviewers submit determination.

4. PI receives determination letter (Approval letter, Rejection letter, or Issues Letter with required revisions).
5. If needed, PI makes modifications and resubmits.

4.3 Using IRB Manager

NYC DOE Data Requests and IRB submissions go through IRB Manager:
https://nycdoe.my.irbmanager.com/

4.3.1 Before you begin:

You must use your institutional email address to create an account. If you are a DOE employee but you are submitting a research protocol for a graduate program, you must use your university email address to create an account. You may not use a non-institutional email address to create an account (Gmail, Yahoo, Hotmail, etc.).

If you already have an account but forgot the password, do not create a new account. Just reset your password. If you haven't logged in for a while, your account may be deactivated. If so, please email IRB@schools.nyc.gov or RPSPresearch@schools.nyc.gov and ask that your account be reactivated. Do not create a new account.

Specific requirements for IRB submissions:

- If you are a university student, your faculty advisor will need an IRB Manager account and relevant CITI training in order to add them to your protocol.
- If you are a university student or external researcher, your institutional IRB will need an IRB Manager account in order to be added to your protocol.

4.3.2 To create an account:

1. On the IRBManager login page, click on "Click here to register."
2. Enter your institutional email address and confirm.
3. Fill in the relevant information about your organization/institution, name, and contact information.
4. Click Register.

4.3.3 To submit an IRB protocol or Data Request:

After logging in, click on the "Start xForm" link under Actions in the top left corner. Select the type of form you need to submit.

Available forms include:

- **Credentialing** – Use this form to submit CITI certification
- **Data Requests** – Use this form to submit a new Data Request
- **IRB New Protocol Submission Form (v. 4.5)** – Use this form to submit a new IRB protocol

Available forms for users with an open IRB protocol, accessed through your open protocol:

- **Add or Remove Study Staff** – Use this form to add or remove staff from your study

- **Amendments Submission** – Use this form to submit a minor modification to your study
- **Closure** – Use this form to close your study
- **IRB Protocol Continuing Review/Renewal Request Application 2.0** – Use this form to renew your study (studies are typically only approved for one year at a time)
- **Protocol Violation, Deviation, Adverse Event, and/or Unanticipated Problem Report** – Use this form to report any protocol violations, deviations, adverse events, or unanticipated problems

If you need to make a major modification to your study, use the "Copy for Amend" function. Download instructions from IRB Manager here: 4.5+ Amendment Instructions (this link requires being logged into your IRB Manager account).

If you would like to see all of the questions on a form before you begin completing it, click on the Print icon next to the form to access a view where you can print.

4.4 Submitting to IRB Manager

4.4.1 General Instructions

To start a form for a new study:

1. Log into IRB Manager.
2. Look in the top left corner of the window, for the menu under "Actions"
3. Click on the "Start xForm" link under Actions.
4. To start a new study protocol form, click on "IRB New Protocol Submission Form (v. 4.5)."

To access a form specific to an existing protocol (such as a continuation or amendment form):

1. Log into IRB Manager.
2. Go to your Dashboard.
3. Scroll to the bottom of the page and click on the blue number of the protocol where you want to submit the new form.
4. Select "Start xForm" from the "Actions" menu on the left.
5. From here you can submit a minor amendment form, add/remove study staff, closure form, continuation request, or a protocol violation.

Common issues with submitting a form

- If someone other than the study PI is submitting the form in IRB Manager, it will be sent to the PI for final signature and submission. The submitter must click through the form all the way until they click the "Submit" button to ensure the form has been fully submitted.
- Protocols submitted by students will be sent to the faculty advisor for final review and submission.
- Protocols with the following status have not been fully submitted:
    - Data Entry Stage
    - PI Signature for Coordinator submission
    - Faculty Advisor Approval

4.4.2 Protocol xForm

The xForm is the primary protocol form that researchers fill out to submit to the NYC DOE IRB. In this form, submitters provide information about the proposed research study, including:

- Study information, documentation of institutional IRB approval, funding information
- PI and research study team personnel information
- Research locations
- Research questions
- Data collection methods, data collection tools
- Study subject populations, inclusion/exclusion criteria
- Risks/benefits to subjects
- Subject compensation procedures
- Recruitment procedures, screening procedures
- FERPA and PPRA requirements
- Consent and assent procedures
- Principal Permission
- Data confidentiality and subject privacy protections

Recommendations for successful submissions:

- Institutional Approval for External Studies
    - All External studies must receive approval from the institutional IRB before submitting to the NYC DOE IRB. The institution/university will serve as the IRB of Record for the study.
- Brevity, clarity, and consistency
    - Ensure answers to protocol questions are brief and clear. Text copied from grant proposals or dissertation chapters is typically not appropriate to answer IRB protocol questions. Please read the questions carefully and answer them completely. Incomplete or unrelated responses will delay review.
    - Ensure all elements of the protocol and attachments are consistent with one another. Inconsistencies will delay review.
- Attachments
    - Do not attach documents with unusual characters or symbols in the file name (such as "|")
    - Do not upload blank attachments.
- Research Personnel
    - List all study personnel on the protocol, along with up-to-date CITI certification. Please note, the DOE IRB requires completion of the 26 DOE CITI courses. Please see CITI certification for more information.
    - All submissions must identify a contact person for the IRB of Record, usually someone from the institutional IRB's office. They will need to create an IRB Manager account.
    - Student submissions must include the faculty advisor.
    - DOE staff members submitting protocols for research being conducted outside of their DOE job responsibilities (such as for an advanced degree) must adhere to the following requirements:

- Use your university email address to create an account and submit the protocol. Do not use your DOE email address.
- List the study as External. DOE employees or affiliates who are conducting research to complete a graduate degree are considered external researchers. Even though the researcher is a DOE employee, they are not conducting their dissertation research on behalf of the DOE, so the study is considered external.
- Identify yourself as a student.
- Identify yourself as affiliated with the DOE.
- Include your Conflicts of Interest Board waiver letter.

4.4.3 Credentialing

Researchers can submit a Credentialing form to provide CITI certification. Please note, CITI certification must adhere to NYC DOE IRB CITI requirements.

4.4.4 District Sponsor Request Form

[Coming soon.]

4.4.5 Data Request

[Coming soon.]

4.4.6 Amendment -- Updated May 2024

There are several kinds of amendments a researcher can submit, depending on the changes being proposed. Please review the following to determine what kind of amendment you need to submit.

- Add/Remove Contacts Form
  - To add or remove contacts from the research team, or change PI
  - Must include CITI certificates
  - Cannot change anything else about the form
- Administrative Amendment
  - Simple amendment form – does not copy the entire protocol.
  - This amendment can only be used for the following:
    1. Uploading translated versions of documents that have already been approved by the NYC DOE IRB.
    2. Uploading signed principal letters (original principal letter must have already been approved by the NYC DOE IRB).
    3. Adding or removing schools from the study.
- Standard Amendment
  - Copy for Amend – This will copy the entire protocol and you will need to update/revise any sections related to your proposed amendment.
  - This amendment must be used for any other proposed change to the protocol.

- Instructions to Copy for Amend (also available for download here: https://nycdoe.my.irbmanager.com/Attachments/791883a7-a192-4f83-b52c-7080a813896e)
    1. Go to your Dashboard.
    2. Scroll to the bottom of the page and click on the blue number of the protocol where you want to submit the amendment.
    3. Scroll to the bottom of the page and select the initial review event ("Initial Submission") and click on the blue text.
    4. In the left-hand "Actions" column, select "xForms"
    5. First the first "IRB New Protocol Submission Form" and click on the icon that is a picture of a yellow folder with a green plus sign.
    6. You should get a pop-up message saying, "Copy for Amendment?" Click OK.
    7. Describe your amendment and attach appropriate documents. Click Next.
    8. You will now see your original submission. Go through the original protocol and update/revise appropriate sections in accordance with your amendment submission.
        - If you are changing documents, please attach versions with tracked-changes as well as clean versions.
        - Ensure all changes you are making to the protocol are explained in the amendment description. Making additional changes to the protocol that are not included in the amendment description will slow down pre-screening and processing time, and your amendment may be returned to you for clarification.
    9. When you are finished with all revisions, click Submit.

Resubmissions or amendments that include changes to attachments must include versions of the attachments that clearly show what has been changed. This can be shown either with tracked changes or by highlighting. Please also include a clean version of the document.

4.4.7 Protocol Violation/Deviation

[Coming soon.]

4.4.8 Continuation -- Updated May 2024

Studies are approved for one calendar year at a time. If any study activities continue beyond one year after the approval date, researchers need to submit a Continuation form to request another year of approval. Continuation forms should be submitted 2-3 months prior to the study expiration date. If the researcher needs to make any changes to the study, do not make them in the Continuation form. Submit an Amendment form instead.

For complex multi-year studies in which procedures may change over time as the study evolves, we prefer that researchers keep all related activities in a single submission and submit amendments and continuations (rather than closing the study and submitting a new study with the updated procedures).

4.4.9 Closure

[Coming soon.]

4.4.10 Other processes

[Coming soon.]

5. NYC DOE Research Policies

The NYC DOE IRB may conduct a DOE Research Policy Review to ensure a protocol aligns with DOE-specific policies, beyond the IRB review. The NYC DOE research policies apply to all studies within its jurisdiction. While the Research Policy Review is not an IRB review, NYC DOE research policies are heavily informed by federal research regulations.

5.1 Considering doing research in NYC public schools

5.1.1 Demonstrating value to the DOE -- Updated May 2024

Research must demonstrate alignment with the DOE's priorities. See the Chancellor's pillars here: https://www.schools.nyc.gov/about-us/vision-and-mission/four-pillars-for-building-trust-in-nyc-public-schools

Proposals to conduct any research with schools, students, or staff must demonstrate clear and direct value to the NYC DOE. Researchers can demonstrate this in one of two ways:

1. Justify why the research needs to happen in NYC public schools by explaining how the research:
    - Aligns with NYC DOE priorities, without duplicating existing work
    - Will be used by the NYC DOE
    - Provides direct benefits/services to students or schools
    - Is different from other work that has been done on the subject
2. Provide evidence of support from a "District Sponsor" (a central office or superintendent office staff member, or a principal in certain cases)

1. Justify why the research need to happen in NYC public schools

Justification that cites contribution to general knowledge or academic discourse as the value to NYC DOE is not adequate. Participation in research requires using DOE resources, both tangible and intangible, so proposed research must demonstrate value to the DOE that outweighs demands on DOE resources.

2. Provide evidence of support from a District Sponsor

In order to facilitate the use of research to inform policy and practice, we highly encourage researchers to work with NYC DOE practitioners to ensure research is relevant, timely, and useful for decision-making.

Researchers may demonstrate evidence of the value of their research to NYC schools through obtaining a detailed letter of support from a District Sponsor from the central office, district, or school explaining how the DOE will use the results to inform policies and decision-making.

- Strong letters of support demonstrate how the study aligns with the priorities of the NYC DOE, what NYC DOE policies or programming decisions the study will inform, and how the NYC DOE will access and use the study findings.
- Obtaining support from a District Sponsor does not guarantee study approval by the IRB.
- Securing a district sponsor does not commit the NYC DOE to using findings or indicate an endorsement of study results.

We highly recommend that the following types of proposals secure support from a District Sponsor prior to submission (and do not rely only on the justification explanation). Approval for these types of studies with justification only, and without district sponsorship, is rare:

- Proposals from:
    - Graduate students who are not DOE employees
    - University professors
    - Research firms
- Studies of interventions, curriculum, technology, or professional development

If a study requires access to FERPA-protected student data, a District Sponsor may be required in order to meet the FERPA studies exception. See more information here: https://infohub.nyced.org/working-with-the-doe/research-irb/faqs-for-external-data-requests

Exceptions

There are some limited cases where justification and/or district sponsorship may not be required for NYC DOE IRB approval:

- Proposals from DOE staff members conducting dissertation research may not need support from a District Sponsor, but must adhere to the additional requirements detailed later in this guide.
    - *Note, a District Sponsor may still be required to qualify for a FERPA exception for access to student data.*
- Certain required federal studies (NAEP, NTPS, ECLS, HS longitudinal study, school pulse panel, SSOCS), may not require support from a District Sponsor. See here for more examples: https://nces.ed.gov/surveys/

Reasons a study may not be approved

- Justification for why the study needs to happen in NYC Public Schools is inadequate, or cites "contribution to general knowledge or academic discourse" as the primary reason.
- Study does not need to happen in schools or in the education context.
- The NYC DOE IRB reserves the right to reject submissions that have gone through multiple rounds of feedback but remain incomplete or not in compliance with DOE policies or form instructions.

Difference between a "Letter of Support" from a District Sponsor and the "Principal Permission Letter"

The **Letter of Support from a District Sponsor** can be collected prior to DOE IRB review and approval, and is meant to be a demonstration of the value of the proposed research to the DOE. The letter of support comes from a DOE staff person, and conveys how the research will help inform policy and make decisions. The Letter of Support can also serve as evidence that the research is being done "on behalf of the DOE," which is necessary if the researcher intends to access FERPA-protected data and wants to use the FERPA "studies" exception. The completed Letter of Support can be attached in the "Other attachments" section of the IRB submission form.

The Letter of Support would typically come from a DOE central office, superintendent's office, or borough staff person. In rare cases where the research would only occur at a single school, a letter of support may come from a single principal. The researcher may reach out to DOE

central/superintendent/borough staff with a proposed project to solicit a letter of support (while making clear that the project has not been approved by the IRB yet).

Strong letters of support demonstrate how the study aligns with the priorities of the NYC DOE, what NYC DOE policies or programming decisions the study will inform, and how the NYC DOE will access and use the study findings.

The **Principal Permission Letter** is collected after DOE IRB review and approval. An unsigned draft of this letter should be attached to the DOE IRB submission form for review and approval.

The principal permission letter must include detailed information about the study, including:

- Research questions, design, and methodology
- Recruitment process
- Participant burden
- Confidentiality/anonymity
- Risks/benefits
- Uses of the data
- Anything needed from the school (such as, identifying a space to conduct interviews, a location to post a recruitment flyer, approval to conduct an intervention tied to the research)
- Signature line and date for the principal to give their permission to conduct the study in their school, including the title of the study, protocol number, and the school name

While the NYC DOE IRB may approve a study, it is still ultimately up to the principals to give permission for the research to happen in their schools. Approval by the NYC DOE IRB does not guarantee access to any particular school, individual, or data. The researcher is responsible for making appropriate contacts and getting the required permissions and consents before initiating the study.

Researchers may discuss their study with principals before official NYC DOE IRB approval, but they may not collect the formal principal permission letter until the study has been approved by the NYC DOE IRB. After the researcher has received NYC DOE IRB approval, they may contact principals to request formal permission to conduct the study in their schools.

Overall, we require external submissions to demonstrate the overall value of their study to the NYC DOE prior to review by the NYC DOE IRB. One way to do this is through a Letter of Support. Then, once a study has been approved, researchers would approach individual school principals to obtain permission to conduct their specific, IRB-approved study procedures in that school.

5.1.2 Burden

[Coming soon.]

5.1.3 Equity

[Coming soon.]

5.1.4 In-person or Virtual Studies -- Updated May 2024

While strict COVID restrictions on in-person research are no longer in effect, the use of virtual or online study procedures remains common and the NYC DOE IRB does allow for both virtual and in-person study activities. As a result, NYC DOE IRB asks that researchers clearly explain what activities would occur in-person and what would occur virtually, and ensure this is clearly communicated in the protocol submission and all materials given to participants.

The NYC DOE IRB also requires study personnel to seek out and follow all school visitor policies and procedures (including health and safety protocols) when entering school buildings.

5.1.5 Study Personnel -- Updated May 2024

Principal Investigator

[Coming soon.]

Research Study Staff

[More coming soon.]

Tele-recruiters

Researchers must include tele-recruiters in the Research Staff table in the submission form. Some of the larger federal survey studies may decide to identify dedicated NYC-specific recruiters to ensure they follow our recruitment policies. Since these tele-recruiters will not be entering schools or interacting with students or data, they likely will not need to go through the PETS security clearance process. Please see the section on Security Clearance below.

Graduate student research

The NYC DOE IRB considers graduation student research submissions on a case-by-case basis.

Graduate student submissions:

- Must submit a detailed, thorough, and complete IRB application. If a submission does not answer all questions, or clearly has not complied with directions in the form, it will be rejected.
- Must include evidence of review from the university/college IRB.
    - Please note, even if your institution's IRB has determined your project to be exempt, expedited, or not human subjects research, you are still required to submit to the NYC DOE IRB for review of compliance with NYC DOE research policies.
- Must demonstrate strong support from a faculty advisor, including support completing and submitting the NYC DOE IRB application.
- Must not put undue burden on NYC public schools, students, families, or staff.

Some graduate programs require extremely fast timelines for thesis or dissertation completion. The DOE IRB's timelines for reviewing and approving studies often do not align with the requirements of these programs. The DOE IRB will not expedite protocol review due to fast graduate program timelines. If your graduate program requires a very fast thesis/dissertation timeline, we recommend finding research opportunities elsewhere.

Submissions from graduate students who are also DOE employees must follow additional policies:

- DOE employees must obtain a determination from the NYC DOE Ethics Office or NYC Conflicts of Interest Board and attach the letter to the IRB application.
- DOE employees conducting research for an advanced degree cannot use student data or other data collected through their employment for research without a COI waiver, an approved Data Request, and a signed data non-disclosure agreement (NDA) executed with their university/institution.
- DOE employees conducting research for a degree may not engage in research activities or collect data for research without approval from the NYC DOE IRB.
- In rare cases, a DOE employee may request to use data previously collected as part of their normal work activities for a research project. These requests are reviewed on a case-by-case basis.

The timeline of review of dissertation studies depends on a few things:

- Is the student a current DOE employee?
    - If yes, they do not have to demonstrate value to the DOE, since a DOE employee gaining advanced education is a value in itself. They will still need to explain the value of their study in the application, but they are not required to provide a letter of support from a district sponsor.
    - If no, they should plan to obtain a letter of support from a district sponsor in the DOE to demonstrate the value of their research. If they do not submit this letter in their initial submission, the application will be returned to them, adding time to the process.
- Does the study involve direct data collection from students (surveys, interviews, focus groups, observations, etc.)?
    - If yes, studies involving direct data collection from students are typically reviewed by the full board.
    - If no, the study may be reviewed expedited if it only involves data collection from adults. (However, if an adult-only study potentially poses increased risk to participants, as determined by the DOE IRB, it may still go to the full board.)
- Does the study involve using individual-level student administrative data (either requested from the DOE, or in a person's possession through their work with students as a DOE employee)?
    - If yes, studies involving individual-level student data need to go through some additional steps (adding time to the process):
        - The student must submit and received approval of a Data Request
        - The student may need to obtain a DOE District Sponsor to meet the FERPA exception requirement
        - The student's institution would need to sign the data non-disclosure agreement (NDA)

Conflicts of Interest Board

If you are affiliated with the NYC DOE, but conducting research outside of your DOE job responsibilities, such as for an advanced degree, you must contact the NYC DOE Ethics Officer, Ms. Samantha Biletsky (SBiletsky@schools.nyc.gov), prior to submitting to the NYC DOE IRB to determine if a Conflict of Interest Exemption is required for the proposed research.

See here for more information about Conflicts of Interest, and to access the Research Waiver Request Form. (DOE login credentials are required to access this page.)

Note that the DOE rarely permits DOE staff to conduct research in their own school or with students, parents, teachers, or other staff that are under the supervision of or in a position of subordination to any member of the study team.

CITI Training

CITI Training Requirements

The NYC DOE IRB requires all researchers to complete the 26-module Social & Behavioral Research – Basic/Refresher course (ID 184110) **that is affiliated with the NYC DOE**. Researchers must affiliate themselves with the NYC DOE in CITI in order to access and complete this course. Documentation of completion of the NYC DOE affiliated course must be provided for IRB review at the time of protocol submission, or prior to submission using the Credentialing xForm in IRB Manager. Certificates of completion of the NYC DOE course are valid for 5 years, after which point a Refresher course will be required.

If you have used the same email address to create your IRB Manager account and to complete the CITI training with the NYC DOE, your course completion records will automatically upload into your IRB Manager user profile, and will show up in any form you submit. This is the preferred method. However, if you used a different email address or your records are not transferring over for some reason, please submit a Credentialing form to upload your completion certificate manually.

If your research is subject to FERPA, select the Family Educational Rights and Privacy Act (FERPA) course for question 4. If no part of your research is subject to FERPA, select the Information Privacy Security (IPS) course most applicable to you.

All parties are strongly encouraged to complete the Conflicts of Interest course, although it is not required. If you are a DOE employee, or otherwise affiliated with the DOE, the Conflicts of Interest course is recommended, and may be required.

If your institution has a CITI or other training program that you would like to use as a substitute, please submit a request to IRB@schools.nyc.gov that includes the list of courses and demonstrates how these courses align with the DOE requirements. To note, the course list must align with the DOE course requirements, including the 26 modules (see list of modules in the Appendix).

Faculty advisors only need to have the full NYC DOE CITI training if they will be engaged in any research activities for this proposed study, or working with any study data from this study. Engaged in research activities could include recruiting participants, consenting participants, conducting data collection, or reviewing data collected from research participants. If faculty advisors will be engaged in research activities, they will also need to be listed on the protocol under “Research Staff.” If faculty advisors will not be engaged in any research activities for this study, CITI certification from their home institution is adequate.

Accessing CITI Trainings

Researchers who are submitting protocols to conduct research in NYC schools may complete CITI trainings as a NYC DOE affiliate. In your CITI account, researchers may affiliate themselves with the NYC DOE in order to access our required courses. Please see instructions below.

1. Access the CITI website here: https://about.citiprogram.org/en/homepage/
2. Log in or Register
    a. If you have an existing CITI account, log in and follow instruction to add the NYC DOE as an affiliated institution.
        i. In the blue "Welcome" banner, click "Add Institutional Affiliation". Enter "New York City Department of Education" and follow instructions. You may affirm you are an affiliate of the NYC Department of Education, since you are applying to conduct research with us.
    b. If you do not have an existing account, click "Register" and set up an account with "New York City Department of Education". You may affirm you are an affiliate of the NYC Department of Education, since you are applying to conduct research with us.
3. Navigate to the Homepage and click on "View Courses" for New York City Department of Education. Follow instructions on CITI training instructions document.

Security Clearance and PETS

PETS, Security Clearance, and Fingerprinting

All personnel named in an approved IRB protocol who are designated to conduct research in NYC public schools, with NYC DOE staff or students, or using NYC public school student data, must complete the NYC DOE security clearance process.

Research staff are required to have NYC DOE security clearance if they are doing any of the following:

- Entering schools
- Interacting with students in person
- Interacting with students virtually
- Accessing student direct identifiers*
- Accessing teacher direct identifiers* (if data includes evaluation data)

**Direct identifiers may include name, date of birth, address, contact information, and non-coded ID number*

The NYC DOE security clearance process involves the following steps:

1. PI receives IRB approval from the NYC DOE IRB, including approval letter naming all research team member names.
2. For each research team member, email required information and scanned copies of required documents to IRB@schools.nyc.gov, including:
    a. Stamped DOE IRB Approval Letter
    b. Government Issued State ID
    c. Signed Social Security Card
    d. Current email address and phone number

3. The DOE IRB will verify this information and enter it into the PETS system.
    a. Note: We understand individuals may feel uncomfortable emailing SSN information. If so, please state in your email that you would like to verify your SSN over the phone and we will set up a call.
4. Within 7 business days, researchers will receive a nomination email from PETSAdminSupport@schools.nyc.gov. This email will outline all next steps in the security clearance process, including login access to Applicant Gateway where all required forms can be found.
5. Researchers must complete the required steps and forms in the Applicant Gateway. This may consist of completing fingerprinting and/or a Background Questionnaire (see below for more information about fingerprinting).

The PETS system does not send any confirmation to researchers if they become eligible. It is the study PI's responsibility to ensure all research staff contacting schools or entering schools are fully eligible in PETS. Please contact IRB@schools.nyc.gov if you have questions.

The NYC DOE takes the safety of our students, staff, and schools very seriously. The security clearance process is not optional. If researchers do not follow the NYC DOE's requirements for security clearance, the study may be paused or terminated, the IRB of Record will be notified, funders may be notified, future studies may not be approved, and the Office of Special Investigations may be involved. It is the PI's responsibility to ensure all research staff are cleared to enter schools.

If a researcher's eligibility status changes, and they become ineligible for some reason, the NYC DOE IRB will contact the study PI to inform them and to direct them to remove that researcher from schools immediately.

Fingerprinting

A researcher may need to complete fingerprinting for the security clearance process. If so, once all required forms are completed and signed, follow the directions provided in the Applicant Gateway to schedule the fingerprinting appointment through IdentoGo. Please note:

- Fingerprinting is no longer conducted at 65 Court Street.
- Fingerprinting is conducted on an appointment-only basis.
- The cost for fingerprinting is currently $101.75.

What if I'm already eligible in PETS?

Security clearance is role-specific, so individuals are cleared for specific roles and vendors. Any researchers doing research in DOE schools must be entered into PETS on the IRB vendor roster. If researchers already have fingerprints on file with the NYC DOE IRB, or are already eligible in PETS under a different vendor's roster, they still need to submit the required documents to the IRB inbox and complete any required steps. The researcher may not need to be re-fingerprinted, and they may just need to update responses in the Background Questionnaire. **If a researcher is already in PETS but not on the IRB vendor list, they are not cleared to enter schools for research. They must be found eligible on the IRB vendor list.**

- For example, an individual may be eligible in PETS under a vendor who provided tutoring services in schools a couple years ago. In this case, the individual may be "Eligible" under the vendor "ABC Tutoring, LLC". This does not mean this individual is cleared to enter schools for a research project. They must be listed as "Eligible" under the vendor "Institutional Review Board" to be able to enter schools for research.

What if a researcher does not have an SSN?
Researchers must have an SSN in order to be entered into PETS and to obtain security clearance. We understand that some research studies include international university students who do not have SSNs. Unfortunately, there is no option at this time to add these individuals into PETS under the IRB vendor.

5.1.6 Research Design -- Updated May 2024

Quality of research
[Coming soon.]

Randomized control trials, control groups
Studies that involve student-level randomization within a school are considered on a case-by-case basis and are rarely approved by the NYC DOE IRB. In a limited number of cases, the NYC DOE IRB may approve a study using randomization between schools.

The NYC DOE IRB's policy on the use of randomized controlled trials considers both methodological challenges and ethical concerns.

Methodological Considerations

- Educational systems like the New York City public schools are highly complex organizations, and it is challenging to adhere to the strict inclusion/exclusion criteria and intervention implementation requirements in this environment. Specifically, the following methodological challenges often occur in public school systems:
    - Variables can rarely be controlled tightly.
    - Contamination of effects can compromise randomization, especially where student interaction is moderate to extensive.
    - Blinding, a cornerstone of clinical RCTs, is virtually impossible in studies conducted in schools.
    - Schools are particularly unique settings, and a randomization design may not actually control for the contextual factors that may impact outcomes.
    - Interpreting results of RCTs in schools is not as simple as saying, "It works," or, "It doesn't work." (e.g., if it works with low-income students in the rural south, does that mean it will work with middle-income students in the urban north?)

Ethical Considerations

- In the public school setting, RCTs that deny services to a control group that has been created solely for the purpose of the research experiment are ethically and administratively problematic. Distribution of services or benefits that appears to be arbitrary, or random, may be

perceived as unfair in the school environment, where instruction and interventions are often differentiated based on carefully considered student needs, not randomly.

How the NYC DOE IRB considers RCT designs:

Rationale for the design

- The Board will consider:
  - Is there is a clear scientific and policy rationale for using an RCT?
  - Would another research methodology produce the desired outcome?
  - Does the research design address an important policy or practice question that is a priority for the DOE and participating schools (e.g., will it lead to increased school attendance, improved educational outcomes)?
- Recommendations:
  - Provide a clear and detailed explanation of the proposed design in your submission.
  - Consider other study designs (see below).

Strength of the study versus risk/burden on participants

- The Board will consider:
  - Is the margin of improvement large enough to warrant an RCT?
  - Does the proposal communicate clear thinking about indicators (e.g. How will improvement be measured? How will data on the indicators be collected?)?
  - Does the proposal communicate a deep understanding of the sample: Who is the target population? Is the sample large enough to make it really random? Is the sample representative of the larger population? When will random assignment take place within schools? Following randomization, are the treatment and control groups comparable along important indicators?
  - Does the potential benefit to students/schools outweigh the concomitant burden to school staff of the sample size/time commitment required for an RCT?
  - Is the proposed study population particularly vulnerable? Would the RCT result in inequitable educational opportunities for students within the same school?
- Recommendations:
  - Make a strong case for why the study must be designed in this way.
  - Clearly explain the intended participant population, including why it was selected and how you know it will yield a strong design.
  - Justify the exclusion of some students from receiving the intervention (some ideas: RCT design is required by study funder and intervention wouldn't be possible without the study funding, low data collection burden on students, many students will still receive the intervention through the delayed treatment model, etc.)
  - Consider ways to provide equivalent experiences for control populations.

Feasibility of the study design

- The Board will consider:
  - Would the school principal agree to an RCT in their school? School leaders need to be able to make instructional decisions in the best interest of their students, and an RCT

design might prevent school leaders from providing students with the services they need.
    - Is the RCT implementation logistically feasible given the complicated scheduling in schools?
    - Will adequate resources be available for the development/implementation phase of the program, including:
        - Attention and sensitivity to stakeholder perspectives/concerns: recruitment activities that consider the position of the control group; honest discussion of what will be expected and potential risks and benefits; adequate time for control schools to decide whether it is worth it to participate.
        - Careful piloting of recruitment/informed consent procedures
        - Respect for the need for tight control of the randomization process
- Recommendations:
    - In your submission, explain the logistical feasibility of the research design. Demonstrate an understanding of the school's operations and how the research design would fit in.
    - Provide evidence that the school leader is likely to agree to participate in the research design. Please note, this does not mean that the principal just agrees to participate in the intervention, but that they also understand the design and agree to random assignment.
    - Explain how you will implement attentive and sensitive recruitment and implementation procedures that allow for informed consent and adherence to a randomization process.

Consider other study designs:

- Offer the intervention to the control group at the conclusion of the study.
    - If timing prevents offering the intervention to students in the control group (due to student matriculation), offer it to control schools the following year.
- Offer something equivalent to the control group (such as, access to resources, instruction, compensation, etc.).
- Delayed treatment
    - Offer the intervention or treatment condition to the control group on a delay, either later in the year, or the following year.
- Phase-in treatment
    - For example, the study is run twice within the school year, once per semester. Students or schools who did not receive the intervention in the first semester would begin receiving the intervention in the second semester.
- Rotation design
    - For example, assuming a study with two groups, one group is assigned treatment and one is control. Then those roles switch, with the previously treated becoming the control and the previously controlled becoming treated.
- Multiple treatments
    - Offer multiple treatments and test them against each other.
- Take advantage of existing randomization that occurs as part of the operations of the school system

    - For example, random selection is used in the NYC DOE student admissions process. As part of the admissions process for most DOE public school programs, each applicant is assigned a random number, as in a lottery. These random numbers are used in cases where there are more applicants than seats available at a specific program.
- Alternating treatment (combine rotating and delayed treatment)
    - Between two groups of schools, assign alternating grades to treatment/control each year, and include follow up treatment to control students in the following year.

Interruptions to instructional time

In almost all cases, research activities cannot take place during or in any way interfere with instructional or professional development time. If approved, researchers should work with school staff to find an appropriate time and location to conduct research activities.

In very rare cases, researchers may justify a proposed interruption of instructional time or required classroom activities. However, this is rarely permitted.

Research on programs, interventions, professional development, or other programs

When a research project is connected to an intervention or program, the IRB submission must carefully explain the following:

- The intervention activities
- The research activities
- If participation in research is required for participation in the intervention.
- What data would be collected for the intervention only, what data would be collected for research only, and what data would be collected for both the intervention and for research.
- Participant recruitment and consent materials must make clear what activities are part of the intervention, what activities are part of research, and if research is required for participation in the intervention.
    - If the research is not required for the intervention, the researcher may want to use two separate consent forms, one for agreeing to participate in the intervention, and another form for agreeing to the research.

In cases where participation in research is required for participation in an intervention, the Board will carefully consider the risks and benefits of the project to determine if the intervention could be offered without the research, and to ensure students/families/staff are not being denied an opportunity if they do not agree to participate in the research.

Product testing

The NYC DOE IRB does not typically approve research that is considered product testing. Research may be considered product testing if any of the following apply:

- School/site inclusion criteria are based on convenience or cost considerations for the researcher
- Subject inclusion criteria are characteristics of the market or audience where the researcher plans to market a product resulting from the research

The NYC DOE IRB may approve research that could be considered product testing if there is adequate justification for the benefits to NYC public schools, the research directly benefits NYC public schools or participants, or there is demonstrated support from the NYC DOE.

Risks and Benefits

The NYC DOE IRB takes a fairly conservative stance on risks and benefits, given that study subjects within our jurisdiction include children and their families, and these children are legally obligated to be in school. As such, the NYC DOE IRB requires researchers to thoroughly explain and justify the anticipated risks and benefits of research. The Board will consider if the risks are justified.

The NYC DOE IRB is particularly concerned about certain types of risk, including risks of:

- Psychological harm (discomfort, embarrassment, worry, anxiety)
- Physical harm
- Legal harm
- Financial harm (damage to employability, insurability)
- Social harm (damage to reputation)
- Breach of confidentiality
- Breach of subject privacy or anonymity

Note: Collection of sensitive data including subjects' religious affiliation, sexual history, drinking/drug behaviors, discipline history, mental health status, or other private information may expose participants to the above risks.

For all the risks identified, researchers must explain:

- The probability of risk (how likely is it that harm will occur)
- The magnitude of harm (how severe would harm be if it happened)

Minimal risk means the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Studies involving greater than minimal risk
[Coming soon.]

Benefits
[Coming soon.]

5.1.7 FERPA & PPRA

Please review the Data Request FAQs here for more information: https://infohub.nyced.org/working-with-the-doe/research-irb/faqs-for-external-data-requests

[More coming soon.]

5.1.8 Data Security

[Coming soon.]

5.2 Recruitment and Consent

5.2.1 Research site inclusion/exclusion criteria

Please explain in detail how you are selecting the sites for the research. School inclusion criteria such as having “a diverse student population” is not adequate. Convenience sampling is rarely approved.

5.2.2 Principal Letter -- Updated May 2024

Researchers are required to get permission from the principal in order to conduct research in a school. If research is about a school but the research activities would happen away from the school, researchers may still be required to get principal permission to do the research.

While the NYC DOE IRB may approve your study, it is still ultimately up to the principals to give permission for the research to happen in their schools. Approval by the NYC DOE IRB does not guarantee access to any particular school, individual, or data. The research PI is responsible for making appropriate contacts and getting the required permissions and consents before initiating the study.

The principal permission letter must include detailed information about the research, including:

- Research questions, design, and methodology
- Recruitment process
- Participant burden
- Confidentiality/anonymity
- Risks/benefits
- Uses of the data
- Anything needed from the school (such as, identifying a space to conduct interviews, a location to post a recruitment flyer, approval to conduct an intervention tied to the research)
- Signature line and date for the principal to give their permission to conduct research in their school, including the title of the study, protocol number, and the school name

You may discuss your research with principals before official NYC DOE IRB approval, but you may not collect the formal approval letter until your research has been approved by the NYC DOE IRB.

After you have received NYC DOE IRB approval, you may contact principals to request formal permission to conduct research in their schools. When contacting a principal to request permission to conduct research, please send the approved stamped principal permission letter along with the NYC DOE IRB stamped approval letter. Each principal agreeing to participate must sign the principal permission letter. After obtaining signed principal permissions letters, please submit an amendment to your protocol in IRB Manager attaching the signed letters.

The principal permission letter can be addressed to and signed by a site director if the site is a pre-K NYCEEC or CBO-run center.

Please note, Principal Permission is different from principal consent to participate as a research subject. Principal permission is to get permission from the principal to conduct research in their school and with their students/staff/families. Principal consent is to participate as a research subject and participate in data collection activities for the research.

5.2.3 Participant Recruitment -- Updated May 2024

Recruitment of research participants
The NYC DOE IRB has specific rules and recommendations for recruiting in schools.

In the submission form, provide a detailed description of the proposed recruitment activities. To prevent delays in review time, please explain exactly **who will be asking whom for what, where, and when?**

- Who: Who is contacting potential subjects? In what context?
- Whom: Who is being contacted as a potential subject? Are you contacting teachers first, then students?
- What: What is being asked of potential subjects? What are the steps? Take home a flyer? Click on a link? Sign a consent form? Give verbal consent? Take a consent form home? Provide information for screening?
- Where: Where are potential participants being contacted? How are they being accessed (in person, email, etc.)?
- When: When is this happening? How long do potential subjects have to consent? Do they take a flyer home and return it later? Do they consent in the moment?

The following recruitment activities are typically **not allowed**:

- Recruitment materials may not come from a person is a position of authority over the potential research subject. NYC DOE staff may not send research recruitment materials to subordinates or anyone over whom they have authority.
    - For example, researchers may not ask principals to assist them in identifying and recruiting school staff to participate in their study, since the principal has authority over school staff, and a principal recruiting for a research study may be coercive.
- Researchers may not recruit research subjects using contact information that was obtained or accessed for another purpose. NYC DOE employees or other affiliates who have proprietary access to internal email lists may not use this access for the purposes of study subject recruitment. Please note, teacher emails are rarely posted publicly, and the DOE does not typically share staff contact information externally.
    - If a DOE employee is conducting research outside of their DOE work (such as completing a dissertation), they may not use their DOE position to access email addresses.
- If another organization has collected DOE subject contact information for their own purposes separate from the research, they may not share that contact information with research staff for

recruitment. Instead, the other organization may passively forward a recruitment email to the DOE staff members, who could then reach out to the research team if they are interested.
    - For example, an organization has provided professional development to teachers and has a list of teacher email addresses collected when teachers signed up for the PD. Research was not mentioned when the teachers signed up for the PD. Later on, a research firm is interested in studying the impacts of the PD program. The PD organization may not share the teacher emails with the researchers for recruitment. Instead, the PD organization may passively forward a recruitment email from the researchers.
- Researchers may not ask participants for other people's contact information, even in the case of snowball sampling.
- Researchers cannot offer rewards to children for returning parent consent forms.

The following recruitment activities are typically allowed after approval by the NYC DOE IRB:

- With permission from the school principal, researchers may post a flyer in the school staff lounge, distribute flyers in staff mailboxes, request a meeting with school staff, or ask a staff member who is not in a position of authority to passively forward recruitment materials to school staff.
    - For example, a school office staff member may forward a recruitment email from a researcher to the teachers.
- With permission from the school principal and classroom teacher, researchers may provide recruitment materials to be sent home to families in students' backpacks.
- Provide materials with easy ways to contact the researcher to opt in to a study, such as researcher email, or flyers with a QR code that links to an interest form.
- Researchers can ask participants to passively forward information about a study to others, as long as they do not supervise or hold any authority over those people (to avoid coercion).
- After obtaining NYC DOE IRB approval for the study, researchers can recruit NYC DOE school staff using publicly available email addresses.

What does it mean to "passively forward"?

The NYC DOE IRB often recommends having someone passively forward recruitment materials, but what does this mean?

- *Forward means to send an email along to someone else without including the original sender on the message.*
- *Passively means to not add any personal message or encouragement to participate.*
    - *Messages like "FYI – research study" or a blank message would be considered passive.*
    - *Messages like "Please sign up to participate in this study! It will be an amazing opportunity for our school!" or "Review and complete the attached consent form." would be considered not passive and would not be allowed.*

How does it work?

- *A school staff member may receive an email from the researcher with information or attachments about the approved study. The staff person can then forward the email directly to other people, with a blank or passive message in the email body. Interested recipients can then reach out directly to the researcher to express interest in participating in the study.*

Notes about other recruitment methods

- Snowball sampling
    - Researchers may not ask participants for other people's contact information.
    - Researchers may ask participants to passively forward information about a study to others, as long as they do not supervise or hold any authority over those people (to avoid coercion).
- Entering schools
    - Researchers must be cleared by the NYC DOE IRB and the Office of Personnel Investigations before they can enter schools. This includes completing fingerprinting and clearing the background check.
    - Researchers must obtain approval from the school principal before entering the school to conduct recruitment or research activities.
    - Researchers must follow all school visitor policies, including COVID precautions.
    - Recruitment activities in schools must not interfere with regular school activities.
    - Any recruitment activities happening in schools must be detailed in the IRB protocol and principal permission letter.
- Accessing student roster data
    - In some cases, researchers may request student roster data in order to facilitate research recruitment. Certain studies may qualify to request roster data for screening or recruitment. However, roster data is not typically shared with external researchers. It may be shared in rare cases (such as, for federal studies with access to student data under the FERPA audit exception, or other circumstances). In order to access student roster data, the researcher must submit a data request to the NYC DOE, must qualify for a FERPA exception, and must sign an NDA.
- Accessing NYC DOE staff contact information
    - The NYC DOE and its staff cannot share staff contact information with researchers.
- Accessing publicly available contact information
    - Researchers may use publicly available contact information (such as email addresses posted on school websites) to recruit potential participants, as long as this is approved by the NYC DOE IRB and the school principal, as applicable. Researchers may use public principal emails to request permission to conduct research at their school, after NYC DOE IRB approval.
- Using social media to recruit
    - Researchers may use social media to recruit research participants. However, this recruitment must align with the following guidelines:
        - Researchers who are not doing research on behalf of the NYC DOE may <u>not</u> use DOE-managed social media accounts to recruit for research.
        - Research that is about NYC public schools, students, families, or staff must be reviewed and approved by the NYC DOE IRB, even if recruitment is not happening in schools, and would happen entirely through social media.
        - In social media recruitment posts in groups or on personal social media, researchers must identify themselves as researchers.
        - If posting in a private group, the researcher may need to obtain permission from the group moderator before posting.

- Advertising compensation in recruitment materials
    - Compensation cannot be used as a recruitment enticement. If research participants will be compensated for their participation, this may be stated on recruitment materials, but it cannot be in the title or heading of any recruitment materials. Statements in recruitment materials about the compensation must accurately describe the ways participants can receive compensation.
        - Bad example: "Sign up for this research study and receive $25!"
        - Good example: "Sign up for this research study to share your perspectives! Eligible participants who complete the survey will receive $25 for their time."
- Accessing school staff contact information from professional development sessions
    - [Coming soon.]

Researchers may not retain students' contact information for other future research projects. Researchers may retain student contact information for future contact within the same study, if this is approved in the parental consent form.

5.2.4 Participant Screening -- Updated May 2024

Screening is when you obtain information from a potential participant in order to determine if they are eligible to participate in your study. Screening activities start the moment the investigator obtains information about the prospective participant to determine if they are eligible for the research. Screening individuals to obtain and record information to determine eligibility involves obtaining identifiable private information and is considered human subjects research for research subject to 45 CFR 46.

Screening may require getting informed consent, since you are obtaining identifiable private information. You may be eligible to request a waiver of consent for screening procedures.

The NYC DOE IRB may approve a research proposal in which an investigator will obtain information for the purpose of screening, recruiting, or determining the eligibility of prospective subjects without their informed consent if either of the following conditions are met:

- The investigator will obtain information through oral or written communication with the prospective subject, or
- The investigator will obtain identifiable private information by accessing records.

Certain studies may qualify to request roster data for screening or recruitment. However, roster data is not typically shared with external researchers. It may be shared in rare cases (such as, for federal studies with access to student data under the FERPA audit exception, or other circumstances). If you plan to use roster data, you must list it in the "Study Description" section of the submission form in IRB Manager, under the question that asks about "the use or access of existing data."

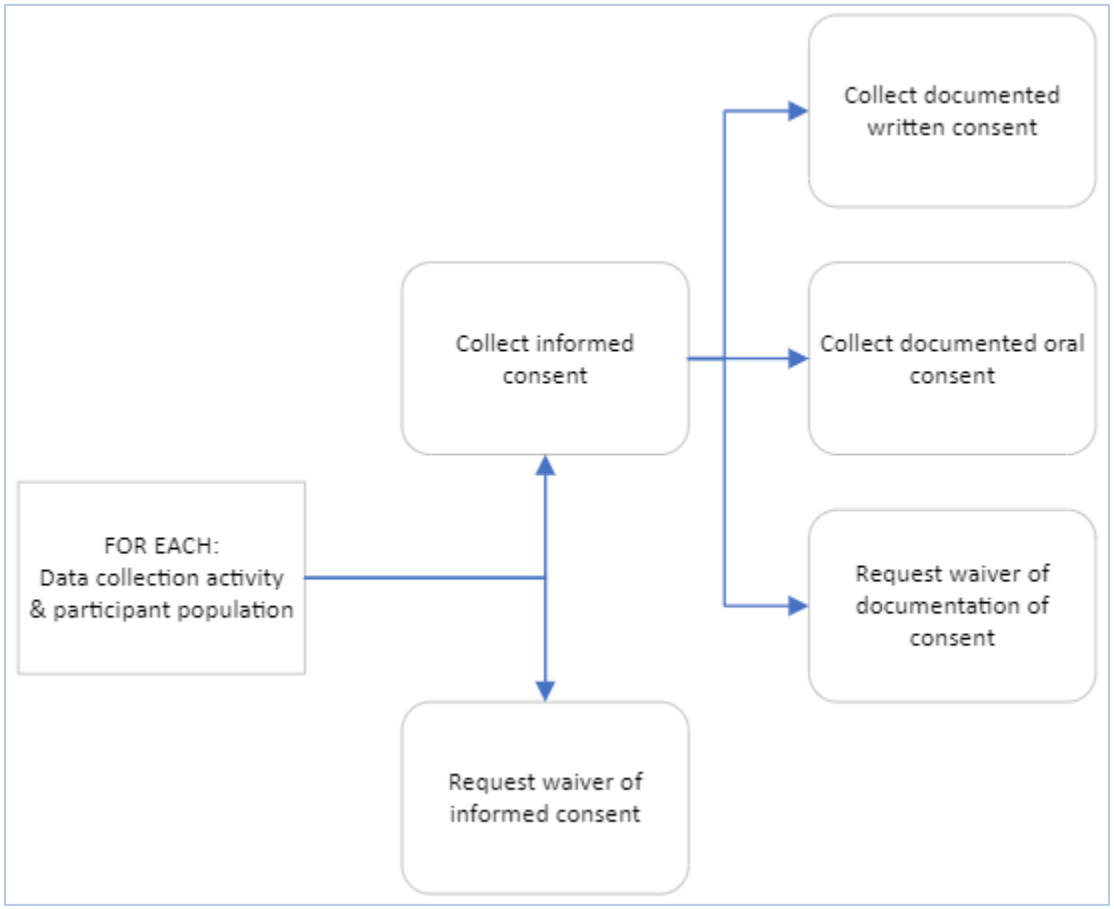
5.2.5 Participant Consent -- Updated May 2024

General consent policies

In your study proposal, you must explain your consent procedures for each data collection activity and each participant population. For each activity and population, you will need to determine the appropriate consent procedures. The NYC DOE IRB takes a conservative stance on participant consent. Even if a study is not officially human subjects research, we expect submissions to account for consent, either by collecting consent or providing a strong justification for requesting a waiver of consent.

You may collect informed consent or request a waiver of informed consent. If you are collecting informed consent, you may collect documented written consent, documented oral consent, or you may request a waiver of documentation of consent.

Consent Decision Chart:



The NYC DOE IRB requires researchers to account for specific consent and assent procedures for each research subject population. This may include collecting consent/assent or requesting a waiver. See the chart below.

Research submissions must provide the following consent/assent procedures for the following participant populations, or request waivers for each:

	Required Consent/Assent Procedures or Waiver		
Study Participants	**Adult consent**	**Parental consent**	**Child assent**
Adults	**X**		
DOE students 18 or older	**X**	**X**	
DOE students under 18		**X**	**X**

Consent Form Templates

The NYC DOE IRB provides adult and parental consent form templates with all necessary sections for researchers' use. We recommend using the DOE consent form template to ensure you include all required sections. Please modify the template as needed to reflect your study. Do not upload signed consent forms into IRB Manager.

Ensure the consent form includes contact information for both the home institution IRB and the NYC DOE IRB (IRB@schools.nyc.gov).

If you plan to audio or video record, the consent form must have a separate consent signature line specifically for recording.

If you intend to retain deidentified data for future use, include this in the consent form.

Informed Consent

Before involving a human subject in research, the researcher must obtain informed consent from the subject. The basic elements of informed consent are described in §46.116 and summarized here.

Prospective research subjects must be given the opportunity to discuss and consider whether or not to participate in the research. The consent process should minimize the possibility of coercion or undue influence. Adult and parental consent forms must be written in plain language that is understandable to the subject, and must not exceed the 8th grade reading level.

There are several ways a researcher can collect consent:

- Documented written consent – provide prospective participants with a comprehensive consent form, and the participant signs on paper or electronically
- Documented oral consent – provide prospective participants with a short form stating that elements of informed consent were presented orally, participant signs on paper or electronically, researcher must provide written summary of what is to be said to the participant
- Waiver of requirement to collect documented signed informed consent form – to qualify for a waiver, the researcher must meet IRB requirements, and must still provide a written document to participants

These methods are described in further detail below.

An IRB may waive the requirement to obtain informed consent for research if the IRB finds and documents that:

- The research involves no more than minimal risk to the subjects;
- The research could not practicably be carried out without the requested waiver or alteration;
- If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;
- The waiver or alteration will not adversely affect the rights and welfare of the subjects; **and**
- Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

Note, a waiver of parental consent for access to student administrative data is never granted. (If a FERPA exception is applicable, parental consent is not required, so would not require a waiver.)

Documented Written Consent

Most commonly, informed consent is documented on a written consent form and signed by the subject. A written copy should be provided to the subject. The full form may be read to the subject by the researcher.

Documented Oral Consent

Sometimes consent is collected orally. In this case, the researcher provides the required informed consent information to the potential subject verbally, and provides a written short form version of the consent form that is signed by the subject. In this case, a witness must be present for the verbal presentation, and must also sign the short form. A copy of the full summary of informed consent information must be provided to the subject.

Waiver of Documented Consent

The NYC DOE IRB may waive the requirement for the researcher to obtain a signed informed consent form in certain cases, if:

- The only record linking the subject and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject (or legally authorized representative) will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern;
- The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context; or
- The subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects or legally authorized representatives with a written statement regarding the research.

Electronic Consent
Researchers may choose to collect informed consent electronically. For example, a study may include an online survey, and the first page of the survey may be the consent/assent page. If you plan to collect consent electronically, consider the following.

If you are collecting documented informed consent:

- Explain how you will provide access to all the informed consent information (link to a PDF? Download a doc?)
- Clarify how you will collect subject names and signatures on the electronic platform (separate page? Virtual signature? Type in name?)
- Describe how consent information will be stored (in survey platform, other place)
- Explain if subjects' consent name/signature will be connected to other data collected for research (will consent info be connected to research data collection or not)

If you are getting informed consent, but requesting a waiver of documentation of consent:

- Explain how you will provide the opportunity to consent (such as, a statement on the first page of a survey and a checkbox saying, "I consent to participate")
- Explain how you will provide access to all the informed consent information

Adult Consent
Adult consent procedures or a request for a waiver are required for any research activities conducted with adults.

Parental Consent
Parental consent procedures or a request for a waiver are required for any research activities conducted with NYC DOE students, including students over 18. The parental consent form should be written to describe what the child will do as part of the research.

The parental consent form is different from the adult consent form. If a parent will also be a research participant themselves, they will need to sign a separate adult consent form for their own participation.

If you intend to access student administrative data and you do not qualify for a FERPA exception, you will need to collect parental consent to access this data. Ensure the consent form describes the administrative data in detail. Include a separate signature line for parents to consent to the data sharing.

If you will be using a FERPA exception to access student administrative data, do not include a signature line in the parental consent form, since this will override any FERPA exception. Instead, include an explanation that you will access student administrative data for this study through a FERPA exception, and that you are not requesting parental consent to access the data.

DOE Students over 18
For research participants who are DOE students aged 18-21, the NYC DOE IRB requires both parental consent (signed by parent/guardian) and adult consent (signed by adult student).

Child Assent
The NYC DOE IRB requires assent procedures or a request for a waiver for any participants under the age of 18. The assent procedures must explain what happens if a child chooses not to participate. Parents may not administer assent for their children. Teachers may not administer assent for students, unless they are part of the research study team. The proposal must provide a clear explanation of how the assent process will occur with children, including who will administer assent, how any questions will be addressed, and how children will provide assent.

Informational Letters
For some research procedures, a waiver of parental consent is granted, but the NYC DOE IRB requires researchers to instead distribute an information letter to parents. The information letter can include the same sections as the consent form, but would not include a signature line, or would include an opt out signature line, if required.

Consent forms for multiple research activities/populations
You may combine multiple research activities for the same participant population in a single consent/assent form, if appropriate given the study design and timeline.

If the study involves DOE students who are both under and over 18 years old, you may combine the child assent and adult consent forms. Please include two signature lines on the form – one for students 17 and under to provide assent, and one for students 18 and older to provide consent. In this case, the form must include all of the required elements for adult consent. This may not be an appropriate option if the form is also being used to collect assent from young students.

Parental consent for unaccompanied minors
While rare, sometimes unaccompanied minors are targeted for research participation. In this case, obtaining parental consent is difficult or impossible.

The federal guidance states:
"In addition to the provisions for waiver contained in §46.116 of subpart A, if the IRB determines that a research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children), it may waive the consent requirements in Subpart A of this part and paragraph (b) of this section, provided an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and provided further that the waiver is not inconsistent with federal, state, or local law. The choice of an appropriate mechanism would depend upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, status, and condition."

In these cases where it does not make sense to collect parental consent, the NYC DOE IRB may waive the requirement, as long as appropriate considerations and protections are in place. These considerations and protections might be, ensuring the nature of the research activities are low risk, considering the child's maturity to provide assent, or ensuring a trained assent monitor is in place for any child assent

process where there is no parental consent. The basic idea is to ensure children are not coerced into participation, are able to make an informed decision about participation, feel empowered to consent or decline, feel comfortable reporting concerns, and are adequately protected from harm throughout the research.

In the research proposal, the submission would request a waiver of parental consent for these students specifically, and then explain how the researcher would protect those children throughout the process.

5.3 Interactions with Research Subjects

5.3.1 Asking children sensitive questions

The NYC DOE IRB pays careful attention to protecting our students. The following types of questions are considered sensitive, and are typically reviewed with extra scrutiny by the Board. If research intends to ask about these sensitive topics, researchers must provide substantial justification for why it is necessary, and how they will be protecting this information. In many cases, asking about these topics is not allowed.

The NYC DOE IRB typically does not allow these types of sensitive questions:

- Place of birth (of child, or family members)
- Immigration status
- Address
- Questions with answers that could lead to potential incrimination (such as, asking about illegal behaviors)
- Questions with answers that could trigger mandated reporting (such as, asking about violence in the home)

The following questions are allowed, but with the following recommendations:

- Gender (recommend having inclusive, non-binary options)
- Parent/guardian information (recommend having inclusive, non-binary options, instead of "Mother" and "Father")

5.3.2 Procedures for conducting school or classroom observations -- Updated May 2024

School Observations

Requests to conduct school observations (such as school walkthroughs, building observations, etc.) require NYC DOE IRB approval, and are considered on a case-by-case basis. IRB submissions must include a clear justification for the school observation and a detailed protocol or description of what will be observed. In some cases, it may be necessary to provide a parent/student information letter to inform students and families about the presence of researchers in the school conducting observations. Recording of school observations is rarely approved. After DOE approval, the researcher must work with

the school principal to determine additional requirements for a school walkthrough (such as, who would escort the researcher, where they are allowed to go, etc.).

Classroom Observations and Consent

In reviews and determinations, the DOE IRB has typically considered any observations in schools (including classrooms, hallways, meetings) as private and subject to requirements for consent. There may be some specific situations that would be considered public (such as public meetings or events occurring in a school building) where we might not require active consent. That said, the DOE IRB often applies additional requirements depending on the details of the study.

The DOE IRB usually takes a fairly conservative approach to observations happening in schools, and we typically require some sort of consent or notification for observations.

Typically, for classroom observations where the students are not the subjects of the observation, we require active teacher consent, approve a waiver of parental consent for students, and require an informational letter to be sent home to parents informing them of the observation. If the observation entails additional sensitivity or risk (perhaps a sensitive subject area, or an especially vulnerable population), we ask the researcher to send an opt out informational letter to parents so they can opt their child out of the observation if they wish.

For classroom observations where students are the focus, in addition to teacher consent, we require active parental consent and student assent for all students in the classroom, since it is unrealistic for a researcher to keep track of consented and unconsented students in a classroom observation.

As an alternative, due to the applicability of §46.117(c)(1)(ii) (that the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context), researchers may request a waiver of parental consent for students' participation in the classroom observations. Approval of this waiver is contingent upon the following:

- To comply with the waiver requirements of minimal risk, the researcher must clarify how the observation protocol will ensure no identifiable data is collected about students.
- The researcher may not interact with students in the classroom.
- The researcher must provide and distribute a parent information letter describing the classroom observations (and include an opt out option, if applicable, as described above).
- Classroom observations may not be audio or video recorded.

If the researcher wants to audio record the observation, the DOE IRB has stricter rules. For observations of classroom activities that are interactive (where students are expected to be talking, and where it is likely student voices will be captured in the audio recording), we ask the researcher to either explain how they will avoid capturing student voices in the recording, or obtain active parental consent and student assent for all students in the classroom, along with teacher consent. If the observation will just capture a teacher's instruction (where it is not expected that students will be talking much), the board may approve a waiver of parental consent with an informational letter for parents (with an opt out option as appropriate), along with teacher consent. We rarely allow video recording of students.

In cases where there are co-teachers in a classroom, both teachers must give consent for classroom observations, even if just one teacher is the focus of the study.

Consent Requirements for Classroom Observations

		Consent Requirements		
Type of Observation	Audio recorded?*	Teacher consent	Parental Consent	Student Assent
Classroom observation of **teacher instruction only** (students are not subjects of observation)	No or Yes	**Required**	Eligible for waiver Info letter required	Optional
Classroom observation of **teacher instruction and student behaviors** (student words/actions will be captured in observation notes or recordings)	No	**Required**	Eligible for waiver, but must prove minimal risk Info letter required	Optional
	Yes	**Required**	**Required**	**Required**

*Video recording is rarely approved, and only approved under special circumstances.

5.3.3 Conducting Focus Groups -- Updated May 2024

The NYC DOE IRB recommends using the following procedures when conducting focus groups:

- The focus group protocol should begin by setting expectations or norms for participants, including:
    - Do not share specific names or identifying information that could identify any students or other non-participants.
    - Do not share specific details that would break the confidentiality of students or other non-participants.
    - Do should not take screenshots or record the focus group activity.
    - Information shared in this focus group is meant for the participants and researchers only. Please do not share information from the focus group conversation with others who were not part of the group.
    - Participate in the focus group from a quiet and private place. If you cannot be in a private space, please wear headphones to avoid unintentionally sharing information with others in the space who are not a part of the focus group.
- Prior to starting any recording, ask for additional verbal consent for recording focus groups, even if you already collected documented consent that included consent for recording.

5.3.4 Conducting Interviews -- Updated May 2024

Prior to starting any recording, ask for additional verbal consent for recording interviews, even if you already collected documented consent that included consent for recording.

5.3.5 Collecting artifacts

Some studies request access to artifacts, such as student work, teacher lesson plans, or agendas from professional learning sessions. Student work is protected under FERPA, so would require parental permission or a FERPA exception to access for research purposes. Requests to collect artifacts containing identifiable information are reviewed on a case-by-case basis.

Requests to collect artifacts that do not include identifiable information or student work are typically allowed (for example, teacher lesson plans, professional development agenda), but must be explained in the submission. This explanation must include specific details of what would be collected and how it would be used or analyzed to answer the research questions.

5.3.6 Collecting data from educational applications -- Updated May 2024

Studies that intend to use data collected from students or school staff from third party applications or websites used in the classroom must include a detailed description of this data in the NYC DOE IRB submission form. This data collection may include:

- Data entered into an app for the app to function (username, grade level)
- Data collected by the app through students' interaction (usage time, progress, screen capture)
- Assessments conducted in the app
- Data collected for app functionality (responsive lessons)

A detailed description of this data use must be included in the IRB application, even if it is data the submitter has access to already.

Please note, all vendors of third-party software are required to complete the DOE's compliance process and OTI's cloud review process before conducting business with the DOE. See more information here: Data Privacy and Security Compliance Process (nyced.org)

5.3.7 Collecting any medical or biometric data

With rare exceptions, the DOE does not allow collection of medical or biometrics data from students, including blood pressure, finger stick blood tests, fit bits, pedometers, etc. In rare cases, the NYC DOE IRB has approved collection of student height and weight with adequate justification, parent consent, and explicit considerations for student privacy.

5.3.8 Recording (audio, video, photography)

Recording may include audio, video, photographic or other recording of research subjects for the purposes of data collection for research or evaluation. Recording the voice and/or image of an individual creates a type of record that requires unique handling and storage, particularly if the content may be considered sensitive. As with all research procedures, the dignity of human subjects should be respected. Therefore, only what is necessary for the purpose of the study should be recorded. Research subjects must be informed prospectively that such recording will occur, and be provided with information about the storage, confidentiality, and future use of the resulting tape or digital record.

Requirements for Submissions Requesting Recording

If a research protocol involves the recording of research subjects, the study team must include the following elements in their protocol and associated materials for IRB review:

- The type of recording (e.g. video, photo, audio, etc.), that will be utilized.
- Specific identifiers that will be recorded, either intentionally or not (e.g., partial facial features, full facial features, subject's name).
- People who will have access to the recording(s).
- Mechanisms in place to protect the privacy of the person(s) being recorded (e.g. blurring faces, explicitly not recording full facial features or other direct or indirect identifiers, not audio-recording names or other identifying information, etc.).
- Clear indication of when the recording(s) will be destroyed or that recording(s) will be kept indefinitely/specified duration.
- Use(s) of the recording(s), including educational or commercial purposes, analysis by the research team, or future unspecified use or sharing.
- Compensation, if any, to subjects for allowing themselves to be taped.

NYC DOE IRB Policies on Recording

The NYC DOE IRB applies additional consideration to proposed recording of children/minors, parents, DOE staff, or recordings in a school.

- **Video recording** for research purposes is not generally permitted, with some very limited exceptions that are made on a case-by-case basis.
- **Audio recording** is permitted, but requires explicit documented consent from all adult participants, documented (age permitting) assent from the child, and documented parental permission. Please see the section above on classroom observations for consent requirements for classroom observations.
- **Photographing** for research purposes is considered on a case-by-case basis. Photographs that include full facial features are not generally permitted. Photographs of student work require prospective FERPA authorization through parental permission, or qualification for a FERPA exception.
- **Recording virtual interactions** (such as over Zoom or Microsoft Teams) is allowed, following the same consent requirements and policies detailed above. Additionally, submissions must explain the steps taken to ensure the protection of recordings. When recording using a virtual telecommunication tool or platform, the submission will need to explain where the recording would be stored and if it would stored/owned/used by the tool/platform. The NYC DOE IRB recommends using institutionally licensed versions of tools/platforms since they usually have more robust data security protection measures in place.

In general, recordings should be protected using the same data security procedures as other data collected, including secure storage using password protection and encryption, and secure data transmission. See Data Security section for more information [coming soon].

Include Recording in the Consent Form
If recording is an integral part of the research and not an optional procedure, a separate informed consent document is not required. However, documentation of the considerations listed above must be included within the body of the informed consent document for the overall study. It is important that this information be clearly stated, preferably preceded by a heading, so that it is clear to the subject that a recording will be made.

If the recording is not required as part of the research procedures, then the consent document must include a specific statement indicating that participation in the research study is not contingent upon agreeing to be recorded. A separate consent signature for permission to record will be necessary and must be included within the body of the informed consent document. The DOE consent form templates include this separate recording signature section for reference.

Additional Circumstances

- Some studies request that teachers record themselves teaching and submit this recording to researchers. These requests are reviewed on a case-by-case basis. In reviewing these requests, the Board looks at if teacher would provide consent, the burden on teachers, if student voices would be captured in the recording, the sensitivity of the content, if the recording would be video or just audio, and the details of the described procedures for recording and submitting (where would the recording device be located, what platform would be used for teachers to submit recordings, etc.).

Transcription services
[Coming soon]

5.3.9 Compensation for research -- Updated May 2024

The NYC DOE has specific policies pertaining to study subject compensation.

DOE Personnel Compensation

- NYC Conflicts of Interest Rules prohibit teachers and other NYC DOE staff from receiving compensation in exchange for participation in research studies. Compensation/gifts that benefit the entire school may be donated directly to the school.
- Researchers may no longer contribute to a specific teacher or classroom. Contributions must be made to the school.
- Compensation can be in the form of gift cards given to the school or funds deposited into the school's bank account. Compensation for research must be used in alignment with the school's standard operating procedures. Any compensation of $10,000 or more must go through the NYC Fund for Public Schools.
- Anything purchased by the school using funds received through research compensation belongs to the school. Individual school staff who participated in the research activities cannot be directly compensated, and items purchased using research compensation funds do not belong to any individual staff members.

- Exceptions to this policy are extremely rare and securing a waiver can be a lengthy process requiring a thorough review by the DOE Ethics Officer, the NYC Conflicts of Interest Board and, ultimately, the Office of the Schools Chancellor.
- Some DOE programs, especially Universal Pre-K programs, are located in Community-Based Organizations (CBOs). CBO staff are not members of the United Federation of Teachers and are not salaried DOE employees. Researchers conducting studies in CBOs should check with the CBO's leadership to determine whether staff in their facility can be compensated for participating in research.

Quid Pro Quo Compensation

- Compensation cannot be offered to schools on a quid pro quo basis, meaning the amount of compensation cannot be tied to the amount of research participation by the school. Quid pro quo compensation has the potential to compromise the voluntariness of the schools or individual research subjects' participation in the study.
- The following examples would be considered quid pro quo compensation and would not be allowed:
    - Basing the amount of a school donation on the number of teachers who agree to participate in the research.
    - Donating more to a school if teachers complete more data collection surveys.

Student Compensation

- Gifts may be given to students for their participation. For elementary school students, stickers, pens, or gift cards not to exceed $15 is allowed. For middle and high school students, the value of the incentive should not exceed $25. Amounts beyond this could be coercive. Requests to compensate more than these amounts are reviewed on a case-by-case basis.

Parent Compensation

- Compensation for parents/guardians can be based on the number of hours required for their participation in the research (for interviews, and focus groups) or per completed research activity (e.g., survey, interview) where the amount of time involved might vary depending on the type and number of research activities requested of parents. Compensation should not involve a sum of money that would be perceived as coercive (as determined during IRB review).

Other notes on compensation

- Compensation may be monetary or non-monetary in nature. Reimbursement for out-of-pocket expenses is not considered compensation and, if applicable, should be described separately in the protocol and consent document.
- Research proposals will need to describe when and where study subjects will be compensated and detail the mechanisms that will be in place to ensure study subject privacy when distributing compensation.
- Research proposals may need to describe how participants will be compensated if they withdraw from the research.

    - For example, explain if study subjects will be compensated for completing half of the proposed research procedures and specify how much they will receive for partial or incomplete participation.
- Raffles are not appropriate methods of compensation.

How the Board reviews compensation procedures

The NYC DOE IRB considers the following when reviewing plans for compensating individual participants who are not DOE employees:

- Compensation must be fair, given the amount of time and effort participants must give to the research activities. Submissions may provide justification for the proposed amount of compensation.
- If the amount of compensation varies, the method for calculating the amount of compensation must be explained in the protocol and explained to participants.
- The timeframe and amount of compensation must be made clear to participants. If compensation is connected to completion of research activities, or distributed in phases, this must be clearly explained.

The NYC DOE IRB considers the following when reviewing plans for compensating schools:

- Compensation is distributed directly to the school.
- Compensation is not based on the amount of research participation in the school (such as, compensation based on the number of teachers who fill out a survey).
- Compensation may be based on the number of potential participants.
- The amount of school compensation must be clearly explained in the Principal Permission letter.
- If the amount of compensation varies, the method for calculating the amount of compensation must be explained in the protocol and explained to school principals.

Compensation Procedures

In the submission to the NYC DOE IRB, the researcher must clearly explain how any compensation will be distributed. If compensation will be distributed in person, this process must be explained. If compensation will be distributed electronically, this process must be explained, and the researcher must explain how they will collect any participant contact information, if that contact information will be connected with any research data, how the researcher will keep contact information collected for research separate from any research data (if applicable), and if they will keep the contact information for any other purposes.

5.3.10 Deception or Non-Disclosure -- Updated May 2024

Some research studies use deception or non-disclosure as part of the research procedures. The NYC DOE IRB rarely approves of deception in a research study in our jurisdiction. Use of deception in research with students is not likely to be approved. Certain types of deception in research with adults might be used when there is no other way to obtain unbiased data from respondents and when the benefits far outweigh the risks.

Use of deception requires a detailed debriefing protocol to be used with respondents at the conclusion of their participation in the research, when they are informed that deception was used. A debriefing script must be attached for IRB review as a study instrument.

Deception relating to guarantees of confidentiality or anonymity for research participants is never permitted. It is up to the discretion of the NYC DOE IRB to determine whether deception or non-disclosure is appropriate.

6. Appendices

6.1 Definitions

- *Human subjects*: 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.
- *Research*: A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.
- *NYC DOE schools or affiliates*: This includes any students, school-based staff, non-school-based staff, parents recruited through the schools, or other NYC DOE affiliates as determined by the NYC DOE IRB.

6.2 CITI Training Requirements

NYC DOE CITI Course Requirement

- Social & Behavioral Research (ID: 184110)
- Required Modules: 26
    - Conflicts of Interest in Human Subjects Research (ID: 17464)
    - Students in Research (ID: 1321)
    - Unanticipated Problems and Reporting Requirements in Social and Behavioral Research (ID: 14928)
    - History and Ethical Principles - SBE (ID: 490)
    - Defining Research with Human Subjects - SBE (ID: 491)
    - The Federal Regulations - SBE (ID: 502)
    - Assessing Risk - SBE (ID: 503)
    - Informed Consent - SBE (ID: 504)
    - Privacy and Confidentiality - SBE (ID: 505)
    - Vulnerable Subjects - Research Involving Workers/Employees (ID: 483)
    - Populations in Research Requiring Additional Considerations and/or Protections (ID: 16680)
    - Research with Children - SBE (ID: 507)
    - Research in Public Elementary and Secondary Schools - SBE (ID: 508)
    - Internet-Based Research - SBE (ID: 510)
    - Consent and Subject Recruitment Challenges: Remuneration (ID: 16881)
    - Consent Tools Used by Researchers (ID: 16944)
    - Introduction To Community-Engaged Research (CEnR) (ID: 16994)
    - Introduction to Community-Based Participatory Research (CBPR) (ID: 16995)
    - Ethical and Practical Considerations in Community-Engaged Research (CEnR) (ID: 16996)
    - Consent in the 21st Century (ID: 17060)
    - Consent with Subjects Who Do Not Speak English (ID: 17260)
    - Consent and Cultural Competence (ID: 17263)
    - Belmont Report and Its Principles (ID: 1127)

    - Research with Persons who are Socially or Economically Disadvantaged (ID: 16539)
    - Illegal Activities or Undocumented Status in Human Research (ID: 16656)
    - Cultural Competence in Research (ID: 15166)
- Optional Modules
    - Humanitarian Use Devices (HUDs) (ID: 16306)
    - Research with Older Adults (ID: 16502)
    - Research and HIPAA Privacy Protections (ID: 14)
    - Research with Subjects with Physical Disabilities & Impairments (ID: 16657)
    - Research Involving Subjects at the End-of-Life (ID: 16658)
    - Ethical and Appropriate Uses of Administrative Data for Research and Evaluation (ID: 19826)
    - The IRB Administrator's Responsibilities (ID: 13813)
    - Gender and Sexuality Diversity (GSD) in Human Research (ID: 16556)
    - Research with Critically Ill Subjects (ID: 16592)
    - Research with Decisionally Impaired Subjects (ID: 16610)
    - External IRB Review (ID: 16711)
    - Phase I Research: Understanding Phase I Research (ID: 16873)
    - Phase I Research: Protecting Phase I Subjects (ID: 16874)
    - Informed Consent and Incidental Findings in Research with Human Subjects (ID: 17342)
    - Overview of the Clinical Trial Agreement (CTA) (ID: 17356)
    - Understanding the Terms of the Clinical Trial Agreement (CTA) (ID: 17357)
    - Role of the Researcher and Site in Managing the Clinical Trial Agreement (CTA) (ID: 17358)
    - Clinical Trial Agreement (CTA) Negotiation for Researchers and Sites (ID: 17359)
    - Disaster and Conflict Research, Part 1: PI Responsibilities (ID: 17384)
    - Disaster and Conflict Research, Part 2: Best Practices and Recommendations (ID: 17385)
    - Single Institutional Review Board (sIRB) Use and Administration: When Relying on a sIRB (ID: 17387)
    - Single Institutional Review Board (sIRB) Use and Administration: When Serving as a sIRB of Record (ID: 17388)
    - Single Institutional Review Board (sIRB) Use and Administration: Authorization Agreements (ID: 17392)
    - Consent and Biobanks and Associated Databases (ID: 17254)
    - Consent and Subject Recruitment Challenges: Therapeutic Misconception (ID: 17259)
    - The IRB Member Module - 'What Every New IRB Member Needs to Know' (ID: 816)
    - International Research - SBE (ID: 509)
    - I Have Agreed to be an IRB Community Member. Now What? (ID: 13018)
    - Hot Topics (ID: 487)
    - Research with Prisoners - SBE (ID: 506)

6.3 Guidance for DOE students completing research -- Updated May 2024

While the NYC DOE IRB does not review or approve research conducted by DOE students, the DOE IRB has developed basic guidelines to assist schools overseeing student research and data collection. These guidelines embody many of the federal regulations governing research with human subjects as well as policies and procedures that reflect the jurisdictional concerns of the NYC DOE. These guidelines are recommendations, and the DOE IRB does not review or approve research conducted by DOE students.

- Students may conduct research with other students in their own school or at other schools, provided that they submit a research proposal to their teacher outlining:
    - the research topic
    - design/methodology
    - risks/benefits
    - measures that will be taken to protect the privacy and confidentiality of research participants
    - who will have access to the data
    - how the research findings will be used
- Students conducting research with other students must make it clear that participation is voluntary, and participants can withdraw at any time or chose not to answer any questions.
- Students conducting classroom observations should obtain the consent of the classroom teacher(s). Data collection should not distract from classroom instructional time.
- Survey instruments should include a check box for students to indicate they have agreed to be surveyed, thus protecting the anonymity of respondents. When a research project involves a pre- and post-test, a list of the names of respondents to the pre-test and the research ID numbers assigned to them should be stored in a secure location. After the post-test, all names should be removed from survey instruments and replaced with research ID numbers.
- For projects including interviews or focus groups, student researchers should provide an assent form (for students 17 and under) or consent form (for students 18 and over) to be signed and dated by the research participant.
- On any transcripts of interview or focus groups, names of student participants should be replaced with research ID numbers to ensure the privacy and confidentiality of participants.
- Interviews and focus groups may be audiotaped with the permission of participants.
- Videotaping public school students for research purposes is prohibited by DOE policy.
- All data collected from research participants should be reported anonymously.
- Student researchers should refrain from collecting information that might expose study participants to (1) psychological risk such as discomfort, embarrassment, worry or anxiety; (2) social risk such as damage to reputation; (3) risk of breach of confidentiality or anonymity.
    - Examples of this type of information would be religious affiliation, sexual identity and behaviors, use of alcohol, drugs, illegal behaviors, and other information that might be self-incriminating.
- Student researchers should not use deception in recruiting other students to participate in their research. The purpose of the research should be clearly stated.
- Teachers and students should ensure that all hard copy and electronic data are securely stored to prevent unauthorized access, disclosure, or loss. Hard copy records should be stored in a manner that limits access to only authorized individuals. For example, filing cabinets/areas should be locked and placed in secured/locked rooms.