Use this IRB Review Application if **your study is minimal risk and qualifies under exempt category 1**:

 Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students’ opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

**Stop. This form cannot be completed if:**

* Your study does not satisfy the above criteria.Please complete the [SBER and Records IRA](https://research.weill.cornell.edu/sites/default/files/irb_review_application_-_sber_and_records.docx).
* Your study is collecting information from a participant’s medical record, information pertaining to illegal conduct, or information that could be damaging to an individual’s financial standing, employability, and/or reputation. Please complete the [SBER and Records IRA](https://research.weill.cornell.edu/sites/default/files/irb_review_application_-_sber_and_records.docx).

First time users of this form are encouraged to set-up a walkthrough [consultation with the IRB](https://weillcornell.az1.qualtrics.com/jfe/form/SV_8B8nCOcC8q7pUN0). Contact irb@med.cornell.edu or hrpo@med.cornell.edu with any questions.

\* **Please note**:

* Use and submission of this version of the IRA attests that the information provided is accurate and the proposed activities below will not deviate in formal implementation.
* Procedures beyond those detailed below are not the only options available to you but may warrant use of a different IRA.  The IRB recommends setting up an [IRB Consultation](https://weillcornell.az1.qualtrics.com/jfe/form/SV_8B8nCOcC8q7pUN0) to discuss and determine the best way forward.

|  |  |
| --- | --- |
| Title: |  |
| Version Date: |  |
| Funding Source(s): |  |
| Principal Investigator: |  |
| Study Sponsor: |  |
| Participating Sites/Collaborators: |  |
| **IRB (WRG number):** |  |

## Background/Purpose/Study Aims:

Briefly and clearly state the overall purpose of the study in a few sentences.

Provide a non-technical explanation in lay terms to justify why the research needs to be done and what its relevance will be (generally this section should not be longer than a couple paragraphs). Describe the relevant prior scientific or scholarly literature and gaps in current knowledge. If applicable, describe any relevant preliminary data. Include references at the end of this protocol.

Specifically describe how the research is standard educational practice and not likely to adversely impact students’ opportunities to learn required educational content or the assessment of educators who provide instruction (e.g., educational experiences that trainees would otherwise undergo, regardless of whether research is being conducted. This includes but is not limited to didactic instruction, small group educational activities like problem-based learning groups, simulation, and clinical learning experiences in the inpatient or outpatient setting). If the research is a non-standard practice and/or will adversely impact the students’ opportunities to learn or the assessment of educators, please complete the SBER and Records IRA.

List research objectives or specific aims.

## Study Population:

Describe the participant population such as age range, gender, and ethnic background (~1-2 sentences). Include your targeted sample size. List the inclusion/exclusion criteria (characteristics that people must have to be included in or excluded from participating in the research). If there are any age, ethnic, language, or gender-based exclusion criteria, provide a justification. Justify the inclusion/exclusion of vulnerable populations.

|  |  |  |
| --- | --- | --- |
| Population | Included/Excluded? | Justification |
| Adults unable to consent | [ ]  Included [ ]  Excluded |  |
| Individuals who are not yet adults (infants, children, teenagers) | [ ]  Included [ ]  Excluded |  |
| Pregnant women | [ ]  Included [ ]  Excluded |  |
| Prisoners | [ ]  Included [ ]  Excluded |  |
| Adults with diminished capacity to consent | [ ]  Included [ ]  Excluded |  |
| Individuals who are not able to clearly understand English | [ ]  Included [ ]  Excluded |  |

## Vulnerable Populations:

Explain why vulnerable populations need to be included in this research. Reference IRB policies for information about various populations. Vulnerable populations include but are not limited to: pregnant women; those who lack consent capacity, including the mentally ill; prisoners; cognitively impaired participants; children; and employees.

## Recruitment Process:

Describe the plan (when, where, how) to identify potential participants, including database review and data sources if applicable. Specify if any advertising/recruitment materials will be used, including verbal/electronic announcement of the research. Upload recruitment material(s) as supporting documents with your submission. Summarize how you will minimize undue influence/coercion.

## Informed Consent Process (if obtaining consent):

Describe the process (when, where, how, who) for obtaining informed consent including considerations for privacy. If research involves minors, describe the assent process (when, where, who) and how guardian permission will be obtained. Outline the steps taken to avoid coercion and indicate how consent will be documented. If applicable, describe how participant comprehension will be ensured and the process to determine whether an individual is capable of consent. Describe plans, if applicable, to use a legally authorized representative. If the research involves adults with diminished capacity to consent, explain how their agreement to participate will be obtained and documented. If the study includes obtaining consent electronically, explain the process and system to be used. Upload all consent/assent documents/scripts as separate word document(s) with your submission.

## Data Collection Procedures:

Provide a thorough description of all project procedures, data sources, interventions, assessments, and participant activities in a sequential format. Describe how information will be captured (e.g., audio or video recorded, observations, note taking, computer task, etc.).

## Study Duration/ Study Timeline:

Note the expected number and duration of contacts/meetings/procedures, time commitment for participants, and include an approximate end date of the study (including data analysis).

## Study Locations:

Specifically describe the established or commonly accepted educational setting (note, if it is not an established nor commonly accepted educational setting, please complete the [SBER and Records IRA](https://research.weill.cornell.edu/sites/default/files/irb_review_application_-_sber_and_records.docx)). Include any external sites or any affiliated sites taking part in the research (sites with an [existing reliance agreement](https://research.weill.cornell.edu/compliance/human-subjects-research/institutional-review-board/human-research-compliance/single-irb)). Upload Letter(s) of Support with your submission.

If you will be receiving/sending data to and from another institution, indicate which institution.

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| --- | --- | --- |
| Name of External Site | Responsible IRB*i.e., Site’s local IRB; WCM IRB; Note engaged in research* | Site Role*i.e., recruitment, protocol dictated procedure including consenting, sending/receiving identifiable data and/or specimens, etc.* |
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| --- | --- | --- | --- |
| Name of Affiliated Site | Included/Excluded? | Responsible IRB *i.e., Site’s local IRB; WCM IRB; Note engaged in research* | Site Role*i.e., recruitment, protocol dictated procedure including consenting, etc.* |
| Columbia | [ ]  Included [ ]  Excluded |  |  |
| Cornell Ithaca | [ ]  Included [ ]  Excluded |  |  |
| Cornell Tech | [ ]  Included [ ]  Excluded |  |  |
| CUNY Hunter College | [ ]  Included [ ]  Excluded |  |  |
| Gracie Square | [ ]  Included [ ]  Excluded |  |  |
| Hospital for Special Surgery (HSS) | [ ]  Included [ ]  Excluded |  |  |
| Memorial Sloan Kettering Cancer Center (MSKCC) | [ ]  Included [ ]  Excluded |  |  |
| New York State Psychiatric Institute (NYSPI) | [ ]  Included [ ]  Excluded |  |  |
| NYP-Brooklyn Methodist Hospital (BMH) | [ ]  Included [ ]  Excluded |  |  |
| NYP-Queens | [ ]  Included [ ]  Excluded |  |  |
| Park Terrace Care Center | [ ]  Included [ ]  Excluded |  |  |
| Rockefeller | [ ]  Included [ ]  Excluded |  |  |
| Rogosin | [ ]  Included [ ]  Excluded |  |  |

## Participant Compensation:

Describe any compensation to participants (financial and nonfinancial), including amounts and payment schedule (class credit, merchandise cards, transportation expenses, cash, check, etc.). Include the timing of such compensation in relation to study activities as well as who will receive the incentive.

## Risk to Participants:

State any reasonably foreseeable risks (e.g. psychological, physical, social, economic, or legal), discomforts, hazards, or inconveniences related to participation in the research and assess their likelihood and seriousness. Include how these risks will be minimized. If applicable, describe risks to others who are not participants.

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| --- | --- |
| **Risk:** |  |
| Probability: | [ ]  Highly probable [ ]  Somewhat probable[ ]  Unlikely [ ]  Highly unlikely | Magnitude: | [ ]  Life-threatening/disabling (Grade 4) [ ]  Severe and undesirable (Grade 3)[ ]  Moderate (Grade 2)[ ]  Mild (Grade 1) |
| Mitigation Plan: |  |
| **Risk:** |  |
| Probability: | [ ]  Highly probable [ ]  Somewhat probable[ ]  Unlikely [ ]  Highly unlikely | Magnitude: | [ ]  Life-threatening/disabling (Grade 4) [ ]  Severe and undesirable (Grade 3)[ ]  Moderate (Grade 2)[ ]  Mild (Grade 1) |
| Mitigation Plan: |  |
| **Risk:** |  |
| Probability: | [ ]  Highly probable [ ]  Somewhat probable[ ]  Unlikely [ ]  Highly unlikely | Magnitude: | [ ]  Life-threatening/disabling (Grade 4) [ ]  Severe and undesirable (Grade 3)[ ]  Moderate (Grade 2)[ ]  Mild (Grade 1) |
| Mitigation Plan: |  |
| **Risk:** |  |
| Probability: | [ ]  Highly probable [ ]  Somewhat probable[ ]  Unlikely [ ]  Highly unlikely | Magnitude: | [ ]  Life-threatening/disabling (Grade 4) [ ]  Severe and undesirable (Grade 3)[ ]  Moderate (Grade 2)[ ]  Mild (Grade 1) |
| Mitigation Plan: |  |
| **Risk:** |  |
| Probability: | [ ]  Highly probable [ ]  Somewhat probable[ ]  Unlikely [ ]  Highly unlikely | Magnitude: | [ ]  Life-threatening/disabling (Grade 4) [ ]  Severe and undesirable (Grade 3)[ ]  Moderate (Grade 2)[ ]  Mild (Grade 1) |
| Mitigation Plan: |  |

## Benefits to Participants:

Describe the potential benefits to individual participants from joining the research (state if there are no direct benefits to participants) or benefits to the overall research field. (Sample text: This research does not present any direct benefit to the participants. However, the research provides an opportunity to gain a better understanding of…)

## Privacy of Participants:

Privacy refers to an individual and their right in controlling the extent, timing, and circumstances of access of others to themselves. Individuals have greater concerns about privacy whenever the requested information is of a sensitive nature. Describe procedures to protect participants’ privacy including privacy considerations during recruitment, informed consent if applicable, and data collection (such as access to private rooms, closed doors, etc.). Describe the setting in which the participant will be interacting with a researcher. Indicate how the research team is permitted to access any sources of information about the participants.

## Data Management and Confidentiality:

Describe what will happen with data (electronic, paper, recordings, etc.) from the time it is collected until the data are permanently de-identified (no ability to link an individual to his/her/their data) or destroyed, if applicable. Describe who will have access to the data, how data will be handled/maintained securely, and process for transmission of data. Explain how researchers will ensure the protection of data against unauthorized disclosure. Describe how the confidentiality of project data will be maintained. Specify what identifiers and information will be included or associated with the data and who will maintain identifiers. Also, describe when and how data will be destroyed as well as how data will be handled if the participant withdraws from the study.

Considerations for securely storing data include:

* Paper records are locked in a secure location.
* Electronic records are stored on password protected or encrypted computer as appropriate based on sensitivity of data.
* Identifiers are stored separately from project data.
* For identifiable data, a coding process will be used to store data without identifiers, the link stored separately from all other project records.

## References:

List all the references used in the background section.

Endnote and Reference Manager are the software tools for publishing and managing bibliographies and are used frequently for citations and managing your own libraries.