Use this IRB Review Application if you have completed the [Therapeutic Studies JCTO Protocol template](https://jcto.weill.cornell.edu/system/files/download/intranet_only/iit_protocol_template_-_therapeutic_drug-device_v3_final.docx) and/or have a study which will use a device/drug or implement a clinical trial. If you are initiating a biorepository, complete the IRB Review Application – Biorepository. Please delete the instructions and sample text after you complete each section. Do not delete the section headings; if the heading does not relate to your research insert N/A.

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.

You may also view the [Therapeutic JCTO Protocol Guidance Document](https://research.weill.cornell.edu/files/guidance-irbreviewapplication-therapeuticjctoprotocolguidancedocx) for additional information to assist with completing this application.

|  |  |
| --- | --- |
| Title: |  |
| Version Date: |  |
| Funding Source(s): |  |
| Principal Investigator: |  |
| Study Sponsor: |  |
| IND/IDE Number: |  |
| 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. Describe the relevant prior scientific or scholarly literature and gaps in current knowledge. Provide the scientific or scholarly background for, rationale for, and significance of the research based on the existing literature and how will it add to existing knowledge. If applicable, describe any relevant preliminary data. Include references at the end of this protocol.

List research objectives, specific aims, and state the hypotheses to be tested.

Describe the primary and secondary endpoints, including safety endpoints.

## Study Population:

Describe the participant population such as age range, gender, and ethnic background. List the inclusion/exclusion criteria (characteristics that people must have to be included in or excluded from participating in the research). Justify the reasons for exclusions. Note that if you have inclusion/exclusion criteria, please explain the screening process in the Screening Procedures section. If your study is aimed at addressing issues that affect a certain community or group, set-up a [consultation with the IRB](https://weillcornell.az1.qualtrics.com/jfe/form/SV_8B8nCOcC8q7pUN0) to review what is required. The IRB will work with you to confirm if the target community needs to be involved in the design and conduct of the study.

Generally, study populations in clinical research should (and often do) mirror the characteristics of the population affected by a particular illness or condition or reflect the characteristics of the population intended to use the product. As an important ethical principle, justice, and fairness in distribution of the opportunities and potential benefits of participation in research drive an affirmative commitment to diverse inclusion. Describe any activity to increase diversity in clinical research ([click here to access a best practices resource).](https://mrctcenter.org/diversity-in-clinical-research/wp-content/uploads/sites/11/2021/09/MRCT-Center-Diversity-Guidance-Document-Version-1.2.pdf)

Indicate specifically whether you will include or exclude any of the following special populations: (You may not include members of these populations as participants in your research unless you include them in the description of your participant population.). Justify any inclusion/exclusions 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 individuals  | [ ]  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:

(See list above and confirm details are in line with information under JCTO protocol section 4.6, if used) Outline how researchers are ensuring that appropriate steps are taken for their consent and additional safeguards that have been included to protect the rights and welfare of these participants. If your study involves pregnant individuals, fetuses, neonates of uncertain viability, or nonviable neonates, set-up a [consultation with the IRB](https://weillcornell.az1.qualtrics.com/jfe/form/SV_8B8nCOcC8q7pUN0) to review what is required. Reference IRB policies for information about various populations.

## Recruitment Process:

Describe the plan (when, where, how) to identify potential participants, including database review and data sources if applicable. Indicate who will make initial contact and how, and if physicians or staff refer participants. 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.

## Screening Procedures:

Describe the screening process (how researchers will confirm that potential participants meet inclusion/exclusion criteria) and what will happen to screening/eligibility data for individuals who are not eligible to participate.

## Informed Consent Process:

Describe the process (when, where, how, who) for obtaining informed consent including considerations for privacy. If applicable, include any waiting period between informing participants and consenting. Include the process to ensure ongoing consent. Describe steps that will be taken to minimize the possibility of coercion or undue influence. 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 research involves minors, describe the assent process and how guardian permission will be obtained. 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 consent/assent documents/scripts as separate word documents with your submission.

or

If the study qualifies for a waiver of documentation of informed consent (absence of signature), provide information explaining why the research meets the waiver of documentation criteria at [45CFR46.117(c)(1)](https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46/subpart-A/section-46.117).

If the study qualifies for a waiver of informed consent/assent, provide information explaining why the research meets the waiver criteria at [45CFR46.116(f)(3)](https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46/subpart-A/section-46.116) and/or [45CFR46.408](https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46/subpart-D).

## HIPAA Authorization:

Include a description of the creation, use, and/or disclosure of protected health information (PHI), a statement whether HIPAA authorization will be obtained from all or some participants or a description of what alternatives will be used, list everyone who will have access to PHI (including IRB, sponsors, FDA, data safety monitoring boards, and others), a list of what PHI will be collected, used, and/or disclosed including the source(s), and why PHI obtained for this research are the minimum information needed to meet the research objectives ([visit the WCM IRB website](https://research.weill.cornell.edu/compliance/human-subjects-research/institutional-review-board/research-team-resources/project) for a list of data types that qualify as PHI). Describe the plan to protect and store PHI from improper use and disclosure and specify and justify the earliest opportunity to destroy PHI and how it will be destroyed. If PHI will not be destroyed, provide a justification. Explain how the use or disclosure of PHI involves no more than minimal risk to the privacy of individuals and why the research could not be practicably conducted without access to and use of PHI.

or

If the study qualifies for a waiver of HIPAA authorization, provide information explaining why the research meets the waiver criteria at [45CFR164.512(i)(2)(ii)](https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-C/part-164/subpart-E). Include the following 1. if you are requesting a waiver for the entire project (authorization will not be sought from participants) or recruitment only (identify eligible participants who then sign an authorization), 2. whether the waiver will adversely affect the privacy rights of the participant, 3. an explanation as to why the research could not be practicably carried out without the waiver, and 4. an explanation that the research could not practicably be conducted without access to and use of protected health information.

## Data Collection Procedures:

Provide a thorough description of all project procedures, interventions, assessments, and participant activities in a sequential format. Include frequency, amount, and method of blood draws if applicable. Describe how information will be captured (e.g. audio or video recorded, observations, note taking, computer task, etc.). Clearly indicate what procedures are standard of care and what procedures are experimental. Describe group assignment and the research procedures for each group. Upload any data collection documents/surveys/etc. with your submission.

**Dosing and Administration:**

Include product storage and stability information as well as dosing and administration information if applicable.

## 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). Include a diagram/table/graph if appropriate. Outline if participation increases the duration of clinical care.

## Study Locations:

Describe all sites/locations where your research team will conduct the research (e.g., where recruiting participants, research procedures will be performed, etc.), including any external sites conducting analytical procedures with project data. Please note 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.

|  |  |  |
| --- | --- | --- |
| 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.* |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

##

|  |  |  |  |
| --- | --- | --- | --- |
| 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 |  |  |
| 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 |  |  |

## International Research:

Assess the relevance of the research to the region/country. Also, assess the local context that affects the research, such as cultural norms. Explain the research teams’ qualifications/expertise for conducting research in the locale(s). Describe the plan for monitoring the international components of the research. Explain any site requirements, laws relevant to the research (e.g. GDPR), or state department warnings regarding travel to the international location(s).

## Participant Compensation:

Describe any compensation to participants (financial and nonfinancial) including amounts and payment schedule (class credit, merchandise cards, transportation expenses, cash, check, etc.). Including whether tax information is required (if so, this must be reflected in the informed consent form), whether payments will be pro-rated if a participant withdraws early, etc. Include who will receive the incentive. Explain why this is a reasonable compensation for the research.

## Economic Burden to Participants:

Describe any costs that participants may be responsible for because of participation in the research. If applicable, include whether medical insurance will cover costs.

## Lifestyle Considerations:

Describe any restrictions during any parts of the study pertaining to lifestyle and/or diet (e.g., food and drink restrictions, timing of meals relative to dosing, intake of caffeine, alcohol, or tobacco, or limits on activity), and considerations for household contacts. Describe what action will be taken if prohibited medications, treatments or procedures are indicated for care (e.g., early withdrawal).

## Risk to Participants:

There are risks of stress, emotional pain, inconvenience, and possible loss of privacy and confidentiality when joining a research study. In addition, state any reasonably foreseeable risks (e.g. psychological, physical, social, economic, or legal), discomforts, hazards, or inconveniences related to participation in the research. Describe the probability, magnitude, duration, and reversibility of the risks. When appropriate, provide a statement that the particular treatment or procedure may involve risks to the participant (or to the embryo or fetus, if the participant is or may become pregnant) which are currently unforeseeable. Include how all risks will be minimized. If applicable, describe risks to others who are not participants.

|  |  |
| --- | --- |
| **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) |
| Duration: |  | Reversibility: | [ ]  Reversible [ ]  Irreversible |
| 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) |
| Duration: |  | Reversibility: | [ ]  Reversible [ ]  Irreversible |
| 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) |
| Duration: |  | Reversibility: | [ ]  Reversible [ ]  Irreversible |
| 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) |
| Duration: |  | Reversibility: | [ ]  Reversible [ ]  Irreversible |
| 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) |
| Duration: |  | Reversibility: | [ ]  Reversible [ ]  Irreversible |
| 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, 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/specimens 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. Confirm whether a Certificate of Confidentiality will be obtained.

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.

## Provisions to Monitor the Data to Ensure the Safety of Participants

If using a JCTO protocol template, write “See Section 15 of the protocol.” If not using a JCTO protocol template, please complete the information below.

Describe the plan to periodically evaluate the data collected regarding both harms and benefits to determine whether participants remain safe. The plan might include establishing a data monitoring committee and a plan for reporting data monitoring committee findings to the IRB and the sponsor. Specify the conditions that trigger an immediate suspension of the research. Specify any state laws related to mandatory reporting.

Describe the plan to monitor data for safety. Include:

* Who will monitor the data for safety concerns? Describe the entity that will conduct the monitoring, such as a data monitoring committee, data and safety monitoring board, medical monitor, researcher, or independent physician.
What data will be reviewed? Describe the specific data to be monitored.
* How often will the monitoring occur? Specify the frequency of the monitoring, such as points in time or after a specific number of participants are enrolled.
* How often will cumulative data be reviewed? Describe the frequency and procedures for analysis and interpretation of the data.
* What are the reporting mechanisms? Describe the procedures for communication from the data monitor to the IRB and sites.
* Describe the actions to be taken upon specific events or end points.

## Data and Specimen Banking

If data or specimens will be banked for future use, describe where the data or specimens will be stored, how long they will be stored, how the data or specimens will be accessed, and who will have access to the data or specimens. List the data to be stored or associated with each specimen. Describe the procedures to release data or specimens, including: the process to request a release, approvals required for release, who can obtain data or specimens, and the data to be provided with specimens.

## Sharing of Results with Participants

Describe whether results (study results or individual participant results, such as results of investigational diagnostic tests, genetic tests, or incidental findings) will be shared with participants or others (e.g., the participants’ primary care physicians) and if so, describe how the results will be shared.

## Withdrawal of Participants

Describe anticipated circumstances under which participants will be withdrawn from the research without their consent. Include a description of follow-up if applicable. Describe procedures that will be followed when participants withdraw from the research, including partial withdrawal from procedures with continued data collection.

## Sample Size:

Provide a sample size (number of participants or number of records) and an explanation as to how you arrived at that number. Indicate, if applicable, the number of participants that will be screened.

## Approach to Analysis:

What and how do you plan to analyze the data you collect? Consider consulting a statistician before finalizing the protocol, if appropriate for your research.

## Resources Available

Describe the resources available to conduct the research: For example, as appropriate:

* Justify the feasibility of recruiting the required number of suitable participants within the agreed recruitment period. For example, how many potential participants do you have access to? What percentage of those potential participants do you need to recruit?
* Describe the time devoted to conducting and completing the research.
* Describe necessary facilities.
* Describe the availability of medical or psychological resources that participants might need as a result of anticipated consequences of the human research.
* Describe the process to ensure that all persons assisting with the research are adequately informed about the outlined protocol, the research procedures, including safety and ethical considerations, and key research personnel duties, functions, and expectations.

## Mentorship Plan for Medical Trainees Conducting Research

If this project involves medical trainees, describe the plan to mentor them through the research process, from proposal development, to study execution, to publication. Consider the advising, collaboration, and communication process, along with efforts to advance planning, decision making, and independence in your trainees.

## References:

If using a JCTO protocol template, write “See Section 16 of the protocol.” If not using a JCTO protocol template, please include all references.