Use this IRB Review Application if you have completed the [Non-Therapeutic Studies](https://jcto.weill.cornell.edu/system/files/download/intranet_only/iit_protocol_template_-_observational-correlative_v3_final.docx) or [Tissue Use/Chart Review JCTO template](https://jcto.weill.cornell.edu/system/files/download/intranet_only/iit_protocol_template_-_chart_review-tissue_use_v3_final.docx), the Education Protocol Template and/or have a study which will conduct social, behavioral, or educational research. 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 [Non-Therapeutic/Chart Review JCTO Protocol Guidance Document](https://research.weill.cornell.edu/files/guidance-irbreviewapplication-non-therapeuticandchartreviewjctoprotocolguidancedocx) for additional information to assist with completing this application.

|  |  |
| --- | --- |
| 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.

List research objectives or specific aims.

## Adequacy of Resources/Qualifications

Briefly describe the resources in place to conduct the study as well as the qualifications of the key research personnel to conduct the proposed study in a way that assumes the rights and welfare of participants are adequately protected. Examples include personnel, training, funding, equipment etc.

## Study Population:

Describe the participant population such as age range, gender, and ethnic background (~1-2 sentences). 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. Note that if you have inclusion/exclusion criteria, please explain the screening process in the Screening Procedures section.

Or

If applicable, delete the table below and provide a detailed description of the characteristics of the participant records and/or biospecimens you will be reviewing and collecting data from (i.e. age range, gender, physical health, medical criteria).

|  |  |  |
| --- | --- | --- |
| 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 and how researchers are ensuring that appropriate steps are taken for obtaining their consent and additional safeguards that have been included to protect the rights and welfare of these participants. 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.

## 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 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.

Or

If the study qualifies for a waiver of documentation of informed consent (absence of signature), provide information explaining why the research meets the wavier 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:

If applicable, 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. Describe how information will be captured (e.g. audio or video recorded, observations, note taking, computer task, etc.). For records/biospecimens research, include information about what records/biospecimens are being accessed and how. Upload data collection documents/surveys/etc. with your submission.

## 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). For records/biospecimens research, include the time frame for all records/biospecimens.

## Study Locations:

Describe the 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.

|  |  |  |
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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 |  |  |
| 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.). 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, 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.

## Data Banking

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

## Withdrawal of Participants

Describe anticipated circumstances under which participants will be withdrawn from the research without their consent. 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/biospecimens) 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.

## 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.

**Privacy Office Requirements:**

Please note, some of the information may be repeated from above.

## Data Management Plan

In this section, please describe how you plan to obtain, store, and manage data. For an overview of services available for electronic patient data management, please see the [ARCH website](http://arch.weill.cornell.edu). An informatics consult is not mandatory, but you are encouraged to contact arch-support@med.cornell.edu for help filling out this section if you are unsure how best to extract data for the study.

* **Manual data abstraction from NYP/WCM electronic health record systems**

If the study involves manual chart review of NYP/WCM electronic health record (EHR) system data, please describe the approach here. Of note, [WCM policy](https://its.weill.cornell.edu/policies/121-integrity-policy) requires all manual chart abstraction studies use [REDCap](https://its.weill.cornell.edu/services/research-informatics/electronic-case-report-forms-ecrfs) or other secure electronic data capture system rather than Microsoft Excel. If not, please state “N/A.”

## Manual data collection via survey

If the study involves collecting data directly from participants (e.g., patients, clinicians), please describe use of [REDCap or Qualtrics](https://its.weill.cornell.edu/services/research-informatics/online-surveys). If not, please state “N/A.”

## Automated data extraction from NYP/WCM electronic health record systems and/or research data repositories

If the study involves obtaining a report automatically extracted from [an electronic health record (EHR) system](https://its.weill.cornell.edu/services/research-informatics/electronic-health-record-reporting) such as Epic, [an ARCH research data repository (RDR)](https://datacore.weill.cornell.edu/datacatalog/), or existing [REDCap project](https://its.weill.cornell.edu/services/research-informatics/electronic-case-report-forms-ecrfs) designed to support future studies, please describe the approach here. If not, please state “N/A.”

## Data sets obtained from outside NYP/WCM

If the study involves obtaining a data set from an entity outside of NYP/WCM, please describe the approach here. Examples include but are not limited to data sets from [INSIGHT](https://insightcrn.org/), other academic medical centers, payors (such as CMS), and public sources. If not, please state “N/A.”

## Other data collection

If the study involves obtaining patient generated data (e.g., data collected through a mobile app), completion of paper case report forms, or use of any other data collection mechanism not described above, please describe the approach here. If not, please state “N/A.”

## Data storage and analysis

[Per WCM policy](https://its.weill.cornell.edu/policies/1106-device-encryption), analysis of sensitive information must take place on computers that are tagged, managed, and encrypted by the Information Technologies & Services Department (ITS). If you do not have a device that meets these criteria, the [Data Core](https://its.weill.cornell.edu/services/research-informatics/wcm-data-core) may meet needs. Please describe the approach for storing and analyzing data for the study. If you plan on conducting your analysis in the Data Core, please state accordingly.

Please note that data described as “de-identified” must comply with the [HIPAA Safe Harbor definition](https://www.hhs.gov/hipaa/for-professionals/privacy/special-topics/de-identification/index.html). For example, a de-identified data set CANNOT contain actual dates of service or birth.

If you have questions about data storage and analysis, please email arch-support@med.cornell.edu.

# Data and/or Specimen Sharing

## Receiving Data and/or Specimens

 Will you be receiving data or specimens from other institutions as part of this study? If yes, please describe below. If not, state “N/A.”

* **Receiving Data and/or Specimens from Other NewYork-Presbyterian Campuses**

Will you be receiving data or specimens from any of the following entities? If so, please indicate which entity with an X. If not, state “N/A.”

* NYP/Brooklyn Methodist Hospital
* NYP/Lower Manhattan Hospital
* NYP/Queens
* NYP/Medical Group
* Columbia Doctors
* NYP/Allen Hospital
* NYP/Columbia University Irving Medical Center
* NYP/Hudson Valley Hospital
* NYP/Lawrence Hospital
* NYP/Morgan Stanley Children's Hospital
* **Receiving Data and/or Specimens from Other Institutions**

## Will you be receiving data and/or specimens from any institution not listed above? Examples include but are not limited to Cornell University (Ithaca), Cornell Tech, Weill Cornell Medical College-Qatar, Vanderbilt University, New York State Department of Health, Google, and Blockbuster Video. If so, please specify below. If not, state “N/A.”

## Sending Data and/or Specimens

Will you be sending data or specimens to other institutions as part of this study? If yes, please describe below. If not, state “N/A.”

* **Sending Data and/or Specimens to Other NewYork-Presbyterian Campuses**

Will you be sending data or specimens to any of the following entities? If so, please indicate which entity with an X. If not, state “N/A.”

* NYP/Brooklyn Methodist Hospital
* NYP/Lower Manhattan Hospital
* NYP/Queens
* NYP/Medical Group
* Columbia Doctors
* NYP/Allen Hospital
* NYP/Columbia University Irving Medical Center
* NYP/Hudson Valley Hospital
* NYP/Lawrence Hospital
* NYP/Morgan Stanley Children's Hospital
* **Sending Data and/or Specimens to Other Institutions**

## Will you be sending data and/or specimens to any institution not listed above? Examples include but are not limited to Cornell University (Ithaca), Cornell Tech, Weill Cornell Medical College-Qatar, Rockefeller University, Hunter College, Hospital for Special Surgery, Memorial-Sloan Kettering Cancer Center, Vanderbilt University, New York State Department of Health, Google, and Blockbuster Video. If so, please specify below. If not, state “N/A.”