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 repository, insert N/A. This template is only to be used for the establishment of a biorepository (storage and maintenance) for potential future use, not testing and research.

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.

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

## Background/Purpose:

Briefly and clearly state the overall purpose of the repository in a few sentences. Include potential future uses of the repository.

Provide a non-technical explanation in lay terms to justify the biorepository and what its relevance will be (generally this section should not be longer than a couple paragraphs). Provide the scientific or scholarly background for, rationale for, and significance of the repository based on the existing literature and how it may add to existing knowledge. Include references at the end of this protocol.

## 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 repository). If there are any age, ethnic, language, or gender-based exclusion criteria, provide a justification. Note that if you have inclusion/exclusion criteria, please explain the screening process in the Screening Procedures Section.

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 repository unless you include them in the description of your participant population.) Justify the inclusion/exclusion of vulnerable populations.

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| --- | --- | --- |
| 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:

Explain why vulnerable populations need to be included in this repository 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 individuals, those who lack consent capacity, including the mentally ill, prisoners, cognitively impaired participants, children, and employees.

## Sample Size:

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

## 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 repository. 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 the repository 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 informed consent/assent, provide information explaining why the repository 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/Data and Specimen Banking:

Provide a thorough description of all procedures, participant activities, and assessments/interventions in a sequential format. Describe the nature of the data and specimens, what and how data and specimens will be obtained, and the timing, amount, and frequency of collection. Outline who will conduct data collection procedures. If data collected from a previous study are to be included in this study, indicate the IRB protocol number and whether the consent form from the original study includes provisions to allow for future research 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. Specify whether data/specimens will be released without identifiers, with a limited data set, or with identifiers.

## 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 repository storage and maintenance. If the repository will collect data/specimens over several years, describe the process to assess participants’ willingness to participate (as least annually).

## Study Locations:

Describe the sites/locations where your team will recruit participants, conduct the data collection, and store and maintain data/biospecimens, including any external sites. 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.* |
| Cornell Ithaca | [ ]  Included [ ]  Excluded |  |  |
| CUNY Hunter College | [ ]  Included [ ]  Excluded |  |  |
| Gracie Square | [ ]  Included [ ]  Excluded |  |  |
| Hospital for Special Surgery (HSS) | [ ]  Included [ ]  Excluded |  |  |
| Columbia  | [ ]  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 repository 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 repository.

## 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 biorepository and assess their likelihood and seriousness. When appropriate, provide a statement that the particular 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.

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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 repository (state if there are no direct benefits to participants) or benefits to the overall research field. (Sample text: This biorepository does not present any direct benefit to the participants. However, the biorepository provides an opportunity to…)

## 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 data/specimens are collected until the data/specimens 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 repository. 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.

## Sharing of Results with Participants

Describe whether incidental findings that are clinically significant will be shared with participants or others (e.g., the participants’ primary care physicians) and if so, describe how the results will be shared and by whom.

## Withdrawal of Participants

Describe anticipated circumstances under which participants will be withdrawn from the repository without their consent. Describe procedures that will be followed when participants withdraw from the repository, including partial withdrawal from procedures with continued data collection.

## 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.