

Institutional Review Board

**Instructions for the Informed Consent and HIPAA Authorization for Research Template**

1. This template, developed by Weill Cornell Medicine’s Institutional Review Board (IRB), has been created to assist the Principal Investigator (PI) in the design of their informed consent form (ICF). It is important that PIs adapt their own ICFs to the outline and requirements of their particular study. Ensure descriptions and added details are written in plain language that is clear, easy to understand, and in a way that facilitates comprehension.
2. Do not be concerned by the length of this template. It is long because it contains guidance and explanations which are for you and which you will not include in the informed consent forms that you develop and provide to participants in your research.
3. Consider the method or mode of communication and informed consent process with potential participants. For example, when using email communication consider informing participants that email is not secure way to communicate about your health or to share private information given there are many ways for unauthorized users to access email.
4. In this template:
	1. Square brackets ***[containing red bold and italicized text]*** are instructional to you.
		1. Once the instructions are followed, the ***[bold and italicized text]*** should be deleted from the template before proceeding.
	2. Square brackets containing [red text] are intended as template language to include, if applicable to your study, or to remove, if not applicable to your study.
		1. If the template language is applicable to your study, remove the square brackets and make the font color black.
	3. When you’ve completed the creation of the ICF, there should be no red text remaining.
	4. Please ensure that you update the header and footer.
	5. Prior to submitting to the IRB, convert to PDF first, then delete this instructional page.

TEMPLATE ON THE FOLLOWING PAGE

|  |  |
| --- | --- |
| **Project Title:** |  |
|  |  |
| **Research Project/Protocol #:** |  |
| **Principal Investigator:** |  |
| [Arm/Group] | ***[If there is more than one consent for the study, please indicate the type of consent here (E.g., Screening Consent; Group B Consent). Otherwise, delete this row.]***  |
| **Subject Name or number:**  |  |
| [MRN] | ***[If you will not be obtaining the MRN, please delete this row.]*** |

***[If this study involves minors, and this is a parent consent, or if it involves an LAR signing on behalf of the subject, please include one of the following introductory statements as it applies to your study:]***

***[If for Parental/Guardian Permission]:***

Please note that references to “You” or “your” refer to your child [the child] who will be participating in the study for whom you are providing consent.

***[If use of an LAR]:***

This consent form is written to address a research subject. If you will be providing permission as the legally authorized representative of a subject, the words ‘you’ and ‘your’ should be read as ‘the subject’ and ‘subject’s’.]

**Please note, are you currently or have been (within the last 6 months) a participant in any other research study at Weill Cornell Medicine, New York Presbyterian Hospital or elsewhere? If so, please inform the research team.**

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**INSTITUTION: Weill Cornell Medicine *[If applicable, include other institutions participating in this research under the Weill Cornell Medicine IRB’s approval, including institutions that will be receiving data about the subject and/or locations to which subjects will have to travel for research.]***

**STUDY SPONSOR/FUNDING AGENCY: *[specify sponsor and/or funding source; if internal, state ‘Weill Cornell Medicine’]***

|  |
| --- |
| **KEY INFORMATION ABOUT THIS RESEARCH STUDY*****[Full Board and Expedited studies approved after 1/20/2019 are required to include a Key Information Section (unless your consent form is six pages or shorter, including the Signature blocks). The Key Information Section is required for all studies (Full Board and Expedited) submitted after 4/3/2022. Include the most crucial information from the potential participant’s perspective. The Key Information Section should be concise, no more than 1-2 pages in length.]*** We are asking you to choose whether to volunteer for a research study about [***insert general description of study*]**. This page is designed to give you key information to help you decide whether to participate. We have included detailed information after this page. Ask the research team questions. If you have questions later, the contact information for the research investigator in charge of the study is below.  |
| Purpose: What is the study about and how long will it last? | ***[Briefly describe the purpose of the study and the procedures to be followed in lay terms. Specify if the treatment/intervention administered in this study is similar to, or different from the standard of care the participant would receive if not in the study. For detailed descriptions, use the Consent Document.]*** By doing this study, we hope to learn \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. Your participation in this research will last about **[*state in hours, days, months, years*]**. ***[If testing Food and Drug Administration (FDA)-regulated products for safety or effectiveness, include the following]****:* The purpose of this research is to gather information on the safety and effectiveness of \_\_\_\_\_\_\_\_\_\_\_\_ ***[state name of drug, device, etc. Indicate if the drug, device, or biologic is FDA-approved and whether it is being used in the study for an alternate use or consistent with labeling indications]****.*  |
| Benefits: Key reasons you might choose to volunteer | **[State the most important reason(s) {i.e., potential benefit(s)} of volunteering to participate in this study. For studies with no direct benefit, we suggest:** [The study will not include a direct benefit to you. However, some participants appreciate knowing they have contributed to research that may benefit others in the future.] For a complete description of benefits, refer to the Consent Document below. |
| Risks: Key reasons you might choose NOT to volunteer | ***[State the most important reason(s)/risk(s) why a participant may NOT want to volunteer for this study considering the participant’s perspective. Items to highlight for the participant could include large out of pocket expenses, participant responsibilities that many people might consider burdensome (e.g., abstinence from sexual relations, cigarettes or alcohol, inability to drive a car while taking study medication, need for overnight stays or admittance to a secure facility), potential impact on non-participants (e.g., caregivers, family members, children, partners), or serious implications for future treatment (e.g., use of an experimental intervention may make a standard clinical intervention ineffective or unavailable after the study, or lack of post-trial access to the experimental intervention).]*** *For a complete description of risks, refer to the Consent Document below.**[****If******alternative treatments/procedures are key to the participant’s choice, discuss those that might be advantageous to the subject or indicate if no known alternative exists.]***For a complete description of alternate treatment/procedures, refer to the Consent Document below. |
| Voluntary Participation: Do you have to take part in the study? | If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights or access to care ***[delete ‘or access to care’ if not applicable]*** you would normally have if you choose not to volunteer. ***[Add the following for student volunteers:]***As a student, if you decide not to take part in this study, your choice will have no effect on your academic status or class grade(s).***[Add the following for employees of WCM/NYP]***As an employee of WCM/NYP, if you decide not to take part in this study, your choice will have no effect on your employability or performance review. |
| What if you have questions, suggestions, or concerns? | The person in charge of the study is ***[Principal Investigator]*,** [PI]. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his/her contact information is**: [*PI contact information]***.If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact staff in the Weill Cornell Medicine Institutional Review Board (IRB) between the business hours of 9am and 5pm EST, Monday-Friday at 646-962-8200 or send an e-mail to irb@med.cornell.edu.  |
| **This overview does not include all the information you need to know before deciding whether to take part in the study. Much additional detail is given in the full consent document, which can be found on the pages that follow. Be sure to review the rest of this consent form before deciding about participation.** |

**INTRODUCTION:**

You are invited to participate in a research study. You were selected as a possible participant in this study because ***[State why and how the subject was selected].***

Please take your time to make your decision. It is important that you read and understand several general principles that apply to all who take part in our studies:

The purpose of the study, possible benefits or risks, other options, your rights as a participant, and other details about the study are further discussed below. Any new information that could affect your choice to remain in the study will be given to you as a participant. You should ask any questions you have about the study to members of the research team. You may also want to talk about the study with your primary care doctor and family, loved ones, or friends. The choice to participate, or not, is yours. If you decide to participate, please sign and date where indicated at the end of this form.

**WHY IS THE STUDY BEING DONE?**

The purpose of this study is to ***[explain the reason for doing this study/purpose in lay/simplified language.]***

**HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?**

Participants in the study are referred to as subjects. ***[Insert the following sentence only if multi-site study:*** About ***[if multisite:*** [# of subjects will take part in this study at all sites, and]***]*** # of subjects will be recruited at WCM/NYPH.

**WHAT IS INVOLVED IF I CHOOSE TO PARTICIPATE IN THE STUDY?**

The study will take place at ***[Insert location.] If portions of the study will take place at various locations, please include the following and specify below which procedures will occur at which location(s***) “Some portions of the study may take place at ***[Insert institution/location],*** where the investigators are members of the medical staff.

If you agree to participate in this study, you will be asked to:

* ***[Use bullet points, tables, or charts to explain the research procedures, whenever possible.]***
* ***[Provide a concise and focused presentation, in sequential order, but give enough detail to assure that potential participants can make a truly informed decision.]***
* ***[Be sure to identify the procedures and test articles that are experimental.]***
* ***[If there will be randomization, address as ‘by chance, like flipping a coin’, and indicate if there will be blinding, possible placebo etc.]***
* ***[If surveys, interviews, or questionnaires are to be used, be transparent in the types of questions to be asked.]***
* ***[Specify if there will be genetic testing, and why it is necessary to achieve the goals of the study.]***
* ***[If applicable]*** Advise the researchers of any medications you are taking. In addition, if you are taking any over-the-counter drugs or herbal supplements which you have obtained from the drug store, grocery store, etc., you should advise the researchers.

***[If the subjects may or will be audio/video recorded]:***Your participation [will or may] be [audio/video] recorded. ***[Specify how the recordings will be used, including specifically for the research; Discuss timing of transcription if applicable and disposition (e.g., deletion) of the recordings afterward; explain how the recordings will be kept confidential].***

***[Include the following if the audio/video recordings are optional]***:

Please initial one of the following:

\_\_\_\_\_\_ I agree to be [audio and/or video] recorded.

\_\_\_\_\_ I do not want to be [audio and/or video] recorded.

***[Include the following if the research involves collecting biospecimens, and if applicable:]***

It is possible that we will conduct tests on the biospecimens we collect from you to find out your unique DNA blueprint, also known as “whole genome sequencing”. We will do this because ***[Explain].***

***[Include the following if your study is subject to NIH’s Genomic Sharing Policy\* (even if the data are de-identified]:***

* ***what data types will be shared (e.g., genomic, phenotype, health information, etc.),***
* ***for what purposes (e.g., general research use, disease-specific research use, etc.), and***
* ***whether sharing will occur through open (unrestricted) or controlled access databases (or an approved alternative sharing plan).***

***\*(Researcher guidance on informed consent for genomic data sharing:*** <https://www.hhs.gov/guidance/document/informed-consent-genomic-data-sharing>***)***

***[Include this next section if the research involves the collection of identifiable private information or identifiable biospecimens]***

**CAN MY** [information and/or biospecimens] **BE USED FOR FUTURE RESEACH WITHOUT ASKING FOR MY PERMISSION?**

Yes. If all identifiers (name, date of birth, etc.) are removed, it is possible that the [data and/or biospecimens] collected for this study may be used for future research studies or distributed to another investigator for future research studies without your consent.

OR

No. The [information and/or biospecimens] collected as part of the research, even if identifiers are removed, will not be used, or distributed for future research studies.

***[Include this next section if the research involves collecting biospecimens]***

**WILL I RECEIVE PAYMENT IF MY BIOSPECIMENS ARE USED FOR COMMERCIAL PROFIT?**

By signing the consent form, you acknowledge that you have voluntarily donated your ***[indicate type such as blood, saliva, etc.]*** to WCM for research purposes. WCM has no plans to compensate you for any commercial uses of the products that may be derived from the specimen. WCM will maintain ownership of the specimen.

***[Include this next section if the research may yield results that have clinical relevance for the subject]***

**WILL I BE GIVEN THE RESULTS OF ANY STUDY TESTS OR PROCEDURES THAT ARE DONE?**

***[Include a statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions, e.g., if non-research genetic findings are possible, perhaps have the subject speak with a genetic counselor before signing the consent form etc.]***

**HOW LONG WILL I BE IN THE STUDY?**

We think you will be in the study for ***[Indicate how many months/weeks, until a certain event, etc.].***

***[Where appropriate, state that the study will involve follow-up and the expected timeframe.]***

**WHAT ARE THE RISKS OR DISCOMFORTS OF BEING IN THE STUDY?**

**If risks are minimal include the statement:** The risks involved with participation in this study are low and may include [Insert risks such as loss of confidentiality of data, stress from answering sensitive questions, etc. or state that there no foreseeable risks to participating in this study].

**or**

**If risks are greater than minimal include the statement:**

The procedures involved in this study may involve risks that are currently unforeseeable. Possible risks associated with this study are:

* ***[Provide the information in a concise and focused presentation, concentrating on the risks a subject would most likely want to know about;***
* ***List by regimen the physical and nonphysical risks of participating in the study in categories of likelihood (e.g., likely, rare), magnitude/seriousness (e.g., mild, severe) and temporary or permanent; Nonphysical risks may include such things as the inability to work, psychological risks, risks pertaining to a potential breach in confidentiality, etc. Highlight or otherwise identify side effects that may be temporary or irreversible or long-term or life threatening.]***
* ***[Provide any information on contraception, barrier use and pregnancy testing requirements for the study. Explain what should occur if they or their partner become pregnant while participating in the study. Include a statement regarding unknown risk and/or specific risk that may occur if subject or partner becomes pregnant, is pregnant or is breast-feeding, etc.]***

***[If the research involves imaging studies, include the following paragraph]:***

Please also note that your ***[Insert names of appropriate imaging study(ies) here]*** that is done as part of this study will be read and interpreted by a WCMC Department of Radiology radiologist and the report will be provided to the Principal Investigator. If we see anything in the research-related images we obtain that may have clinical significance to you, the Principal Investigator will share the findings with you or a physician who you may designate. It will be up to you and your designated physician to determine if any further testing or treatment, outside of this research study and at your own cost, is necessary on the basis of this information.

**Considerations for Studies Involving Genetic Testing *[Add as applicable]***

***[Explain that it is possible that, even if the information is currently considered anonymous, that the collected genetic information may be identifiable to the subject in the future; risks to family members; level of clinical relevance (e.g., if a validated test that is linked to a disease is being conducted on the sample) etc.*** [Sample Language: We indicated above that part of this study involves genetic testing. Genetic material contains information about many different traits, like a personal diary. The traits being tested are heritable, which means that they may be passed on from generation to generation within families. It is possible that genetic tests will show a link between your genetic information and a disease or condition. Knowing this information may help you make choices about you or your family’s health care. However, some individuals prefer not to know about their genetic information.]

You (will/will not) be notified of the results of the genetic testing. These results (will/will not) be verified in a certified genetic testing laboratory. You may wish to speak to speak with the investigator, a genetic counselor, or other health professional before signing this consent form.

***[Indicate whether the research subject and their treating physician will be informed of the results of the genetic testing AND if the results will be placed in the subject’s medical record.]***

**ARE THERE ANY BENEFITS TO TAKING PART IN THE STUDY?**

***If the study does not have direct benefits to the research participant, include this statement:***

You will receive no direct benefit from participating in this study; however, there may be societal benefits such as ***[Explain potential benefits to society].***

***[If the study has possible direct benefits to the subject, include this statement:]***

It’s possible that you may benefit from your participation in this study, but this benefit cannot be guaranteed. ***[Describe any potential benefits to the participant. Describe expected benefits to science or society in lay language, avoiding any technical terms.]*** We hope the information learned from this study will benefit other patients with ***[Insert condition under study]*** in the future.

***[For studies that include any aspect of genetic research, include a description of the potential benefits to the subject and/or society, if any, that relate to the genetic aspect of the research.]***

**WHAT OTHER OPTIONS ARE THERE?**

Instead of being in this study, you have these options:

***[Describe and/or list the alternative options, including commonly used therapy(ies) or disclose standard diagnostic procedures or treatment being withheld, other research studies etc. Please specify if any of the study drugs/interventions/devices are available off-label or through standard of care.]***

**WHAT ABOUT CONFIDENTIALITY?**

Efforts will be made to protect your medical records and other personal information to the extent allowed by law. We will take steps to help make sure that all the information we get about you is kept confidential. Your name will not be used whenever possible. However, we cannot guarantee absolute confidentiality. Records of study participants are stored and kept according to legal requirements and may be part of your medical record. You will not be identified personally in any reports or publications resulting from this study. Organizations that may request to inspect and/or copy your research and medical records for quality assurance and data analysis include groups such as:

***[Please remove or add any organizations as they apply to this research.]***

* Weill Cornell Medicine Principal Investigator and study team
* The WCM Institutional Review Board (IRB)
* The Office of Human Research Protection (OHRP)
* Department of Health and Human Services
* ***[Leave in only if applicable]*** [National Institutes of Health]
* ***[Leave in only if applicable]*** [The Food and Drug Administration (FDA) and/or their representatives]
* ***[Insert name of Sponsor/Commercial Entity]*** and/or their representative(s) ***[Insert name of CRO, if applicable]***
* ***[Leave in only if applicable]*** [A Data and Safety Monitoring Board, an independent group of experts, will be reviewing the data from this research throughout the study.]

By signing this consent form, you authorize access to this confidential information. You also authorize the release of your medical records to the Weill Cornell Medicine Principal Investigator and study team by any other hospitals or institutions where you might receive medical care of any kind while you are participating in this study.

Data collected for this study that is stored on a computer will be protected in the following ways: ***[State here whether you are keeping data on a computer that will identify the subjects in the study and/or your coding mechanisms. Explain how you are protecting this information. Give details: For example, is the computer in a locked room, is it part of a network, is a password required for getting onto the system, who has access to these data, etc.] If the study involves videotaping or audiotaping subjects, add a statement regarding the disposition of the tapes (deleted after transcription? Stored indefinitely post-transcription? Where?)]*** In addition, only personnel who are associated with the study will have access to the study specific records in the database.

***[The following section on Certificate of Confidentiality must be included for all NIH, CDC or FDA-funded studies collecting/using identifiable information. Refer to*** [***https://humansubjects.nih.gov/coc/NIH-funded***](https://humansubjects.nih.gov/coc/NIH-funded)***. Do not include this section if it doesn’t apply to your study. Note that sensitive information includes (but is not limited to) information relating to sexual attitudes, preferences, or practices; information relating to the use of alcohol, drugs, or other addictive products; information pertaining to illegal conduct; information that, if released, might be damaging to an individual’s financial standing, employability, or reputation within the community or might lead to social stigmatization or discrimination; information pertaining to an individual’s psychological well-being or mental health; and genetic information or tissue samples.]***

Certificate of Confidentiality has been granted by the Department of Health and Human Services (DHHS). This Certificate will protect the investigators (research/study staff) from being forced to release any research data in which the subject is identified even under a court order or subpoena. This protection is not absolute. For instance, it does not override any state requirement to report child abuse to the appropriate authorities.

***[For studies subject to the NIH Genomic Data Sharing Policy: Insert description to specify, how will subject confidentiality be protected.]***

***[If genetic testing is being conducted: based on the structure of the study, including one of these statements:]***

(1) The samples we use for genetic testing will be permanently stripped of information that could identify you.

***(OR)***

(2) WCMC uses an approved coding system that protects the identity of individuals who provide samples for genetic testing.

***[If this clinical trial will register on ClinicalTrials.gov either because it’s an NIH-funded clinical trial OR it’s an interventional clinical trial evaluating an FDA-regulated drug, device, or biologic (excluding phase 0, phase 1 studies, or device feasibility studies), please include the following statement in the confidentiality section of the informed consent.]*** [A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.]

A Federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

* Health insurance companies and group health plans may not request your genetic information that we get from this research.
* Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
* Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

Be aware that this Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. Nor does this Federal law prohibit discrimination on the basis of an already manifest genetic disease or disorder.

**HIPAA AUTHORIZATION TO USE or DISCLOSE PROTECTED HEALTH INFORMATION FOR RESEARCH**

**Purposes for Using or Sharing Protected Health Information:** If you decide to join this study, Weill Cornell Medicine researchers need your permission to use your protected health information according to a regulation called the HIPAA (Health Insurance Portability & Accountability Act) Privacy Rule. If you give permission, Weill Cornell Medicine researchers may use your information or share (disclose) information about you for their research that is considered to be protected health information.

**Voluntary Choice:** The choice to give Weill Cornell Medicine researcher’s permission to use or share your protected health information for their research is voluntary. It is completely up to you. No one can force you to give permission. However, you must give permission for Weill Cornell Medicine researchers to use or share your protected health information if you want to participate in the study. If you decline to sign this form, you cannot participate in this study, because the researchers will not be able to obtain and/or use the information they need in order to conduct their research. Refusing to give permission will not affect your ability to get usual treatment, or health care from Weill Cornell Medicine.

**Protected Health Information to Be Used or Shared:** Government rules require that researchers get your permission (authorization) to use or share your protected health information. Your medical information may be disclosed to authorized public health or government officials for public health activities when required or authorized by law. If you give permission, the researchers could use or share with the entities identified above any protected health information related to this research study from your medical records and from any test results, which includes ***[You must include all categories of tests and diagnostic procedures including, but not limited, to genetic testing, HIV testing, Hepatitis testing, substance abuse and/or mental health information, which must each be listed if applicable. Please also broadly identify the health information that will be collected for the research. Lastly, include the HIPAA identifiers that will be collected (e.g., name, e-mail address, MRN, etc.)].***

**Other Use and Sharing of Protected Health Information**: If you give permission, the researchers could also use your protected health information to develop new procedures or commercial products. They could share your protected health information with the study sponsor, the WCM Institutional Review Board, inspectors who check the research, government agencies and research study staff. The researchers could also share your protected health information with ***[Name all persons or groups including collaborating researchers or teams at other institutions (naming the institution), labs and consultants, as well as other groups of individuals who may have access to protected health information in this study].***

The information that may be shared with the sponsor and/or government agencies could include your medical record and your research record related to this study. They may not be considered covered entities under the Privacy Rule and your information would not be subject to protections under the Privacy Rule. We will use and share your information only as described in this form; however, people outside WCM who receive your information may not be covered by this promise or by the federal Privacy Rule. We try to make sure that everyone who needs to see your information keeps it confidential – but we cannot guarantee that your information will not be re-disclosed.

**ACCESS TO RESEARCH RECORDS *[Choose to include one of the 2 paragraphs below when applicable to your study:]***

During the course of this study, **you will have access** to see or copy your protected health information as described in this authorization form in accordance with Weill Cornell Medicine policies. During your participation in this study, you will have access to your research record and any study information that is part of that record.

***[OR]***

During the course of this study**, you will not have access** to see or copy certain parts of your protected health information that contains research information as described in this authorization form, in accordance with Weill Cornell Medicine policies. This is done to prevent knowledge of study results from affecting the reliability of the study ***[Include preceding statement only if applicable; Otherwise, please add a statement to indicate the reason why this information is being denied (temporarily or permanently)].*** The part of your private information that you will not have access to is/are: ***[Name the specific part(s)/test(s) of the research record that subjects temporarily will not have access to].*** Your information will be available should an emergency arise, that would require the treating physician to know this information in order to best treat you. Your right to access this information will be reinstated when ***[Insert a specific time frame, such as ‘initial treatment is complete’ or ‘follow-up is complete’].***If youwish to appeal this temporary suspension at any time, please write to the Privacy Officer at the address on this form. By signing this form, you are agreeing to this temporary suspension of your rights to access protected health information. ***[If the access to the records is never reinstated, please revise the last four sentences as applicable.]***

**CANCELING AUTHORIZATION**

**Canceling Permission:** If you give the Weill Cornell Medicine ***[Insert any collaborating site/Institution Name]*** researchers permission to use or share your protected health information, you have the right to cancel your permission whenever you want. However, canceling your permission will not apply to information that the researchers have already used or shared.

If you wish to cancel your permission, you may do so at any time by writing to:

Privacy Office

1300 York Avenue, Box 303

New York, NY 10065

Email: privacy@med.cornell.edu

If you have questions about this and would like to discuss, call (646) 962-6930.

**End of Permission:** Unless you cancel it, permission for Weill Cornell Medicine researchers to use or share your protected health information for their research will never end.

**FUTURE RESEARCH AND RESEARCH REPOSITORY *[This section must be included for all studies collecting or storing data/samples for use in future research beyond the identified research questions/aims. If not applicable, you may delete this section.] [If this study is strictly a repository study, then the below “What is a Research Repository?” language should instead be reflected in the purpose and procedures section and everything except the consent statement should be omitted.]***

**[What is a Research Repository?** A research repository (database) is a collection of information from many individuals. This includes information from individuals directly, from health and medical records, and can sometimes include specimens (like your tissue). The repository (database) may use and/or share the information with researchers for future use, which means they can use the information for purposes beyond the purpose of the current project.

In order to store the information/samples collected in this study for possible future use in someone else's research, you are being asked to make some decisions about your data/sample(s) included in this study. Sometimes people do not want their data/samples stored for future use. We are seeking your additional permission because without that your permission would otherwise only cover use in this study.

The repository (database) will include ***[Specify whether data will be stored with direct identifiers and/or coded]*** about each person whose information is collected. However, the repository does not share information with researchers unless the researchers agree to keep the information confidential. Your data/samples ***[Specify will/will not as applicable]*** [will/will not] be sold for profit and any research which uses your data/sample(s) will have to be approved.

Choose to include one of the two paragraphs below when applicable to your study:

***[Include this paragraph if future research is optional.]***You may agree to allow your data, and/or sample(s) (tissue, blood, urine, etc.) to be used for future research within Weill Cornell Medicine, and/or at outside institutions and private companies ***[Specify outside institutions and/or private companies, if known ahead of time]***, in a research repository. If information goes to an outside entity, then Weill Cornell Medicine cannot ensure the Privacy Rule is followed.

***[Include this paragraph if future research is required in order to participate.]*** In order to participate in this study, you must also agree to allow your data, and/or sample(s) ***[Specify as applicable***: (tissue, blood, urine, etc.)] to be used for future research within Weill Cornell Medicine, and/or at outside institutions and private companies ***[Specify outside institutions and/or private companies, if known ahead of time],*** in a research repository. If information goes to an outside entity, then Weill Cornell Medicine cannot ensure the Privacy Rule is followed.

**RESEARCH PARTICIPANT: On the checklist below, please indicate if you would permit the researchers to store and/or share your *[Describe samples to be stored/shared]* for future research.**

We will use and share your information only as described in this form; however, people outside WCM who receive your information may not be covered by this promise or by the federal Privacy Rule. We try to make sure that everyone who needs to see your information keeps it confidential – but we cannot guarantee that your information will not be re-disclosed.

***[Please add the following sentence if this study will involve obtaining specimens that will be stored at WCM and/or at a non-WCM site or institution.]*** By checking “Yes” and signing this consent form, you agree to give your data, Protected Health Information ***[remove “and/or specimen samples” if not applicable]*** and/or specimens samples to ***[Weill Cornell Medicine and/or Insert non-WCM Site/Institution Name]*** for research purposes.

|  |
| --- |
| * **YES,** I give permission for my ***[Insert data type/PHI/sample type]*** to be stored for future unspecified research by the researchers of this study. I understand that the data and/or samples will be stored for ***[Insert # of years here]*** years ***[Investigator fill in number. If no limit, state data and/or samples will be stored indefinitely]*** and will be destroyed after the research is completed.
* **YES**, I give permission for my ***[Insert data type/PHI/sample type]*** to be **shared** with other qualified **researchers** for future research.
* **NO,** I do not give permission for my ***[Insert data type/PHI/sample type]*** to be stored or shared for future research. ***[If future research is mandatory omit this option.]***
 |

***[Include the following sentence if storage of data type/PHI/sample type for future research is a required part of participating in the study and then choose Option 1 or Option 2]*** By signing this consent form, you agree to give these ***[Insert data type/PHI/sample type]*** to ***[Site/Institution Name]*** for future research.

***[Option 1:]*** If you withdraw consent at a future time, only your unused ***[Insert data type/sample type]*** will be destroyed.

**OR**

***[Option 2:]*** If you withdraw consent at a future time, we will be unable to destroy ***[Insert data type/sample type]*** collected, as there will be no way to link the [Insert data type/sample type] to you.

**WHAT ARE THE COSTS?**

***[Be careful to complete the following language in a manner consistent with the WCM HRBAF.***  ***Subjects should only be told that they will have no costs for specific services (tests, procedures, exams, etc.) if those services are listed on the HRBAF as being billed to the study or the sponsor. If services are listed on the HRBAF as being billed to the patient or insurance company, subjects must be informed here that the costs for the relevant services will be billed to their insurance company and that they will be responsible for any costs not covered by their insurance or by the Sponsor, if applicable.]***

***[If there are no cost to participants]***No. There are no direct costs for taking part in this research study.

***[If there are research-related costs]*** Yes. ***[Describe what subjects will need to pay for (certain tests or procedures, study drug, study device, etc.). Also describe how subjects can find out the estimated cost and if it would or would not be covered by health insurance.]***

***[Include this section if the research involves more than minimal risk: Provide an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained. For additional sample language see draft*** [***FDA Guidance.***](https://www.fda.gov/RegulatoryInformation/Guidances/ucm404975.htm#compensation)***]***

You or your insurance company will be charged for continuing medical care and/or hospitalization that are not a part of the study.

**POLICY/PROCEDURES FOR RESEARCH RELATED INJURY**

**The Policy and Procedure for the Sponsor are as follows:**

***[Include the Sponsor’s statement here]*** The Sponsor, ***[identify by name],*** ***[Specify “will/will not” as applicable]*** pay for care necessitated by a research related injury. ***[If the Sponsor will pay such costs, Medicare/Medicaid cannot be primary payors. If applicable, the language in this section must track the language in the Clinical Trial Agreement with the Sponsor. Please contact the contracts office at*** ***JCTOcontracts@med.cornell.edu*** ***with any questions. The following is acceptable language if the Sponsor specifies that it will only pay costs not otherwise covered by insurance:]***

If you suffer a research related injury, the Sponsor will pay for medically necessary items or services for the diagnosis and treatment of the Research Related Injury as described below:

1. If you have private health insurance, the Sponsor will pay for the costs that are denied or not otherwise paid for by your insurance company.
2. If you do not have any health insurance, the Sponsor will pay for the costs; and
3. If you have Medicare or Medicaid, claims for the costs will first be submitted to the Sponsor for payment, and any remaining balance not paid for by the Sponsor will be submitted to Medicare or Medicaid, subject to applicable Medicare and Medicaid billing rules and regulations.

***[Below 2 paragraphs of additional optional language to be used if this language is included in the Clinical Trial Agreement with the Sponsor:]***

[The sponsor will only pay for research related injuries if the study was properly performed. The sponsor will not pay for injuries resulting from your pre-existing condition unless that condition was made worse by the study drug or the study procedure.

Medical expenses will not be reimbursed if the Research Related Injury is the result of your intentional failure to follow instructions in this consent form or instructions communicated by study personnel or it is the result of the natural progression of an underlying or pre-existing condition.]

**The Policy and Procedure for Weill Cornell Medicine are as follows:**

We are obligated to inform you about Weill Cornell Medicine’s policy in the event injury occurs. If, as a result of your participation, you experience injury from known or unknown risks of the research procedures as described, immediate medical care and treatment, including hospitalization, if necessary, will be available at the usual charge for such treatment. No monetary compensation is available from Weill Cornell Medicine. Further information can be obtained by calling the Institutional Review Board at (646) 962-8200.

**COMPENSATION FOR PARTICIPATION**

You ***[Indicate will/will not, as applicable]*** receive compensation for participating in this study***. [State compensation method (Check, ClinCard), schedule and method to receive payments, and amount. Also include compensation withdrawal schedule. That is, if the participant withdraws prior to study completion, what will be the prorated compensation provided, if any?]***

***[Insert the following 2 sentences if paying by check:]*** [You will be compensated in the amount of ***[Insert dollar amount]*** for each completed study visit. You will receive the check approximately six weeks after you complete the study.]

***[Insert the following paragraph if you will be utilizing ClinCard for stipends:]*** [You will be compensated in the amount of ***[Insert dollar amount]*** for each completed study visit. This will be given to you in the form of a ClinCard. ClinCard can be used as a credit or debit card and funds will be available to you within 5 business days after you complete your study visit. Please also review the ClinCard Frequently Asked Questions provided to you by the study staff.]

***[If compensation will be provided to subjects, the following paragraph should be included:]***

[Your personal information, including name, address, and social security number, will be released to the Finance Department of Weill Cornell Medicine for the purpose of payment, as well as for reporting to the Internal Revenue Service (IRS) if total payments for the calendar year (excluding reimbursements) exceed 600.00 dollars.  You will be asked to complete IRS form W9 for this purpose. At the end of the tax year, Weill Cornell Medicine will use this information to provide you with Federal Form 1099-MISC, Miscellaneous Income, listing your payment as reportable income, if applicable. If you do not complete the W9 form, you may participate in this study, but you will not receive any payments for participating in this study.]

***[Insert the following paragraph if subjects are receiving reimbursements:] [***You may be eligible to receive reimbursement of your travel expenses, depending on the distance you travel to come to Weill Cornell Medicine. You will be required to provide the study coordinator with receipts of your travel expenses. ***[Please include a maximum reimbursement amount, if applicable.]*** Please ask the researchers for additional information. ***[Insert the following sentence if providing reimbursement by check:]*** Your reimbursement will be given to you in the form of a check approximately six weeks after you submit your receipts. ***[Insert the following 3 sentences if you will be utilizing ClinCard for reimbursement:]*** Your reimbursement will be given to you in the form of a ClinCard. ClinCard can be used as a credit or debit card and funds will be available to you within 5 business days after you submit your receipts. Please also review the ClinCard Frequently Asked Questions provided to you by the study staff.]

***[Insert the following Commercial Interest section if applicable.]***

**COMMERCIAL INTEREST**

***[Note to investigator: If anyone involved in the study has a financial interest related to this study, please include a statement using the appropriate language from the choices below.]***

[Materials or data obtained from you in this research may be used for educational or commercial purposes. It is the policy of Weill Cornell Medicine ***[Insert “and the Sponsor,” if applicable]*** not to provide financial compensation to you should this occur.

For Consulting, etc.: Dr. X, ***[Indicate role in the study - choose PI or Co-investigator],*** serves as a ***[Indicate “paid” or “unpaid,” as applicable] [Indicate “consultant” for any of the following relationships - consultant, member of the Scientific Advisory Board, Advisory Board member, etc.]*** for ***[Insert the sponsor, the name of the company whose product is being used or tested, etc.]. [State the relation of the company to the research if that would add valuable information.]***

* Equity ownership: Dr. X, ***[Indicate role in the study], [Indicate “owns stock,” “has an equity ownership,” as applicable]*** in ***[Indicate the name of the entity and its relation to the research - e.g., the sponsor of the study, the company that markets the drug being used, etc.].***
* Royalties: Dr. X, [***Indicate role in the study],*** receives royalties from ***[Indicate the name of the entity and its relation to the research]***.
* Patents or patent applications: ***[Insert name of institution or individual investigator***] holds a patent***[or “has applied for a patent” or “is an inventor” Indicate whatever applies]***for this ***[device or drug, indicate as applicable]*** and has a potential financial interest in the outcome of this study.

If you have any questions or would like additional information about the financial interests described in this paragraph, please contact the Weill Cornell Medicine Institutional Review Board (IRB) at (646) 962-8200 or irb@med.cornell.edu.]

**WHAT ARE MY RIGHTS AS A PARTICIPANT?**

Taking part in this study is voluntary. You may choose to not take part in the study or to leave the study at any time. If you choose to not participate in the study or to leave the study, your regular care will not be affected nor will your relations with Weill Cornell Medicine, your physicians, or other personnel. In addition, you will not lose any of the benefits to which you are entitled.

We will tell you about new information that may affect your health, welfare, or participation in this study.

**CAN I WITHDRAW FROM THIS STUDY?**

You can choose to stop participating in this study at any time**by notifying the investigator identified on the front page of this consent form. They will discuss with you any requested processes (e.g., final study visit, etc.) needed for your safe withdrawal from the study.**

 ***[If FDA-regulated research, include the following statement:]*** After you leave the study, no new information will be collected from you; however, information that has already been collected will remain in the study database and be used to determine the results of the study.

***[Option for non-FDA regulated research]*** After you leave the study, no new information will be collected from you. Information that has already been collected [can be withdrawn from the database if you choose/ will remain in the study database and be used to determine the results of the study/other description].

***[In this section explain what may trigger the choice for withdrawal (e.g., new findings), how to withdraw, and what will happen to the information/samples already collected. Explain any risks associated with withdrawing (e.g., need to taper medications) and steps taken to mitigate those risks.]***

***[Include the following sentence if this ICF has a Future Use section.]***Information specific to the handling of your research records/specimens in regard to future research use can be found in the Future Use section.

***[If participants who withdraw will be asked to permit follow-up of their condition by the researchers, describe the process and option]*** You will be given the option to partially end your participation in this study. This means you could keep doing the research follow-up visits/phone calls only but would not be given any study drug. This way the researchers can continue to ask about your health and any changes in your health. The follow-up visits/phone calls will occur ***[state how often]*** until ***[state when this will end].***

**Removal from the Study by Investigator, Physician, or Sponsor**

The investigators, physicians or sponsors may stop the study or take you out of the study at any time if they feel it is in your best interest, if you experience a study-related injury, if you need additional or different medication, or if you do not follow the study plan. They may remove you from the study for various other administrative and medical reasons. They can do this without your consent.

**WHOM DO I CALL IF I HAVE CONCERNS, QUESTIONS OR COMPLAINTS?**

For questions about the study, a research-related injury, any problems, unexpected physical or psychological discomforts, or if you think that something unusual or unexpected is happening, call ***[Insert Name of Principal Investigator]*** at ***[Insert telephone number and/or Insert Weill Cornell Medicine study-specific email address or Principal Investigator’s Weill Cornell Medicine email].***

***[Note to Researchers: Please include a 24-hour telephone number if appropriate. E.g., greater than minimal risk study. The on-call number should be provided in addition to the PI’s number, if different.]***

If you would like to speak to someone other than the researchers concerning complaints or questions about your rights as a research participant, or you would like to offer input, please contact the WCM Institutional Review Board. Direct your questions to the Institutional Review Board at:

|  |  |
| --- | --- |
| Institutional Review Board1300 York Avenue, Box 89New York, New York 10065 | (646) 962-8200irb@med.cornell.edu |

You may also submit concerns about your rights as a research participant without giving your name (“anonymously”) by using (866) 293-3077 or http://www.hotline.cornell.edu/.

***[PLEASE NOTE: Do not use a page break for signature lines. Signature lines should not stand alone on a page, without preceding text.]***

**RESEARCHER’S STATEMENT**

I have fully explained this study to the subject (or the subject’s legally authorized representative). As a representative of this study, I have explained the purpose, the procedures, the benefits, and risks that are involved in this research study. Any questions that have been raised have been answered to the individual’s satisfaction.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| Signature of person obtaining the consent |  | Print Name of Person |  | Date |

***[The following is to be used when consenting Non-English-Speaking Subjects using a Translated Short Form Consent***

***NOTE: NYP Interpreters cannot serve as a witness for studies.]***

[In case the patient/legal representative does not speak English, an official interpreter has been informed about the purpose, procedures, benefits, risks of and alternatives to the proposed research project and has told the subject/legal representative everything pertaining to her participation in this study and verifies this by signing below.]

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| Signature of Interpreter, if applicable |  | Print Name of Interpreter |  | Date |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| Signature of person present during oral presentation (“Witness”) |  | Print Name of person present during oral presentation (“Witness”) |  | Date |

**SUBJECT’S STATEMENT**

I, the undersigned, have been informed about this study’s purpose, procedures, possible benefits, and risks, and I have received a copy of this consent. I have been given the opportunity to ask questions before I sign, and I have been told that I can ask other questions at any time. I voluntarily agree to participate in this study. I am free to withdraw from the study at any time without need to justify my decision. This withdrawal will not in any way affect my future treatment or medical management and I will not lose any benefits to which I otherwise am entitled. I agree to cooperate with ***[Insert name of principal investigator]***and the research staff and to inform them immediately if Iexperience any unexpected or unusual symptoms.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| Signature of Subject |  | Print Name of Subject |  | Date |

***[If applicable, include the following signature line(s) for parent(s)/guardian(s) or legally authorized representative\* as follows:]***

**[LEGALLY AUTHORIZED REPRESENTATIVE**

***[TO ONLY BE USED FOR STUDIES THAT IRB APPROVED USE OF LAR]***

I, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, on behalf of the research project participant, signed above, have been fully informed of the purpose, benefits, risks of and alternatives to the proposed research project and as his/her legal representative consent to his/her participation in this research project. I have also been informed on the ways in which his/her protected health information will be used and disclosed in connection with participation in the project described above.]

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| Signature of legally authorized representative (LAR) or healthcare proxy |  | Print Name and relationship to participant (when appropriate) |  | Date |

**The research team must provide a signed copy of this consent form to the subject (or subject’s Legally Authorized Representative).**

**[PARENTAL/GUARDIAN PERMISSION**

***[TO ONLY BE USED FOR STUDIES THAT IRB APPROVED USE OF ONE OR TWO PARENT SIGNATURE]***

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| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| Signature of Parent or Guardian |  | Print Name of Parent or Guardian |  | Date |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| Signature of Parent or Guardian |  | Print Name of Parent or Guardian |  | Date |

***[Include the following section when you anticipate enrolling subjects who cannot read or write in any language (and review the applicable HRPP SOP section].***

**Witness to Consent of Subjects Who Cannot Read or Write**

**Statement of Witness:** I represent that the consent form was presented orally to the subject in the subject’s own language, that the subject was given the opportunity to ask questions, and that the subject has indicted his/her consent and authorization for participation (check one box as applicable):

* Making his/her mark above
* Other means; Indicate here: \_\_\_\_\_\_\_\_\_\_

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| Signature of witness for adults unable to read or write |  |  |  | Date |