***Note (REMOVE THIS TEXT BEFORE SUBMITTING):***

* *Use this template if you have completed the Therapeutic Studies JCTO Protocol template for your study and/or you have a study which will use a device/drug or implement a clinical trial. This template is also appropriate for genetic research.*
* *Note: this template can be used in paper form or made into an e-consent document.*
* *Grey boxes with black text in brackets are to be completed.*
* *Red, italicized text in brackets is help text and/or a prompt for information that also must be included.*
* Orange text is optional, sample wording.
* *Do NOT delete the paragraph headings.*
* *Edit this document to reflect your activity and relevant IRB requirements.*
* *Additional applicable sections can be found in* [*Appendix A*](#_Appendix_A)*.*
* *If you are collecting and storing data and/or samples solely for future research use, please use the Repository Informed Consent Form template.*
* *With the guidance language removed, this template has the following readability scores:*
	+ *Flesch Reading Ease: 59.1*
	+ *Flesch-Kincaid Grade Level: 8.8*

# **Research Consent**

**[Title of Project]**

**[Version date]**

*[If for Parental/Guardian Permission]:*

In this document, “I/my/you/your” mean your child [the child]. If your child turns 18 years old while participating in the study, your permission for him/her/them to join or stay in the study is no longer required. *[Minors should sign the adult consent at that time.]*

*[If use of an LAR]:*

In this document, “I/my/you/your” mean the participant you are giving permission to join the study.

Please read this form or have this form read to you. Take your time to make your decision. Make sure we explain the study to you. Ask us any questions. You may also want to talk about the study with your doctor and family, loved ones, or friends. The choice to join the study, or not, is yours. If you decide to join, please sign and date this form.

## **Why is this study being done?**

You are being asked to join a research study that is being done by  [PI name] . *[If this project is funded, identify the funding source.]*  We hope to learn  [describe the purpose of the project] . You are being asked to join because  [insert inclusion/exclusion criteria] .

|  |
| --- |
| **Important information for you to think about:*** **What am I being asked to do?**  [Briefly describe the procedures to be followed in lay terms] .
* **How long will the study last?** If you join the research study, it will take a  [number of hours]  hours over  [include the number of times the participant will be involved in research activities, how long each activity or session will take, etc.] . *[Flexibility is permitted here if a statement regarding spending more time than one otherwise would during standard of care is appropriate rather than a precise number of hours.]*
* **Any possible risks or discomforts?**  [Include the most important risks or those that differ from standard of care] .
* **Will this study help me?**  [Include the most important benefits or those that differ from standard of care] .
* **Do I have to join?** You do not have to be in this study. *[Include any alternatives to participating, if appropriate.]*
 |

**If you are now or have been (within the last 6 months) in any other research study, please tell the research team.**

**What will I be asked to do?**  [Using plain language, provide an accurate description of what the participants will do, what will happen during the project, where procedures will take place, whether any procedures are experimental, time commitment for each procedure, whether there will be randomization, etc. If applicable, include procedures for photographing, audio, or videotaping. State what will be recorded (participant's face/name, will family member or others be identifiable?) Include the setting of the recording, how will recordings be used (e.g. only for tabulation of finite criteria by the research team, for possible use as a teaching tool to graduate or other students who are not members of the research staff).

--If your research involves deception, give as much information as possible without using statements that are part of the experimental deception.

--If your research involves an interview or a survey, be transparent in the types of questions to be asked and inform participants that they can skip any question that makes them uncomfortable and they can stop the interview/survey at any time.

--If your research involves genetic testing, specify why it is necessary to achieve the goals of the study.

--If applicable, 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.] .

*[Does this study involve HIV testing? If yes, add template language for* ***HIV Testing*** *found in* [*Appendix A*](#_Appendix_A)*.]*

*[Does this study involve genetic testing? If yes, add template language for* ***Genetic Testing*** *found in* [*Appendix A*](#_Appendix_A)*.]*

**Do I have other choices?**  [Explain other choices participants have if participants have any, 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.]

**Who will be in the study?** About  [***[if multisite:*** [*number* people will take part in this study at all sites, and]   [number]  people will be asked to join the study at Weill Cornell Medicine/New York Presbyterian Hospital.

**New information that may change your decision to join:** During the study, we will tell you if there is new information or changes to the study that could affect you, your health, or your desire to stay in the study.  [If known, discuss the procedures for informing/updating participants of new information that may affect their decision to participate.]

**What are the risks?**  [Detail any known risk of harm that the participant may experience from participating in the research including physical, psychological, social, economic, legal, or unknown risks. Any risks listed in the protocol must be addressed in the consent form. Include likelihood (e.g., likely, rare), magnitude/seriousness (e.g., mild, severe) and temporary or permanent, and side effects that may be temporary, irreversible, long-term, or life-threatening.] . There are risks of stress, emotional pain, inconvenience, and possible loss of privacy and confidentiality when joining research study.

*[Is this a genetics research study? If yes, add template language for genetics research found in* [*Appendix A*](#_Appendix_A)*.]*

*[Does the study involve opioid use? If yes, add template language for opioid use found in* [*Appendix A*](#_Appendix_A)*.]*

**What about pregnancy?**  [The particular treatment or procedure]  may involve risks to you (or to an unborn baby, if you are or become pregnant) that are currently unexpected.

**What if I am harmed?** *[remove all information below if the study is minimal risk]* If you are injured or become sick because of joining this study, you will have to pay for any emergency treatment.  Weill Cornell Medicine will not pay for these services.

If you have been injured or become sick because of taking part in this study, tell the researcher right away. If you have any questions or believe that you have been treated carelessly in the study, please contact the Office of the IRB at (646) 962-8200 for more information.

*[Sponsor information if applicable:]*

The Sponsor,  [identify by name]   [will/will not] pay for care if you are injured or sick because of being in this study. *[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 are injured or sick because of being in this study, the Sponsor will pay for care to diagnose and treat the injury if:

1. 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. You do not have any health insurance; the Sponsor will pay for the costs; and
3. 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, applying 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:]*

If you are injured or sick because of being in this study, the sponsor will only pay for care if the study was properly performed. The sponsor will not pay for injuries caused by your pre-existing condition unless that condition was made worse by being in the study.

Medical care will not be paid if you are injured or ill because of being in the study if it is because you purposefully did not follow instructions in this consent form or instructions from the researcher or if it is because of the natural progression of an underlying or pre-existing condition.

**Can being in this study help me?**  [Detail any known direct benefits that the participant may experience from participating in the research.] . *[If there is no direct benefit to participants:* Being in this study may or may not help you; however, we hope that information learned will help *[describe anticipated generalized societal benefit of the research.]*.

**Can being in this study benefit the researchers or WCM/NYP?**

*[Include any language required by the Conflict-of-Interest Committee]*

**How will my information be used and protected?**  [Discuss steps that you will take to ensure confidentiality, e.g. where will data be stored, who will have access to the data, how will data be transferred, to whom and where, when will data be de-identified, security of storage, when and how data will be destroyed (including recordings if applicable)] . We will take steps to protect all of your personal information, but we cannot promise confidentiality of all research data. Your name will not be used in any reports about this project. *[Revise the last sentence if you intend to use names or other identifiers in publications.]* The WCM researchers for this project, the WCM Institutional Review Board (IRB), the Office of Human Research Protection (OHRP), Department of Health and Human Services (DHHS), *[National Institutes of Health (NIH), Food and Drug Administration (FDA) and/or their representatives, {Name of Sponsor/Commercial Entity} and/or their representatives, Data Safety Monitoring Board, an independent group of experts,]* may access your records.

*[Is NIH genomic Sharing Policy Language applicable? If yes, add template language from* [*Appendix A*](#_Appendix_A)*]*

*[Is this an imaging studies project? If yes, add imaging studies language from* [*Appendix A*](#_Appendix_A)*.]*

*[Does your study involve conducting a pregnancy test with minors? If yes, add language from* [*Appendix A*](#_Appendix_A)*.]*

*[See* [*Appendix A*](#_Appendix_A) *for template language for biospecimens (whole genome sequencing and/or future use).]*

*[Does this study involve genetic testing? If yes, add template language for* ***Genetic Testing*** *found in* [*Appendix A*](#_Appendix_A)*.]*

We will share your information with a court of law or the government, in the unlikely event this is required by law.

*OR*

*[See* [*Appendix A*](#_Appendix_A) *for Certificate of Confidentiality language if applicable – required for NIH-funded studies collecting/using identifiable information]*

By signing this consent form, you give permission to access your research information. You also give permission for other hospitals or institutions, where you might receive medical care while being in the study, to release your medical records to the WCM researcher and study team.

*[Does your study require posting or registering on ClinicalTrials.gov? If yes, add Clinical Trials template language found in* [*Appendix A*](#_Appendix_A)*.]*

**Will my information be used in the future?**

*[Choose one]*  *[For more information regarding the NIH Data Sharing policy, please set up a consult with the Library by contacting Sarah Ben Maamor (sbm4003@med.cornell.edu) or John Ruffing (jruffing@med.cornell.edu)]*

*[If not banking research data:]*

We will destroy information about you when the study is finished.  Information about you will only be kept for as long as required by regulations and WCM policy and will not be used or shared for future studies.

OR

*[If banking de-identified research data:]*

All information that identifies you (e.g., your name, date of birth) will be removed from the data collected in this project. We will keep your de-identified information in a library that has information from other research studies.  Your information may be used in the future for other research studies without your permission.  Information that cannot identify you or be linked to you will be kept for a long period of time (longer than 50 years).  Some of your information may be placed on scientific databases for others to use.  These may include databases maintained by the federal government.  These data cannot be removed from the library.

OR

*[If banking identifiable research data:]*

We will keep your information in a library that has information from other research studies.  Your information may be used in the future for other research studies.  If you agree to this future use of your data, information that identifies you may be kept for a long period of time (longer than 50 years).  Some of your information that cannot be linked to you may be placed on scientific databases for others to use without your permission.  These may include databases maintained by the federal government.   You may decide to have your information removed from the library at any time by contacting the researcher.  All your information in the library will be destroyed but information about you that has already been shared cannot be destroyed.  You may choose not to participate in the library and still be part of the main study without penalty. *[This must be the case unless the study does not have direct benefit.  If there is no direct benefit, you may replace the last sentence with:* In order to be in the main study, you must agree to your identifiable information entering the library for future use. *where applicable.]*

*[Include future use checkboxes in the signature section.]*

**How will the researchers share my information?**

 [Indicate how information will be shared, with whom, and why OR state that information will not be shared.]

**Will I be paid?**

*[Choose one]*

You will not be paid.

OR

You will be paid  [amount]  by  [method]  for each visit, for a total of  [amount] . You will be paid  [indicate when payment will be recieved] . If you do not complete the entire project, you will be paid  [amount]  for each visit you complete. This payment is considered taxable income. Payments of $600 or more in a calendar year will be reported by WCM to the Internal Revenue Service (IRS). You will be asked to complete a W9 form. At the end of the tax year, Weill Cornell Medicine will use this information to provide you with Federal Form 1099-MISC. If you do not complete the W9 form, you may join this study, but you will not get any payments. *[If applicable, include any alternatives to the payment schedule or information regarding reimbursements.]*

**Do I have to join? Can I** **quit the study?** It is your decision whether to join this study or not. You have the right to choose not to join or to stop your participation at any time. Your decision to join in this research or stop participating will not affect your regular care nor your relationship with Weill Cornell Medicine, your doctors, or other employees. *[If applicable, discuss the process for participants to withdraw once the project has begun, including how participants can request their data not be used for research, and whether data already collected will remain in the study database (data collected will remain in the data if FDA-regulated research). Describe the process and option to continue with follow-up of their condition if applicable – how often and when this will end. If you are using audio or video recording, please state that the participant’s recording will be destroyed should he/she/they decide to withdraw.]*

You will be told about new information that may affect your health, wellbeing, or participation in this study.

*[See* [*Appendix A*](#_Appendix_A) *for template language if European Union General Data Protection regulation applies.]*

*[Does this study involve genetic testing? If yes, add template language for* ***Genetic Testing*** *found in* [*Appendix A*](#_Appendix_A)*.]*

 [Include the anticipated circumstances under which the participant’s participation may be terminated by the researcher, physician, or sponsor without regard to the participant’s or the legally authorized representative’s consent and the consequences of a participant’s decision to withdraw from the research and procedures for orderly termination of participation by the participant.]

**What are the costs?** *[Choose one]* There are no direct costs for being in this research study. *[Participants should only be told that they will have no costs for specific services if those services are listed on the HRBAF as being billed to the study or the sponsor.]*

OR

 [Describe what participants will need to pay and how participants can find out the estimated cost and whether it would be covered by health insurance.]

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

**Will I get the study results?**  [Include a statement regarding whether clinically relevant research results, including individual research results, will be disclosed to participants or others, and if so, under what conditions. State clearly whether or not study results will be placed in the participant's medical record, if this will differ depending on the test or treatment, explain which results will be added to the record, and outline visibility to other clinicians/practitioners who may access the record.]

Medical information collected during the research, such as test results, may be entered into your NYP electronic medical record and will be available to clinicians and other staff at NYP who provide care to you.

**Will I be able to see or copy my information? [Choose to include one of the 2 paragraphs below when applicable to your study:]**

During this study, you will be able to see or copy your protected health information as described in this form per 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 this study, you will not be able to see or copy certain parts of your protected health information as described in this form, per Weill Cornell Medicine policies, because  [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 be able to see or copy is/are:  [name the specific part(s)/test(s) of the research record that participants will not have acces to] .Your information will be available if there is an emergency and the treating doctor(s) need to know this information to best treat you. Your right to see or copy this information will begin when  [insert a specific time frame, such as 'initial treatment is complete' or 'follow-up in complete'] . By signing this form, you are agreeing that you will not be able to see or copy certain parts of your protected health information. If you want to see or copy your information at any time, please write to the Privacy Officer at the address on this form. *[If the access to the records is never reinstated, please revise the last four sentences as applicable.]*

**What if I have questions?**

If you have any questions, concerns, or complaints about the research, please contact:

 [Researcher's name]

 [Department]

 [Address]

 [Phone]

 [Email address]

If you have questions regarding your rights as a research participant, about what you should do in case of any injury or illness because of your study participation, or if you want to get information or give feedback, please contact the WCM Institutional Review Board (IRB) at:

WCM IRB, (646) 962-8200, irb@med.cornell.edu

Website: https://research.weill.cornell.edu/irb

You may also submit questions or complaints without giving your name by calling (866) 293-3077 or visiting http://www.hotline.cornell.edu/.

**HIPAA Authorization for Use and Disclosure of Your Protected Health Information**

As part of this study, we will be collecting health information about you and sharing it with others. This information is “protected” because it identifies you.

**Protected Health Information (PHI)**

By signing this Consent Document, you are allowing the following people to use or release your protected health information for this study:  [list all people or class of people (i.e. researchers and their staff) that will access PHI or you can also create a document to give participants that lists these people] .

This information may include:  [list PHI, e.g. results of physical exams, medical history, body mass index, sensitive diagnoses if applicable, etc.] . We will use this information to:  [include the purpose and describe each use of the requested information] . The health information listed above may be used by and/or released to:  [name or class of persons involved in research; i.e. researchers and their staff] .

In addition to the people listed in this form, there is a chance that your health information may be shared outside of the research study and no longer be protected by federal privacy laws. Examples of this include releases to law enforcement, legal proceedings, health oversight activities and public health measures.

**Right to Withdraw Your Authorization**

Your permission for the use and disclosure of your health information for this project shall not expire unless you cancel it. Your health information will be used or disclosed as long as it is needed for this project. However, you may stop your permission at any time by notifying the WCM Privacy Office in writing. To do this, please send a letter 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 them, please call (646) 962-6930.

Please note that the research team does not have to destroy or retrieve any of your health information that has already been used or shared before your withdrawal is received.

If you have questions about the privacy practices of the institution, you can request a Notice of Privacy Practices from your provider.

**Refusal to Sign**

If you choose not to sign this consent form and permission for the use and disclosure of your PHI, you cannot be in the research study. Your decision to sign this consent form or stop participating will not affect your regular care, benefits, nor your relationship with Weill Cornell Medicine, your doctors, or other employees.

**Signature**

I agree to participate in this research and allow my information to be used in this research. My questions have been answered. I will get a signed copy of this form.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_

Name of Adult Participant Signature of Adult Participant Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_

Name of Parent/Guardian Signature of Parent/Guardian Date

*[If a personal representative signs the authorization, a description of the representative’s authority must be provided.]*

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

Please check 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 this section if you are banking identifiable data to be used for secondary future research:]

**[ ]  YES,** I give permission for my data and informationto be kept for future unknown research. I understand that my data and information will be kept for [number]years *[or state indefinitely]*. I also give permission for my data and information to be **shared** with other qualified **researchers** for future research.

**[ ]  NO,** I do not give permission for my data and informationto be kept or shared for future research. *[If future research is mandatory omit this option.]*

*[Include the following if the study involves genetic tests for research purposes only (cannot predict a disease):]*

I agree to be contacted in the future for research purposes, for information about the study results, and for information about tests on my sample that could benefit my or my family’s medical care.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_

Name of Adult Participant Signature of Adult Participant Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_

Name of Parent/Guardian Signature of Parent/Guardian Date

**Legally Authorized Representative**

I am making a decision on behalf of the research participant who signed above whether to participate in this research. My questions have been answered. I will get a signed copy of this form.

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

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

I confirm that the consent form was presented orally to the participant in the participant’s own language, the participant was given the opportunity to ask questions, and the participant has communicated consent to participate:

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

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

#### **Participant Medical Record Number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

#### **Researcher Signature** (to be completed at time of informed consent)

I confirm that the research study was thoroughly explained to the participant. I reviewed the consent form and answered all questions. The participant appeared to have understood the information.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ ­\_\_\_\_\_\_\_

Name of Research Team Member Signature of Research Team Member Date

# Appendix A

**Instructions**

This resource document contains additional information that may need to be included in your consent form depending on the type of project. Should your consent form require this language, copy and paste the relevant header and content from this document into your consent form. This document provides some sample wording, however, as always, make sure that the content of your consent form is accurate to your project and IRB requirements.

[**Additional Elements:**](#_Additional_Elements_1)

* Future use of biospecimens
* Research involving biospecimens: whole genome sequencing
* HIV Testing
* Pregnancy Tests and Minors
* Opioid Use

[**Ancillary Elements:**](#_Ancillary_Elements)

* Imaging Studies
* NIH Genomic Sharing Policy
* Certificate of Confidentiality *[required for NIH-funded studies collecting/using identifiable information]*
* Clinical Trials*[required if the clinical trial will register on ClinicalTrials.gov]*
* Genetic Testing *[required language for genetics research]*
* European Union General Data Protection Regulation (GDPR)

##

## **Additional Elements**

***[If the research involves future use of biospecimens, include the following paragraph under “How will my information be used and protected?”]:***

Your biospecimens (even if identifiers are removed) may be used for commercial profit and you  [will or will not]  share in any commercial profit.

***[If the research involves*** ***biospecimens, include the following paragraph under “How will my information be used and protected?”]:***

This study involves genome-wide sequencing. Genome-wide sequencing is the study of a complete set of genetic instructions or DNA in a cell. The analysis looks for small changes in the genetic instructions. You should not expect to get genetic or other test results. We will not be conducting tests of your health. Researchers must study samples from many people over many years before they know if the results have meaning. In the rare event that we discover something that may help you prevent or treat a serious illness, we may try to locate you and offer you the information.

***[If the research involves HIV testing, include the following language under “What will I be asked to do?”]:***

This study includes HIV testing.

* HIV causes AIDS and can be spread through sexual activity, sharing needles, by pregnant women to their unborn baby, and by breastfeeding infants.
* There is treatment for HIV that can help you stay healthy.
* People with HIV or AIDS should use practices to protect people from getting HIV.
* HIV testing is voluntary and can be done without identifying you at a public testing center. However, testing is required if you would like to be in this research study.
* The law protects the privacy of HIV related test results.
* The law protects against discrimination based on your HIV status and services are available to address any discrimination.
* If because of this study you are initially diagnosed with HIV, the results must be reported to the New York State Department of Health for contact tracing purposes.
* If because of this study you are diagnosed with HIV, you will be given HIV counseling or a referral for HIV counseling.

***[If the research involves conducting a pregnancy test with minors, include the following language under “How will my information be used and protected?”]:***

We will not tell your parents/guardians about the results of your pregnancy test unless you give us permission to tell them.

***[If the research involves opioid use, include the following language under “What are the risks?”]:***

The medications that you take during this study may cause sleepiness or sedation. You should not drive after taking these medications.

## **Ancillary Elements**

***[If the research involves imaging studies, include the following paragraph under “How will my information be used and protected?”]:***

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 given to the researcher. If we see anything in the images that may have medical importance to you, the researcher will share the findings with you or a doctor of your choosing. It will be up to you and your doctor to decide if any further testing or treatment, outside of this research study and at your own cost, is necessary.

***[Include the following if your study is subject to NIH’s Genomic Sharing Policy\* (even if the data are de-identified] under “How will my information be used and protected?”: (required for studies submitting data to the dbGaP)***

* description to specify how participant confidentiality will be protected
* 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).
* Whether or not research results will be returned to subjects and under what conditions – those representations are consistent with Genome-Wide Association Studies (GWAS) policy that research results may only be returned in rare instances following established procedures at the contributing institutions.

***[If the research includes a Certificate of Confidentiality, include the following, under “How will my information be used and protected?” This section must be included for all NIH-funded studies collecting/using identifiable information.]*:**

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed.  This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know.  The Certificate does not stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others.  The Certificate cannot be used to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate does not stop disclosures required by the federal Food and Drug Administration (FDA).  The Certificate also does not prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research.  The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

***[If you will register and/or post on Clinicaltrials.gov, choose one applicable option below and include the language provided under “How will my information be used and protected?”] For guidance determining whether your study qualifies as a clinical trial per the entities below, please visit*** [***https://research.weill.cornell.edu/integrity-compliance/human-subjects-research/clinicaltrialsgov***](https://research.weill.cornell.edu/integrity-compliance/human-subjects-research/clinicaltrialsgov) ***or contact*** ***registerclinicaltrials@med.cornell.edu******.***

*If your study is interventional and evaluating an FDA-regulated product (regardless of funding source):*

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by US law. This website will not include information that can identify you. At most, the website will include a summary of the study results. You can search this website at any time.

*If your study is an NIH funded clinical trial that is not evaluating an FDA-regulated product:*

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>. This website will not include information that can identify you. At most, the website will include a summary of the study results. You can search this website at any time.

*Note: if your study is NIH funded AND interventional AND evaluating an FDA-regulated product, use the FDA-regulated product language above instead.*

*If your clinical trial (per ICMJE) is to be published in an ICMJE Journal but is not an intervention of an FDA-regulated product, nor a clinical trial funded by NIH:*

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>. This website will not include information that can identify you. You can search this website at any time.

*If your clinical trial is funded by a Common Rule Agency:*

A blank informed consent form will be made available on  [ClinicalTrials.gov or Regulations.gov] .This website will not include information that can identify you. You can search this website at any time.

*If the study (whether observational or interventional) is funded by PCORI:*

A description of this study will be available on <http://www.ClinicalTrials.gov>. This website will not include information that can identify you. At most, the website will include a summary of the study results. You can search this website at any time.

***[For studies that involve genetic testing, include the language below in the designated sections.]***

* ***[In the “What will I be asked to do?” section]***

 [Include a general description of the test, the purpose of the test, a general description of each disease or condition tested for, and the level of certainty that a positive result serves as the predictor for the disease or condition (if applicable)] .

* ***[In the “What are the risks?” section]***

The risks of genetic (DNA) tests are not known. In the future, results of these tests may be related to disease, illnesses, or addiction and allow researchers to predict the risk of getting an illness. We will keep the results private (only scientists working on this research project will know the results). There are unknown risks with genetic testing, including risks to relatives or other groups of people. It is possible that your genetic information could be used to identify you. We will take steps to protect you from the risks of other people finding out about the results of your genetic tests, including insurance companies or future employers.

 [If applicable, include a statement explaining the benefits and risks of consenting to future contact.] .

There are risks of loss of privacy and confidentiality, trouble getting insured or being employed, and being treated badly because of your test results. There are some protections provided by law. For more information, please visit: <http://www.genome.gov/Pages/PolicyEthics/GeneticDiscrimination/GINAInfoDoc.pdf>.

Note, this Federal law does not protect you against discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. Also, this Federal law does not protect against discrimination if you already have a genetic disease or disorder.

You  [will or will not]  be told of the results of the genetic testing. *[If “will”]* A positive result means you may develop or have  [name disease or condition being tested] . These results  [will or will not]  be confirmed in a certified genetic testing laboratory. *[Note: if results were not generated in a NYS licensed laboratory, testing must be confirmed in a CLIA certified laboratory.]*

You may want to speak with the researcher, a genetic counselor, or other health professional before signing this consent form. You may also want to seek further testing on your own after the study.

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

* ***[In the “How will my information be used?” section]***

 [Include a statement that no tests other than those authorized shall be performed on the biological sample and that the sample shall be destroyed at the end of the testing process or not more than sixy days after the sample was taken, unless a longer period of retention is expressly authorized in the consent] .

 [If applicable, include a statement that samples will be used for future genetic tests and the time period during which the tissues will be stored or a statement that the tissue will be stored for as long as deemed useful for research purposes] .

* ***[In the “Do I have to join? Can I*** ***quit the study?” section]***

You may decide to end future use of your samples at any time by contacting  [include name and contact information] .

***[If the European Union General Data Protection Regulation (GDPR) is applicable, include the following language under “How will my information be used and protected?”]***

***Please contact Maria Joseph with questions (******maj2007@med.cornell.edu******).***

The General Data Protection Regulation of the European Union/European Economic Area gives you the right to:

* Access, correct, withdraw, or delete your personal data; however, the research team may need to keep your personal data as long as it is necessary to achieve the purpose of this research;
* Restrict the types of activities the research team can do with your personal data;
* Object to using your personal data for specific types of activities; or
* Withdraw your consent to use your personal data for the purposes outlined in this document.  (However, this withdrawal will only apply to new personal data not yet collected or created.  Personal data already collected or created may continue to be used as outlined in this document.)

*[Include the purpose for each processing operation and whether and how decisions relating to the data will be based solely on automated processing. Include possible risks of data transfers to third countries in the absence of an adequacy decision and appropriate safeguards – US protections are not equivalent to the GDPR]*

*[Where research involves assignment to a treatment based upon personal data, explicit consent from the subject is required. Where decisions are based on sensitive data, the subject must consent to the use of the sensitive data for this purpose. Lastly, subjects must also be informed of how the decision is made, the potential consequences of the decision, the right to obtain human involvement in the decision, and to challenge the decision, if the research allows.]*

*Note, GPDR may also apply to secondary research and use of identifiable data beyond the original uses stated in the consent form will require re-consent of the participants.*

**Where to address your questions or concerns about your personal data**

If you want to make a request relating to the rights listed above or if you have any concerns about how your personal data is being handled, please contact the researcher listed at the end of this form. You may also contact the WCM Data Privacy Committee at dataprivacy@med.cornell.edu. Include your name, reasons for the request, and any other information that you find important.