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

* *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)*.*
* ***This form is only to be used if you are ONLY collecting and storing data and/or samples for future research use. If not, please use the Biomedical Informed Consent Form template. Throughout the template, terms “data and samples” are used. Please remove either “data” or “samples” if use of both are not appropriate.***
* *With the guidance language removed, this template has the following readability scores:*
	+ *Flesch Reading Ease: 62.3*
	+ *Flesch-Kincaid Grade Level: 8.3*

# **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.]*   [Include a statement regarding the potential future use of the data/samples.] . We are collecting these data and samples so they can be made available to future research scientists who hope to learn  [describe the purpose of the project] . This means your data and samples can be used for other people’s research studies. 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.] .
* **Any possible risks or discomforts?** [Include the most important risks] .
* **Will this study help me?** [Include the most important benefits] .
* **Do I have to join?** You do not have to be in this study.
 |

**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.] .

*[Will this repository include samples to be used for genetic research? If yes, add template language for* ***Genetic Research*** *found in* [*Appendix A*](#_Appendix_A)*.]*

**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.  [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.

*[Will this repository include samples to be used for genetic research? If yes, add template language for* ***Genetic Research*** *found in* [*Appendix A*](#_Appendix_A)*.]*

*[Are the procedures considered greater than minimal risk? If yes, add template language for* ***What if I am harmed?*** *found in* [*Appendix A*](#_Appendix_A)*.]*

**Are there pregnancy risks?** The risks during pregnancy are the same as the risks of the overall study listed above. Please discuss your concerns with your doctor before taking part in the study.

**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 in the future 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?** *[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)]*

Your data and samples will be stored for future research use. You will not be asked to sign another consent form before your data and samples are studied. [Discuss steps that you will take to ensure confidentiality, e.g. where will data/samples be stored, who will have access to the data/samples, how will data/samples be transferred, to whom and where, when will data/samples be de-identified if applicable, security of storage, when and how data/samples will be destroyed if applicable]. We will take steps to protect all of your personal information, but we cannot promise confidentiality of all research data. We also cannot promise your information will not be re-disclosed. 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.

*[Will this repository include samples to be used for genetic research? If yes, add template language for* ***Genetic Research*** *found in* [*Appendix A*](#_Appendix_A)*.]*

If your data or samples are given to a non-WCM person(s) or place(s), WCM cannot ensure the federal Privacy Rule is followed.

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

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

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.

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

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.

**How will my information be used in the future?**  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.

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

 [Indicate how information will be shared, with whom, and why.]  .

**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.]*

The samples collected in this study are not available for diagnostic tests. WCM has all rights and ownership of your data and samples. If your data and samples help develop future products, WCM also has all rights from the use of your data and samples and you will not receive financial benefit.

**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.

You are free to change your mind at any time about allowing your identifying data and samples to be kept for future research. Please contact the research team in writing to let them know you wish to end your participation. Please write whether you want the unused identifiable data or samples to be destroyed or if your data and samples could used for other research once identifiers are removed. Note, samples that have been already used for research, as well as any results or information already collected before you withdraw from the study, cannot be destroyed. Also, deidentified data or samples cannot be destroyed.

*[If applicable, include any other details regarding 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). 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.]*

 [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?** There are no direct costs for being in this research study.

**Will I get the study results?** You will not get results from future studies of your data and/or samples.

**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 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. 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]* and will be destroyed after the research is finished. I also give permission for my data and information to be **shared** with other qualified **researchers** for future 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

*[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 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)

* What if I am harmed? *[required for greater than minimal risk studies]*

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

* NIH Genomic Sharing Policy
* Genetic Research *required language for genetics research]*
* European Union General Data Protection Regulation (GDPR)

##

## **Additional Elements**

**What if I am harmed? [required for procedures that are greater than 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. Likely not applicable, but 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.

## **Ancillary Elements**

***[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.

***[For repositories that will involve genetic research, include the language below in the designated sections.]***

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

Your data and information may be used for genetic (DNA) research. Genetic research is an important part of studying the causes of diseases. The causes of many diseases are thought to be caused by combinations of inherited genes and possible various exposures to the environment.

 [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 and research are not known. In the future, results of genetic tests may be related to disease, illnesses, or addiction and allow researchers to predict the risk of getting an illness. 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. Researchers will take steps to protect you from the risks of other people finding out about results of your genetic tests for future research, 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.

There are no plans to inform you, or your relatives, about the results of genetic studies, since at this time the information is not thought to be medically useful.

You will not be told of the results of the genetic testing.

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

 [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] .

***[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.*