Information on Research

Text	Topic and explanations
INTRODUCTION	Sub-header
The purpose of this form is to give you information to help you decide if you want to take part in a research study. This consent form includes information about: - why the study is being done; - the things that you will be asked to do if you are in the study; - any known risks involved; - any potential benefit; - options, other than taking part in this study, that you have. The principal investigator (the lead researcher for this project) **[INSERT OTHER APPROPRIATE TITLE IF THE PI WILL NOT CONDUCT THE DISCUSSION]** will discuss the study with you. If at any time you have questions about the study, please ask a member of the study team. Take all the time you need to decide whether you want to take part in this research study. The purpose of this research is described below in the 'What is Involved in This Study?' **[OR OTHER, AS APPLICABLE]** section of this consent form. This consent form is written to address a research subject. If, however, you will be providing permission as **[INSERT, AS APPLICABLE]** the parent or legal guardian of a minor **[OR]** a legally authorized representative, the words 'you' and 'your' should be read as **[INSERT, AS APPLICABLE]** 'your child' **[OR]** 'the research subject'.	Invitation to Participate (includes description of consent process and use of "you" in the consent form)
INTRODUCTION	Sub-header
The purpose of this form is to give you information to help you decide if you want to take part in a research study. This consent and HIPAA authorization form includes information about: - why the study is being done; - the things that you will be asked to do if you are in the study; - any known risks involved; - any potential benefit; - options, other than taking part in this study, that you have; and - the way your health information will be used and shared for research purposes. The principal investigator (the lead researcher for this project) **[INSERT OTHER APPROPRIATE TITLE IF THE PI WILL NOT CONDUCT THE DISCUSSION]** will discuss the study with you. If at any time you have questions about the study, please ask a member of the study team. Take all the time you need to decide whether you want to take part in this research study. The purpose of this research is described below in the 'What is Involved in This Study?' **[OR OTHER, AS APPLICABLE]** section of this consent form. This consent and HIPAA authorization form is written to address a research subject. If, however, you will be	Invitation to Participate (for use in a Combined Consent and HIPAA Authorization Form) (includes description of consent process and use of "you" in the consent form)

providing permission as **[INSERT, AS APPLICABLE]** the parent or legal guardian of a minor **[OR]** a legally authorized representative, the words 'you' and 'your' should be read as **[INSERT, AS APPLICABLE]** 'your child' **[OR]** 'the research subject'.	
What information is on this form?	Sub-header from minimal risk consent form template
We are asking you to take part in a research study. This form explains why we are doing this study and what you will be asked to do if you choose to be in this study. It also describes the way we (Researchers) would like to use and share information about you. Please take the time to read this form. We will talk to you about taking part in this research study. You should ask us any questions you have about this form and about this research study. You do not have to participate if you don't want to. **[ADD THE FOLLOWING PARAGRAPH <u>ONLY IF THE STUDY WILL ENROLL CHILDREN, THE CHILDREN ARE AT LEAST 12 YEARS OLD AND ARE CAPABLE OF PROVIDING ASSENT,</u> AND PARENTAL PERMISSION IS REQUIRED. THIS CONSENT FORM WILL ALSO BE USED AS BOTH THE ASSENT FORM AND PARENTAL PERMISSION FORM.]** This consent form is written to address a research subject. If consent will be obtained from the parent (or legal guardian) of a minor, the words "you" and "your" should be read as ("your child" or "the research subject").	Invitation to participate (includes description of consent process and use of "you" in the consent form) (from minimal risk consent form template)
What information is on this form?	Sub-header from genetic testing consent form template
We are asking **[INSERT, AS APPLICABLE: (A) YOU, (B) YOUR CHILD, (C) A MINOR FOR WHOM YOU ARE THE PARENT OR LEGAL GUARDIAN OR (D) THE PERSON FOR WHOM YOU ARE A LEGALLY AUTHORIZED REPRESENTATIVE]** to take part in a research study**.** **[INCLUDE, IF PERMISSION FOR PARTICIPATION MAY BE PROVIDED BY THE RESEARCH PARTICIPANT'S PARENT, LEGAL GUARDIAN OR LEGALLY AUTHORIZED REPRESENTATIVE:]** This consent form is written to address the research participant. If, however, you will be providing permission as **[INSERT, AS APPLICABLE: (A) A PARENT, (B) A LEGAL GUARDIAN OF A MINOR OR (C) A LEGALLY AUTHORIZED REPRESENTATIVE]**, the words 'you' and 'your' should be read as **[INSERT, AS APPLICABLE: (A) YOUR CHILD OR (B) THE RESEARCH PARTICIPANT].** **[INCLUDE, IF APPLICABLE:]** A participant who is age 13-17 will **[INSERT, AS APPLICABLE: (A) ALSO BE ASKED TO READ AND SIGN THIS FORM OR (B) WILL BE ASKED TO SIGN A SEPARATE ASSENT FORM]** to indicate his/her willingness to participate in this study. **[INCLUDE, IF APPLICABLE:]** A participant who is age 12 or under will also be asked to **[INSERT, AS APPLICABLE: (A) READ AND SIGN AN ASSENT FORM OR (B) PROVIDE VERBAL AGREEMENT]** to indicate his/her willingness to participate in this study.	Invitation to Participate (includes description of consent process and use of "you" in the consent form) (from genetic testing consent form template)

This form explains why we are doing this study and what you will be asked to do if you choose to participate in it. It also describes the way we would like to use information about you and how we would like to use the **[SELECT: (A) BLOOD SAMPLE(S) AND/OR (B) TISSUE SAMPLE(S)]** ("biological samples") we obtain from you. Please take the time to read this form. We will also talk with you about taking part in this research study. If at any time you have questions about this form or the research study, please ask a member of the study team. Take all the time you need to decide whether you want to take part in the research study. Participation is voluntary; you do not have to participate if you do not want to.	
WHY IS THIS STUDY BEING DONE?	Sub-header
Study purpose We are doing this research study to find out **[INSERT PURPOSE OF THE STUDY IN LAY TERMS. IF INVESTIGATIONAL (OFF LABEL OR UNAPPROVED) DRUGS OR DEVICES WILL BE USED, ALSO INSERT APPLICABLE SAMPLE TEXT]**. You are being asked to take part in this study because **[INSERT GENERAL INCLUSION CRITERIA]**. About **[INSERT TOTAL NUMBER OF SUBJECTS]** people are expected to be enrolled in this study **[EXPLAIN WHETHER THIS IS AT THIS SITE OR AT ALL SITES].**	Study Purpose
Why is this study being done?	Sub-header from minimal risk consent form template
Choose one of the following: We are doing this research study to find out if **[INSERT SPECIFICS]** can help people who have **[INSERT CONDITION]**. **OR** We are doing this research study to better understand how people think about **[INSERT SPECIFICS]**. **[OR]** We are doing this research study to learn more about **[INSERT SPECIFICS]**. **[OR]** We are asking you to take part in this study because **[CHOOSE ONE OF THE FOLLOWING OPTIONS AS APPROPRIATE]** -you have **[INSERT CONDITION]**. -you are scheduled to have **[A ROUTINE MEDICAL CARE PROCEDURE]**. -you are part of **[SOME ORGANIZATION/EVENT]** and we would like information about people in this group. Add if applicable: We also want to find out if **[INSERT SPECIFICS]**.	Study Purpose and Invitation to Participate (from minimal risk consent form template)
Why is this study being done?	Sub-header from genetic testing consent form template
The purpose of this study is to gain a better understanding of the cause of **[DESCRIBE THE MEDICAL CONDITION BEING STUDIED]** (the "Study Medical Condition") through genetic testing. You have been asked to participate in the study **BECAUSE [INSERT, AS APPLICABLE: (A) YOU HAVE THE STUDY MEDICAL CONDITION, (B) YOU**	Study Purpose (from genetic testing consent form

ARE AN UNAFFECTED FAMILY MEMBER OF A SUBJECT WHO HAS THE STUDY MEDICAL CONDITION OR (C) YOU ARE AN INDIVIDUAL WHOSE GENETIC INFORMATION WILL BE COMPARED TO THE GENETIC INFORMATION OF INDIVIDUALS WHO HAVE THE STUDY MEDICAL CONDITION]. We will study the results of the genetic tests being performed to find and possibly confirm associations between the Study Medical Condition and specific genes or genetic variants.	template)
Off label use of an approved drug **[INSERT DRUG NAME]** is being used in an investigational manner (not for the purpose that it is approved for) in this research study. This means that [**INSERT DRUG NAME]** has been approved by the Food and Drug Administration (FDA) for use in **[INSERT CONDITION AND/OR POPULATION OF SUBJECTS IT IS APPROVED FOR]**, but it has not been approved for **[INSERT USE RELATED TO THIS RESEARCH]**.	Use of an approved drug "off-label"
Use of an unapproved drug **[INSERT DRUG NAME]** is an investigational drug. This means that the drug has not been approved by the Food and Drug Administration (FDA) for medical use in patients, but has only been approved for use in research.	Use of an unapproved drug
Use of an unapproved device **[INSERT DEVICE NAME]** is an investigational device. This means that **[INSERT DEVICE NAME]** has not been approved by the Food and Drug Administration (FDA) for medical use in patients, but has only been approved for use in research.	Use of an unapproved device
Use of an approved device being used off-label **[INSERT DEVICE NAME]** is being used in an investigational manner (not for the purpose that it is approved for) in this research study. This means that [**INSERT DEVICE NAME**] has been approved by the Food and Drug Administration (FDA) for **[INSERT CONDITION AND/OR POPULATION OF SUBJECTS IT IS APPROVED FOR]** but it has not been approved for **[INSERT USE RELATED TO THIS RESEARCH]**.	Use of an approved device "off-label"
Why are we interested in talking with you?	Sub-header from 7-11 year old assent form template
We want to tell you about a research study we are doing. Research is a way to learn more about something. **[ADD THE FOLLOWING AS APPROPRIATE:]** This is the way we find out if medicine or other treatments are safe and if they work. We are asking you and other children to be in this research study because you have **[INSERT SIMPLE/LAYPERSON NAME OF MEDICAL CONDITION OR OTHER REASONS FOR INCLUSION. USE VERY SIMPLE LANGUAGE]**. We are working to **[FIND OUT/LEARN MORE ABOUT — I.E. PROVIDE A SIMPLIFIED EXPLANATION OF THE HOW OR WHY YOU ARE DOING THE RESEARCH. USE VERY SIMPLE LANGUAGE]**. It is okay to ask questions about what we are telling you. If you do not understand something, just ask us. We want	Invitation to Participate (from 7-11 year old assent form template)

you to ask anytime you think of a question.	
Why are we interested in talking with you?	Sub-header from 12-17 year old assent form template
We are asking you to participate in this research because **[INSERT SIMPLE/LAYPERSON NAME OF MEDICAL CONDITION OR OTHER REASONS FOR INCLUSION. USE SIMPLE LANGUAGE]**. Before agreeing to participate in this study, it is important that you read this form and talk with the research staff. You should only take part in this study if you want to. This form will explain why we are doing the research and what will happen to you if you are in this research study. We would like to discuss the study and review this form with you. You can ask questions at any time before, during or after our discussion. You will also have time to read this form and ask any questions about the research study. At the end, we will ask you to sign this form if you agree to participate. It is okay to ask questions about what we are telling you. If you do not understand something, just ask us. We want you to ask any time you think of a question.	Invitation to Participate (includes description of consent process) (from 12-17 year old assent form template)
What is this research study about?	Sub-header from 12-17 year old assent form template
In this research study, we want to **[FIND OUT/LEARN MORE ABOUT—I.E. PROVIDE A SIMPLIFIED EXPLANATION OF THE <u>HOW</u> OR <u>WHY</u> YOU ARE DOING THE RESEARCH. USE SIMPLE LANGUAGE]**. There will be about **[INSERT NUMBER]** participants in this study.	Study Purpose and Number of Participants (from 12-17 year old assent form template)
What will happen to you if you are in the study?	Sub-header from 7-11 year old assent form template
[DESCRIPTION OF WHAT WILL TAKE PLACE FROM THE CHILD'S POINT OF VIEW. CHOOSE AS APPROPRIATE:] If you want to be in this study, this is what will happen: • We will ask you to **[INSERT SPECIFICS, E.G., ANSWER SOME QUESTIONS]**. • We will have you do **[INSERT SPECIFICS]**. • We will look at your **[INSERT SPECIFICS, E.G., DOCTOR'S RECORDS]**. **[INDICATE THE APPROXIMATE TOTAL LENGTH OF THE PARTICIPANT'S EXPECTED PARTICIPATION BY THE NUMBER OF DAYS, MONTHS OR YEARS (FROM SCREENING TO FINAL COMPLETION). IF THE STUDY HAS DIFFERENT STAGES, EXPLAIN HOW LONG EACH WILL LAST.]** This research will take **[INSERT HOW LONG TOTAL]**. It will take **[INSERT NUMBER OF VISITS]** visits that each last about **[INSERT AMOUNT OF TIME OF VISIT(S)]**. **[CHOOSE AS APPROPRIATE:]** You may not benefit directly from this study. We hope to learn something that could help other children in the future	Procedures (from 7-11 year old assent form template)

[ADD, IF APPLICABLE:] who have **[INSERT MEDICAL CONDITION]**. **[OR]** We don't know if being in this study will help you. Some of the ways you could be helped are: • You could **[INSERT SPECIFICS, E.G., GET BETTER]**. • Some kids feel **[INSERT SPECIFICS, E.G., LESS PAIN]**. • Feel good about helping other kids.	
What will happen if you agree to be in the study?	Sub-header from 12-17 year old assent form template
[DESCRIPTION OF WHAT WILL TAKE PLACE FROM THE MINOR'S POINT OF VIEW.] The following will be asked of you, if you decide to be in this research study**: [LIST THE PROCEDURES THAT ARE REQUIRED IN THIS RESEARCH. USE A BULLET OR NUMBERING FORMAT]**. **[CHOOSE AS APPROPRIATE:]** • We will ask you to **[INSERT SPECIFICS, E.G., ANSWER SOME QUESTIONS]**. • We will have you do **[INSERT SPECIFICS]**. • We will look at your **[INSERT SPECIFICS, E.G., DOCTOR'S RECORDS]**. • This research will take **[INSERT HOW LONG TOTAL]**. **[INDICATE THE APPROXIMATE TOTAL LENGTH OF THE PARTICIPANT'S EXPECTED PARTICIPATION BY THE NUMBER OF DAYS, MONTHS OR YEARS (FROM SCREENING TO FINAL COMPLETION). IF THE STUDY HAS DIFFERENT STAGES, EXPLAIN HOW LONG EACH WILL LAST.]** This will take **[INSERT NUMBER OF VISITS]** visits that each last about **[INSERT DURATION OF VISIT(S)]**. You will have to come back to the office **[insert total number of times or visits or revise accordingly to briefly indicate what is required of the child in terms of time]**.	Procedures (from 12-17 year old assent form template)
What will I be asked to do if I choose to be in this study?	Sub-header from genetic testing consent form template
If you agree to be in this study, we will schedule an evaluation with **[SELECT, AS APPLICABLE: (A) THE RESEARCHER CONDUCTING THIS STUDY OR (B) YOUR PHYSICIAN]**. **[IF ANY OF THE FOLLOWING DO NOT APPLY, REMOVE THEM.]** Before this visit: • We will collect some information about you, including your medical history. • If you are a patient at Columbia University Medical Center (CUMC) and/or NewYork-Presbyterian Hospital (NYPH), we will review CUMC and/or NYPH electronic medical records and collect information, including **[INSERT SPECIFICS]**. • If we require medical records from outside institutions, we will ask you to sign a separate authorization form to obtain them. We will perform the following procedures during this visit *[modify as appropriate]*:	Procedures (from genetic testing consent form template)

• Three-generation family history • Detailed physical exam • Photographs and video recording of the physical exam • Blood draw of **[N]** tubes (**[N]** teaspoons) of blood • **[OTHER]** Genetic tests that are expected to include WES or WGS will be performed on the DNA in your biological samples. **[ADD, IF APPLICABLE:]** We will also freeze some of the biological samples to repeat or confirm these tests or to perform further analysis for this study. Sometimes we are unable to get sufficient DNA from the first set of biological samples that we collect, and may need to contact you to provide an additional sample so that the genetic tests can be conducted.	
WHAT IS INVOLVED IN THIS STUDY?	PROCEDURES
Procedures **[THIS PARAGRAPH SHOULD INCLUDE ANY RELEVANT DETAILS PERTAINING TO STUDY DESIGN (E.G., RANDOMIZATION, PLACEBO CONTROLLED, DOUBLE OR SINGLE BLIND) AND AN EXPLANATION OF THESE DETAILS IN LAY TERMS.]** Taking part in this study will last **[INSERT TOTAL LENGTH OF STUDY PERIOD]** and will include **[INSERT ACTUAL OR ESTIMATED TOTAL NUMBER OF STUDY VISITS]**. The schedule of study visits and the procedures that will be done at each visit are as follows: [**INSERT DESCRIPTION IN LAY TERMS OF EACH PROCEDURE THAT WILL BE CONDUCTED AT EACH VISIT**]	Procedures (medical)
Procedures **[THIS PARAGRAPH SHOULD INCLUDE ANY RELEVANT DETAILS PERTAINING TO STUDY DESIGN AND AN EXPLANATION OF THESE DETAILS IN LAY TERMS.]** Taking part in this study will last **[INSERT TOTAL LENGTH OF STUDY PERIOD]** and will include **[INSERT ACTUAL OR ESTIMATED TOTAL NUMBER OF STUDY VISITS].** The schedule of study visits and the procedures that will be done at each visit are as follows: **[INSERT DESCRIPTION IN LAY TERMS OF EACH PROCEDURE THAT WILL BE CONDUCTED AT EACH VISIT]**	Procedures (social science or behavioral)
What will I be asked to do if I choose to be in this study?	Sub-header from minimal risk consent form template
[CHOOSE AS APPROPRIATE:] We will ask you to come to **[INSERT LOCATION]**. **OR** We will come to **[INSERT LOCATION]** to see you. Choose as appropriate: We will ask you to complete **[NUMBER]** survey(s) / answer questions.	Procedures (from minimal risk consent form template)

[OR] We will ask you to give a blood sample **[INSERT VOLUME IN TEASPOON, TABLESPOON]**. The blood will be drawn (taken) by **[INSERT SPECIFICS]** and sent to **[INSERT SPECIFICS IF APPLICABLE]** to be tested for **[INSERT SPECIFICS]**. **[OR]** We will contact you in **[INSERT SPECIFIC]** month[s]/week[s] by telephone to **[INSERT SPECIFICS]**. **[OR]** We will get information from your medical records such as **[INSERT SPECIFICS]**. **[OR]** The following tests and procedures will be done on scheduled visits: **[DESCRIBE SIMPLY WHAT THE RESEARCH PARTICIPANT WILL DO OR EXPERIENCE IN CHRONOLOGICAL ORDER. IF SOME PROCEDURES ARE OPTIONAL, IT SHOULD BE CLEARLY NOTED AND STATEMENTS SHOULD BE ADDED TO THE CONSENT FORM SO THAT PERMISSION FROM THE RESEARCH PARTICIPANT CAN BE OBTAINED FOR THE OPTIONAL PROCEDURES (I.E. "I AGREE…" AND " . "I DO NOT AGREE…-"). IF MANY PROCEDURES WILL BE PERFORMED, A TABLE CAN BE USED INSTEAD OF OR IN ADDITION TO A PARAGRAPH.]** **ADDITIONAL LANGUAGE FOR DESCRIBING PROCEDURES IS AVAILABLE AT: CONSENT FORM BUILDER SAMPLE LANGUAGE** This study will last **[INSERT TOTAL LENGTH OF STUDY PERIOD]**.	
Use of Data/Specimens We would like to store the data **[AND/OR]** biological samples that you agreed to provide as part of this study and possibly use them for future research. They will be stored at CUMC either with the researchers on this study or in a central storage facility called a **repository.** With your permission, your data **[AND/OR]** samples will be **stored** at CUMC indefinitely in **identifiable** form**.** Your data **[AND/OR]** samples will be labeled with a code number that the researchers on this study or the people managing the repository will be able to link to you. Also with your permission, your data **[AND/OR]** samples may be **used** by other Columbia researchers or researchers at other institutions, including commercial companies, for research on your **[SELECT: medical condition(s), symptom(s)]** or other conditions. If they are given to researchers who are not researchers on this study, they will only be given in **deidentified** form. This means that your name and other identifying information have been permanently removed from your data **[AND/OR]** samples **OR** that your data **[AND/OR]** samples are coded and the researchers who will use them will not have the key to the code. Any future testing or research using your data **[AND/OR]** samples may lead to the development and use of information, products, tests and treatments having commercial value. You will not receive any compensation that may result from these tests or treatments. **[_____ I agree] [____ I do not agree]** to the **storage** of my data **[AND/OR]** samples at CUMC in identifiable form after completion of this study.	Use of Data/Specimens Updated March 2016 to correlate with the future use language in the WES and WGS consent form templates [Note that the procedures in any repository protocol that will store this material for future use must have storage provisions that are consistent with these statements.]

[____ I agree] [____I do not agree] to the **use** of my data **[AND/OR]** samples for future research and/or testing, including for commercial purposes, that may or may not be related to this study. I understand that my data **[AND/OR]** samples will only be given to researchers in deidentified form or coded. You can change your mind regarding storage and future use of your samples at any time. Please see the Contact section of the consent form for further information.	
Permission for future use **[APPLIES ONLY TO SAMPLES RETAINED IN AN IDENTIFIABLE OR CODED MANNER]** Please initial below to indicate whether or not you give permission for your specimens to be used for future research. **[THE FOLLOWING CHECK BOXES SHOULD BE ALTERED TO MATCH WHAT IS BEING DONE IN THIS RESEARCH STUDY]** _____ (initial) I agree to have my specimens stored for future research by the investigators who are conducting this study. _____ (initial) I agree to have my specimens stored and shared with other investigators who are doing research that is related to this study or my condition. _____ (initial) I agree to have my specimens stored and shared with other investigators who are doing research that is or is not related to this study or my condition.	Permission for future use of samples retained with identifiers or in a coded manner
Permission for future contact The researchers may want to contact you in the future. **[EXPLAIN WHY SOME PARTICIPANTS MIGHT BE CONTACTED IN THE FUTURE, AND HOW OFTEN THIS MAY HAPPEN. ADAPT OPTIONS AS APPROPRIATE.]** Please initial below to show whether or not you give permission for future contact. _____ (initial) I give permission to be contacted in the future for research purposes. _____ (initial) I give permission to be contacted in the future for information relating to this study.	Permission for future contact
Use of specimens collected in this protocol, as described in this protocol only As previously described, the blood samples and data obtained from this study will be used for testing and research on **[IDENTIFY CONDITION UNDER STUDY]** according to the study protocol. Such testing and research may be performed by **[INSERT NAME OF PI]** or other researchers at this institution or other institutions, including commercial entities, but only as described in the protocol for this study. Data and specimens sent to other institutions will we sent **[INSERT APPLICABLE DESCRIPTION]** with identifiers **[OR]** in a coded manner **[OR]** in a de-identified manner (all identifying information removed).	Use of specimens per this protocol
Use of specimens collected in this protocol, for use in other research studies	Future use of specimens for other studies

The blood samples **[AND/OR]** data obtained from this study might be used for future testing and research on **[IDENTIFY CONDITION UNDER STUDY]** according to different study protocols, as well as future testing and research on **[IDENTIFY OTHER POTENTIAL RESEARCH]**. Such future testing and research may be performed by **[INSERT NAME OF PI]** or other researchers at this institution or other institutions, including commercial entities that may not yet be identified.

To facilitate this future testing and research, blood samples **[AND/OR]** data that have been de-identified (all identifying information removed) may be released to other institutions, including commercial entities. Such future testing and research may also lead to the development and use of information, products, tests, and treatments having commercial value. You will not receive any financial compensation that may result from this testing or research, as the specimens used will have been de-identified and it will not be possible to determine if your specimen was used.

Prior to de-identification, the study sponsor may want to contact you or your physician for additional information that would be important to the future project(s).

At the end of this study, if you agree to storage of your any blood samples that remain, they will be stored at **[IDENTIFY STORAGE SITE]** for **[IDENTIFY RETENTION PERIOD]**. The leftover samples may be moved in the future from **[IDENTIFY STORAGE SITE]** to other similar storage facilities to accommodate future testing and research.

All data obtained from this study will be stored at: **[IDENTIFY STORAGE SITE]**

Consent: (please select only one option)

___ I consent to the storage of my blood sample **[AND/OR]** data as described above for potential future research and/or testing with commercial purposes. I also consent to the study sponsor contacting me or my physician for further information.

___ I consent to the storage of my blood sample **[AND/OR]** data as described above for potential future research and/or testing with commercial purposes. I do not consent to the study sponsor contacting me or my physician for further information.

___ I hereby consent to the storage of my blood sample **[AND/OR]** data for potential future research and testing only for the study of **[IDENTIFY CONDITION]**. I also consent to the study sponsor contacting me or my physician for further information.

___ I hereby consent to the storage of my blood sample **[AND/OR]** data for potential future research and testing only for the study of **[IDENTIFY CONDITION]**. I do not consent to the study sponsor contacting me or my physician for further information.

___ I do not consent to the storage of my blood sample after the end of this study.

_____ _____

Printed name Date

_____

Signature	
Permission for future contact for genetic health information It is possible that in the future a genetic test could be done on your stored samples that may give a result that could be important to your or a family member's health. Knowing this information could have risks. For example, it could make you anxious. Or, if insurance companies or employers find out about the results of some genetic tests, it could make it difficult to get insurance or to get a job. Please choose and initial one of the options below to tell us if you want to know about this information. _____ (initial) Yes, please try to contact me if information is found in future studies of my genetic material that would be important to my or my family's personal health. _____ (initial) No, don't contact me about information found from future studies of my genetic material.	Future contact for genetic health information
IF THE RESEARCH WILL INVOLVE MANDATORY AUDIO/VIDEO RECORDING OR PHOTOGRAPHY OF RESEARCH PARTICIPANTS, PLEASE ADD THE FOLLOWING: Audio/video recording or photography We are asking for you to allow us to **[INCLUDE ALL RECORDING PROCEDURES SUCH AS AUDIOTAPE (VOICE RECORDING), VIDEOTAPE (MOVIE), PHOTOGRAPH (PICTURE)]** you as part of the research study. The recording(s) will be used **FOR [INCLUDE PURPOSE OF RECORDING; E.G., ANALYSIS BY THE RESEARCH TEAM, POSSIBLE USE AS A TEACHING TOOL TO THOSE WHO ARE NOT MEMBERS OF THE RESEARCH STAFF (I.E., FOR EDUCATIONAL PURPOSES), COMMERCIAL PURPOSES. IF THE TAPES WILL BE USED FOR COMMERCIAL PURPOSES, THE CONSENT FORM MUST SPECIFICALLY STATE WHETHER OR NOT THE SUBJECT WOULD BE COMPENSATED FOR THIS USE.]**. The recording(s) will include **[INDICATE WHETHER THE SUBJECT'S NAME OR ANY OTHER IDENTIFIER WILL BE RECORDED. IF VIDEOTAPING WILL BE UTILIZED, INDICATE THE EXTENT TO WHICH THE SUBJECT'S IDENTITY WOULD BE MASKED, E.G., FACIAL FEATURES PARTIALLY BLOCKED OUT, RECORDING WILL NOT INCLUDE FACIAL PICTURES, RECORDING WILL INCLUDE FULL FACIAL PICTURES.]** . The recording(s) will be stored **[INCLUDE MEASURES TAKEN TO PROTECT SUBJECT'S PRIVACY, E.G., IN A PASSWORD PROTECTED DATABASE; IN A LOCKED FILE CABINET WITH NO LINK TO SUBJECT'S IDENTITY, IN A LOCKED FILE CABINET AND LINKED WITH A CODE TO SUBJECT'S IDENTITY, IN A LOCKED FILE CABINET AND LABELED WITH SUBJECT'S NAME OR OTHER IDENTIFIABLE INFORMATION] AND WILL BE [INDICATE THE LENGTH OF TIME THE RECORDING(S) WILL BE RETAINED, E.G., DESTROYED UPON COMPLETION OF THE STUDY PROCEDURES, DESTROYED UPON PUBLICATION OF STUDY RESULTS, RETAINED INDEFINITELY.]**. **IF RECORDING IS AN OPTIONAL PROCEDURE, ADD THE FOLLOWING:** Please write your initials next to the choice you make below:	Audio or other recording (from minimal risk consent form template) (can be used for a study of any risk level)

_____ (initial) yes, I agree to recording as described above _____ (initial) no, I do not want to be recorded	
Consent: (please select only one option) ___ I consent to the storage of my blood sample and data as described above for potential future research and/or testing with commercial purposes. I also consent to the study sponsor contacting me or my physician for further information. ___ I consent to the storage of my blood sample and data as described above for potential future research and/or testing with commercial purposes. I do not consent to the study sponsor contacting me or my physician for further information. ___ I consent to the storage of my blood sample and data for potential future research and testing only for the study of **[IDENTIFY CONDITION]**. I also consent to the study sponsor contacting me or my physician for further information. ___ I consent to the storage of my blood sample and data for potential future research and testing only for the study of **[IDENTIFY CONDITION]**. I do not consent to the study sponsor contacting me or my physician for further information. I do not consent to the storage of my blood sample after the end of this study. _____ _____ Printed name Date _____ Signature	Storage and future use of samples and data (with option for sponsor to contact)
Use of specimens collected in this protocol, for use in other research studies The blood samples and data obtained from this study might be used for future testing and research on **[IDENTIFY CONDITION UNDER STUDY]** according to different study protocols, as well as future testing and research on **[IDENTIFY OTHER POTENTIAL RESEARCH]**. Such future testing and research may be performed by **[INSERT NAME OF PI]** or other researchers at this institution or other institutions, including commercial entities, which may not yet be identified. To facilitate this future testing and research, blood samples and data that have been de-identified (all identifying information removed) may be released to other institutions, including commercial entities. Such future testing and research may also lead to the development and use of information, products, tests, and treatments having commercial value. You will not receive any financial compensation that may result from this testing or research, as the specimens used will have been de-identified and it will not be possible to determine if your specimen was used. Prior to de-identification, the study sponsor may want to contact you or your physician for additional information that would be important to the future project(s). At the end of this study, if you agree to storage of your specimens, leftover samples and serum will be stored at **[IDENTIFY STORAGE SITE]** for **[IDENTIFY RETENTION PERIOD]**. The leftover samples and serum may be moved in the future from **[IDENTIFY STORAGE SITE]** to other similar storage facilities to accommodate future testing and research. All data obtained from this study will be stored at: **[IDENTIFY STORAGE SITE]**	Storage and future use of samples and data (with description of potential future use and identification of storage facility) (with option for sponsor contact)

Consent: (please select only one option) ___ I consent to the storage of my blood sample and data as described above for potential future research and/or testing with commercial purposes. I also consent to the study sponsor contacting me or my physician for further information. ___ I consent to the storage of my blood sample and data as described above for potential future research and/or testing with commercial purposes. I do not consent to the study sponsor contacting me or my physician for further information. ___ I hereby consent to the storage of my blood sample and data for potential future research and testing only for the study of **[IDENTIFY CONDITION]**. I also consent to the study sponsor contacting me or my physician for further information. ___ I hereby consent to the storage of my blood sample and data for potential future research and testing only for the study of **[IDENTIFY CONDITION]**. I do not consent to the study sponsor contacting me or my physician for further information. I do not consent to the storage of my blood sample after the end of this study. _____ _____ Printed name Date _____ Signature	
THE STATEMENT BELOW IS APPLICABLE FOR ANY OTHER OPTIONAL PROCEDURES AND SHOULD BE ADDED IMMEDIATELY AFTER THE FULL DESCRIPTION IN LAY LANGUAGE OF THE OPTIONAL PROCEDURE. Please write your initials next to the choice you make below: _____ (initial) yes, I agree to **[INSERT OPTIONAL PROCEDURE]** _____ (initial) no, I do not agree to **[INSERT OPTIONAL PROCEDURE]**	Statement for optional procedures and lines for initials

Risks

Text	Topic and explanations
WHAT ARE THE RISKS OF THE STUDY?	Sub-header
General risks There may be risks or discomforts if you take part in this study. These include: **[DESCRIBE ANY REASONABLY FORESEEABLE PHYSICAL, INFORMATIONAL OR PSYCHOLOGICAL RISKS, DISCOMFORTS OR SIDE EFFECTS AND THE LIKELIHOOD OF THE OCCURRENCE]**. **[IF APPLICABLE, INCLUDE THE FOLLOWING STATEMENT]** There may be other risks of taking part in this research study that we don't know about. If we learn about other risks, we will let you know what they are so that you can decide whether or not you want to continue to be in the study.	General risks

Are there any risks?	Sub-header from minimal risk consent form template
[RISKS (PHYSICAL, SOCIAL, FINANCIAL, PSYCHOLOGICAL, PRIVACY, OR OTHER) AND POSSIBLE DISCOMFORTS NEED TO BE DESCRIBED. DEPENDING ON THE STUDY, THERE CAN BE RISKS RELATED TO CONFIDENTIALITY OF INFORMATION, RISKS FROM PROCEDURES, RISKS FROM INCIDENTAL FINDINGS, AND DISCOMFORTS FROM THE PROCEDURES.] **[CHOOSE ONE OR MORE OF THE FOLLOWING, AS APPLICABLE:]** We do not think that there are any risks to taking part in this study. **[OR]** There are no physical risks related to participating in this research study. **[OR]** You may feel uncomfortable when **[INSERT SPECIFIC]**. **[OR]** You can choose to skip questions if they make you uncomfortable. **[OR]** There may be risks or discomforts if you take part in this study. These include: **[DESCRIBE ANY REASONABLY FORESEEABLE RISKS, DISCOMFORTS OR SIDE EFFECTS AND THE LIKELIHOOD OF THE OCCURRENCE].** **BELOW ARE SUGGESTED TEXTS FOR DESCRIBING RISKS FREQUENTLY LISTED/APPLICABLE IN MINIMAL RISK STUDIES. ADDITIONAL LANGUAGE IS AVAILABLE AT: CONSENT FORM BUILDER SAMPLE LANGUAGE** **[IF THE STUDY INVOLVES COLLECTION OR USE OF PRIVATE INFORMATION:]** Loss of confidentiality A risk of taking part in this study is the possibility of a loss of confidentiality or privacy. Loss of privacy means having your personal information shared with someone who is not on the study team and was not supposed to see or know about your information. The study team plans to protect your privacy. Their plans for keeping your information private are described in the Privacy section of this consent form. **[IF STUDY INVOLVES BLOOD DRAW:]** Blood Draw Risks of having blood drawn are soreness and/or a black and blue mark at the site from where the blood is drawn. Sometimes, people feel uncomfortable at the time of the blood draw. Occasionally people feel lightheaded or weak. There is also a small risk of infection whenever blood is drawn.	Risks (from minimal risk consent form template)
What are the risks of participating in this study?	Sub-header from genetic testing consent form template
[IF BLOOD SAMPLE, SELECT:] There may be slight pain or bruising due to the blood draw. We will use only skilled individuals to obtain blood from you. **[IF TISSUE SAMPLE, INSERT RELEVANT RISK INFORMATION:]** Even without your name and other identifiers, your genetic information is unique to you. There is a potential risk that someone will identify you from your genetic information or learn something about you by looking at your genetic information; this risk may increase in the future as technologies advance and more researchers study your genetic information.	Risks (from genetic testing consent form template)

The Genetic Information Non-discrimination Act is a federal law that prevents insurance companies from using your genetic information to deny health insurance coverage. The law also prevents employers from getting or using genetic information for employment-related decisions. However, the law does not prevent companies that provide life insurance, disability insurance or long-term care insurance from using genetic information. **[INCLUDE THE FOLLOWING 2 PARAGRAPHS ONLY IF RESULTS MAY BE RETURNED:]** Current genetic testing is not an exact science, and you should be aware that the genetic testing being done in this study is considered research testing. As with all research, it is possible that although the test gives us information that we think may be important, we will not know what all of it means. Thus, it is possible that the meaning of the information you are given may change over time as additional research is conducted. The genetic research may identify genetic changes that may require additional testing to evaluate. This could result in anxiety, uncertainty and additional expenses that may or may not be covered by your insurance. The genetic research may identify serious, untreatable genetic conditions. Such a finding can result in unexpected psychological trauma, both for you and your family. The detection of such a condition could also affect the health or health care needs of your siblings, children or other close relatives. Because we cannot say with certainty how information derived from the genetic research could be used in the future, this study may involve risks that are currently unforeseeable.	
Radiation Radiation is an energy that is all around us. It is in the air, water, food, and ground. This is called natural radiation. Radiation is also made by man. It is in our buildings and homes. It is also in medical examinations or treatments such as X-rays. The energy used in X-rays and some other types of scans (such as bone density and Positron Emission Tomography, or PET, scans) is known as radiation. Radiation and the risks of receiving radiation are hard to measure. Experts on radiation agree that there is some risk because radiation exposure adds up over our lifetime. You should always carefully think about how much radiation you will receive from medical examinations or treatments. A millirem (mrem) is a way of measuring radiation. On the average, each person in the United States receives about 300 mrem every year from natural radiation. People also receive about 60 mrems of radiation every year from other things such as a chest or dental X-rays, or from flying in an airplane. For example, if you have a chest X-ray you will receive about 8 mrems of radiation. If you fly in an airplane from Washington DC to Los Angeles, California and back, you will receive about 5 mrems of radiation. This research study includes exposure to radiation. If you have had X-rays in the past or been exposed in other ways to radiation, or if you think that you might be pregnant, you must tell the investigator before you agree to be in the study. In this study, you will receive radiation from **[IDENTIFY PROCEDURE OR PROCEDURES THAT INVOLVE**	Radiation risks

RADIATION]. The estimated total radiation you will receive from the procedures in this study is **[INSERT MREM]**. This is about equal to **[INSERT EXAMPLE SUCH AS CHEST X-RAY(S) OR AIR TRAVEL]**.	
Gadolinium risks	Risks of gadolinium
After being administered, the contrast agent you will receive (Gadolinium) will mostly be eliminated from the body through the kidneys. However, trace amounts of gadolinium may stay in the body for a long time. Recent studies have confirmed that gadolinium deposits can remain in the brain of patients who undergo 4 or more contrast MRI scan. We don't know if these deposits are harmful or can have a bad side effect. **[ADDITIONAL INFORMATION CAN BE ADDED FOR THE SPECIFIC STUDY, I.E WHETHER THE STUDY EXCLUDES SUBJECTS WHO ALREADY HAD MORE THAN A CERTAIN NUMBER OF MRI WITH CONTRAST.].**	Risks of gadolinium
Pregnancy/breastfeeding risks Taking part in this study while you are pregnant could cause harm to your fetus. If you are breastfeeding, taking part in this study could cause harm to your baby. You must not take part in this study if you are pregnant or breastfeeding. If you are a sexually active woman of childbearing age and would like to take part in this study you will have to agree to use two methods of birth control. One must be a barrier method (male or female condom) and the other can be one of the following: o Birth control drugs that prevent pregnancy given by pills, shots, or placed on or under the skin o Diaphragm or cervical cap with a cream or gel that kills sperm o Intrauterine device (IUD) **[INSERT THE FOLLOWING IF BIRTH CONTROL SHOULD BE USED AFTER DISCONTINUATION OF THE STUDY DRUG AND FOR HOW LONG]** You must continue to use both methods of birth control for **[INSERT LENGTH OF TIME]** after you stop taking study drugs. If you think that you have become pregnant while taking part in this study you must contact the investigator or study team right away. **[INCLUDE ANY ADDITIONAL FOLLOW UP REQUIREMENTS]**	Risks for pregnant or breastfeeding women
No Foreseeable Risk To the best of our knowledge, taking part in this study will not hurt you.	No foreseeable risk
Blood Draw Risks of having blood drawn are soreness and/or a black and blue mark at the site from where the blood is drawn. Sometimes, people feel uncomfortable at the time of the blood draw. Occasionally people feel lightheaded or faint. There is also a small risk of infection whenever blood is drawn.	Risk of blood draw
Inconvenience Although it is not a risk, taking part in this study involves the inconvenience of giving **[INSERT AMOUNT OF TIME]** of your time in order to **[INDICATE WHAT THEY WILL SPEND THEIR TIME DOING - E.G., COMPLETE A QUESTIONNAIRE]**.	Inconvenience

Deception As part of this experiment you will not be told about some of the study details. If you were told these details at the beginning of the study, it could change the research results. If you decide to be part of the study, you will be given an explanation of what information was withheld from you at the end of your study participation.	Deception
Psychological Testing/Sensitive Topics This research study involves psychological testing. The questions being asked may be sensitive and personal in nature. It is possible that answering some questions may cause some stress. **[INSERT OPTIONS TO SUBJECT IF THEY SHOULD FEEL UNCOMFORTABLE PROVIDING A RESPONSE OR BECOME DISTRESSED, I.E., THEY CAN SKIP ANY QUESTIONS THEY WISH, THEY WILL BE REFERRED FOR COUNSELING, ETC.]**	Risk from sensitive questions
Loss of confidentiality A risk of taking part in this study is the possibility of a loss of confidentiality. Loss of confidentiality includes having your personal information shared with someone who is not on the study team and was not supposed to see or know about your information. The study team plans to protect your confidentiality. Their plans for keeping your information private are described in the 'confidentiality' section of this consent form.	Risk of breach of confidentiality
Criminal or Civic Liability - Child Abuse If you give us information which suggests that your child or any other child is being abused, we are required by law to report that information to the Administration for Children's Services (ACS). Reporting this information may put you, your family, or others who are involved at risk of questioning and legal action by the authorities.	Risk related to reporting (child abuse) liability
Criminal or Civic Liability - Illegal Activities Telling us about your involvement in illegal activities involves the risk of criminal penalties and/or prosecution if your identity were to be revealed. In some cases, we may be required to report such information. If you give us information that you may hurt yourself or someone else, we must report this information to the authorities.	Risk related to reporting (illegal activities) liability
Will it hurt?	Sub-header from 7-11 year old assent form template
[CHOOSE AS APPROPRIATE:] There is a chance that during the study you could feel uncomfortable, afraid, lonely, or hurt. We will help you with these feelings and you can stop at any time if you want. If you are in the study you could experience any of the following: • You could **[INSERT SPECIFICS, E.G., GET A BRUISE].** • You may feel **[INSERT SPECIFICS]**. • You may feel **[EMBARRASSED/SAD/UNCOMFORTABLE]** by the questions we ask.	Risks (from 7-11 year old assent form template)

• Someone might be able to see the things you tell us but we will try our best to keep this a secret. • The **[INSERT SPECIFICS, E.G., BLOOD SAMPLE]** may hurt. • The study **[DRUG/DEVICE/TREATMENT]** could make you feel **[INSERT SPECIFICS, E.G., DIZZY, HAVE AN UPSET STOMACH].**	
Are there any consequences if you participate in this study?	Sub-header from 12-17 year old assent form template
[CHOOSE AS APPROPRIATE TO DESCRIBE THE RISKS [PHYSICAL, SOCIAL, FINANCIAL, PSYCHOLOGICAL, PRIVACY, OR OTHER] AND POSSIBLE DISCOMFORTS.] There is a chance that during the study you could feel uncomfortable, afraid, lonely, or hurt. We will help you with these feelings and you can **stop** at any time if you want. If you participate in the study you could experience any of the following: • You could **[INSERT SPECIFICS, E.G., GET A BRUISE]**. • You may feel **[INSERT SPECIFICS]**. • You may feel **[EMBARRASSED/SAD/UNCOMFORTABLE]** by the questions we ask. • The **[INSERT SPECIFICS, E.G., BLOOD SAMPLE]** may hurt. • The study **[DRUG/DEVICE/TREATMENT]** could make you feel **[INSERT SPECIFICS, E.G., DIZZY, HAVE AN UPSET STOMACH]**.	Risks (from 12-17 year old assent form template)

Incidental Findings [IN RASCAL, THESE ARE CURRENTLY IN THE RISKS SECTION, NOT A SEPARATE SECTION; CAN REMAIN IN RISKS SECTION]

Text	Topic and explanations
Although the imaging you will have in this study is being undertaken for research purposes only, it is possible that doctors may notice something that could be important to your health. Although not likely, it is possible that the doctors may notice something that may be very serious and could immediately affect your life. If so, we will contact you to explain what was observed. If you so desire, we will also talk with your private physician. If you do not have a private physician, we will refer you to an appropriate clinic for follow-up. It will be your choice whether to proceed with additional tests and/or treatments to evaluate what we observed, and you or your insurer will be responsible for these costs.	Incidental Findings from Radiographic Scans (For use when the PI or a co-I is a physician and is qualified to explain incidental findings from a scan)
Unexpected Findings from Radiographic Scans Although the imaging you will have in this study is being undertaken for research purposes only, it is possible that doctors may notice something that could be important to your health. Although not likely, it is possible that the doctors may notice something that may be very serious and could immediately affect your life. If so, a doctor working with our research team will contact you to explain what was observed. If you so desire, we will also talk with your private physician. If you do not have a private physician, we will refer you to an appropriate clinic for follow-up. It will be your choice whether to proceed with additional tests and/or treatments to evaluate what we observed, and you or your insurer will be responsible for these costs.	Incidental Findings from Radiographic Scans (For use when the PI and co-Is are not physicians and not otherwise qualified to explain incidental findings from a scan)

Benefits

Text	Topic and explanations
ARE THERE BENEFITS TO TAKING PART IN THE STUDY?	Sub-header

Potential direct benefit You may or may not receive personal (direct) benefit from taking part in this study. The possible benefits of taking part in this study include **[DESCRIBE ANY BENEFITS TO THE PARTICIPANT WHICH MAY REASONABLY BE EXPECTED FROM THE RESEARCH]**.	Direct benefit
No direct benefit You will not receive personal (direct) benefit from taking part in this research study. However, the information collected from this research may help others in the future.	Indirect benefit
Will you benefit from being in this study?	Sub-header from 12-17 year old assent form template
[CHOOSE AS APPROPRIATE TO DESCRIBE THE BENEFITS:] You will not benefit directly from this study. We hope to learn something that could help other children in the future **[ADD, IF APPLICABLE:]** who have **[INSERT MEDICAL CONDITION].** **[OR]** Taking part in this study may help you feel better or may make your **[INSERT MEDICAL CONDITION]** go away, but we do not know this for sure.	No direct benefit or may be direct benefit (from 12-17 year old assent form template)
Are there any benefits?	Sub-header from minimal risk consent form template
You will not benefit from taking part in this study, but your participation may help people who have **[INSERT CONDITION]** in the future. **[OR]** You may or may not receive personal **[DIRECT]** benefit from taking part in this study. The possible benefits of taking part in this study include: **[INSERT SPECIFICS]**.	No direct benefit or may be direct benefit (from minimal risk consent form template)
Are there benefits to taking part in this study?	Sub-header from genetic consent form template
[SELECT THE APPROPRIATE OPTION, DEPENDING UPON WHETHER RESULTS WILL BE RETURNED] **[ALTERNATIVE NO. 1, FOR USE IF RESULTS WILL BE RETURNED:]** If you agree to take part in the study, and choose to receive results, there may be direct medical benefit to you. If a genetic predisposition for a medical condition is found, knowing this information may help determine how to manage your medical care. We hope that in the future, information learned from this study will benefit other people with similar findings. However, if the sequencing does not find information that would affect your medical care or well-being, there may not be any direct benefit to you. The knowledge gained may increase our understanding of genetic testing and	Potential direct benefit depending upon whether results of genetic testing will be returned (from genetic testing consent form template)

results of genetic tests, and help patients in the future. **[ALTERNATIVE NO. 2, FOR USE IF RESULTS WILL NOT BE RETURNED:]** This study will not directly benefit you. However, information that is learned may increase our understanding of genetic testing and results of genetic tests, and help patients in the future.	

Alternative Procedures

Text	Topic and explanations
WHAT OTHER OPTIONS ARE THERE?	Sub-header
Alternatives You may choose not to take part in this research study.	Alternatives for non-treatment studies
Alternatives You do not have to take part in this study to get treatment for your condition. **[DESCRIBE OTHER TREATMENTS AND/OR DIAGNOSTIC PROCEDURES THAT ARE AVAILABLE OUTSIDE OF THE STUDY. IF THE STUDY TREATMENT IS AVAILABLE WITHOUT TAKING PART IN THE RESEARCH STUDY, INCLUDE A STATEMENT TO THAT EFFECT HERE. ALSO INDICATE IF ANY STANDARD DIAGNOSTIC PROCEDURES OR TREATMENTS MAY BE WITHHELD OR DELAYED AS A RESULT OF STUDY PARTICIPATION.]**	Alternatives for treatment studies

Confidentiality

Text	Topic and explanations
WHAT ABOUT CONFIDENTIALITY?	Sub-header
Any information collected during this study that can identify you by name will be kept confidential. We will do everything we can to keep your data secure, however, complete confidentiality cannot be promised. Despite all of our efforts, unanticipated problems, such as a stolen computer may occur, although it is highly unlikely. **[DESCRIBE PROCEDURES FOR MAINTAINING CONFIDENTIALITY, SUCH AS THE FOLLOWING STATEMENTS]** Your **[INSERT AS APPLICABLE:** data, biological samples, questionnaire responses, health information, etc.] will be assigned a code number, and separated from your name or any other information that could identify you. The research file that links your name to the code number will be kept in **[SELECT AS APPLICABLE:** a locked file cabinet, an encrypted data file, a password-protected computer] and only the investigator and study staff will have access to the file. The following individuals and/or agencies will be able to look at and copy your research records **[REMOVE ANY THAT ARE NOT APPLICABLE]**: - The investigator, study staff, Columbia University staff, **[INSERT IF APPLICABLE:** NewYork-Presbyterian Hospital staff] and medical professionals who may be evaluating the study or providing services for the study - Authorities from Columbia University **[INSERT IF APPLICABLE:** and NewYork-Presbyterian Hospital], including the Institutional Review Board ('IRB') - The Office of Human Research Protections ('OHRP') **[INSERT IF APPLICABLE:** and the United States Food and	Confidentiality protections

Drug Administration ('FDA'); - If this study is sponsored (money or supplies are being provided), the sponsor of this study, **[NAME SPONSOR]**, including persons or organizations working with or owned by the sponsor - Other government regulatory agencies (including agencies in other countries) if the sponsor is seeking marketing approval for new products resulting from this research.	
WHAT ABOUT CONFIDENTIALITY?	Sub-header
Any information collected during this study that can identify you by name will be kept confidential. We will do everything we can to keep your data secure, however, complete confidentiality cannot be promised. Despite all of our efforts, unanticipated problems such as a stolen computer may occur, although it is highly unlikely. Access to your health information is required to be part of this study. If you choose to take part in this study, you are giving us the authorization (i.e. your permission) to use the protected health information and information collected during the research that can identify you. The health information that we may collect and use for this research may include medical history that may be considered sensitive. **[IF YOU ARE COLLECTING HIV TEST RESULTS, HISTORY OF DRUG OR ALCOHOL ABUSE, OR MENTAL HEALTH INFORMATION IT MUST BE STATED HERE. IF YOU ARE NOT COLLECTING HIV TEST RESULTS, HISTORY OF DRUG OR ALCOHOL ABUSE, OR MENTAL HEALTH INFORMATION, INCLUDE A STATEMENT THAT THE PROJECT DOES NOT INVOLVE COLLECTING HEALTH INFORMATION THAT MAY BE CONSIDERED SENSITIVE.]** Information about you may be obtained from any hospital, doctor, and other health care provider involved in your care that is needed for this research purpose, including [**INSERT LIST IF NECESSARY].** [**REVISE AS NECESSARY IF IDENTIFIERS WILL BE SHARED OUTSIDE OF CUMC/NYP]** Any research information that is shared with people outside of Columbia University Medical Center and NewYork-Presbyterian Hospital will not include your name, address, telephone number or any other direct identifier unless disclosure of the information is required by law or you have authorized the disclosure. **[DESCRIBE PROCEDURES FOR MAINTAINING CONFIDENTIALITY, SUCH AS THE FOLLOWING STATEMENT]** Your **[INSERT AS APPLICABLE:** data, biological samples, questionnaire responses, health information, etc] will be assigned a code number, and separated from your name or any other information that could identify you. The research file that links your name to the code number will be kept in **[SELECT AS APPLICABLE:** a locked file cabinet,an encrypted data file, a password-protected computer] and only the investigator and authorized study staff will have access to the file. The following individuals and/or agencies will be able to look at, copy, use, and share your research information **[REMOVE ANY THAT ARE NOT APPLICABLE]**: - The investigator, study staff, Columbia University staff, **[INSERT IF APPLICABLE:** NewYork-Presbyterian Hospital staff] and medical professionals who may be evaluating the study or providing services for the study - Authorities from Columbia University **[INSERT IF APPLICABLE:** and NewYork-Presbyterian Hospital], including the Institutional Review Board ('IRB') - The Office of Human Research Protections ('OHRP') **[INSERT IF APPLICABLE:** and the United States Food and Drug Administration ('FDA')] - **[ADD, IF THIS STUDY IS SPONSORED (MONEY OR SUPPLIES ARE BEING PROVIDED)]** The sponsor of this study, **[NAME SPONSOR]**, including persons or organizations working with or owned by the sponsor - Other government regulatory agencies (including agencies in other countries) if the sponsor is seeking marketing	Confidentiality protections (for use in a Combined Consent and HIPAA Authorization Form)

approval for new products resulting from this research. - **[LIST OTHER ENTITIES THAT MAY RECEIVE AND PROCESS PHI, I.E. DATA COORDINATING CENTER, DATA SAFETY AND MONITORING BOARD/COMMITTEE …]** **[CHOOSE ONE OF THE FOLLOWING STATEMENTS:]** Your authorization to use and share your health information does not have an expiration (ending) date. **[OR]** Your authorization to use and share your health information will expire when the research is completed. Once your health information has been disclosed to a third party (for example, a pharmaceutical company participating in a study), federal privacy laws may no longer protect it from further disclosure. You may change your mind and revoke (take back) this consent and authorization at any time and for any reason. To revoke this consent and authorization, you must contact the Principal Investigator**, [INSERT CONTACT INFORMATION].** However, if you revoke your consent and authorization, you will not be allowed to continue taking part in the Research. Also, even if you revoke this consent and authorization, the Researchers and the Sponsor (if applicable) may continue to use and disclose the information they have already collected. **[FOR BLINDED STUDIES, IF APPLICABLE, ADD:]** To maintain the integrity of this research study, you generally will not have access to your protected health information related to this research until the study is complete. At the conclusion of the research and at your request, you generally will have access to this information.	
WHAT ABOUT CONFIDENTIALITY?	Sub-header
Any information collected during this study that can identify you by name will be kept confidential. We will do everything we can to keep your data secure, however, complete confidentiality cannot be promised. Despite all of our efforts, unanticipated problems, such as a stolen computer may occur, although it is highly unlikely. If you choose to take part in this study, you are giving us the authorization (i.e. your permission) to use the protected health information and information collected during the research that can identify you. The health information that we may collect and use for this research may include medical information that may be considered sensitive. [**IF YOU ARE COLLECTING HIV TEST RESULTS, HISTORY OF DRUG OR ALCOHOL ABUSE, OR MENTAL HEALTH INFORMATION IT MUST BE STATED. IF YOU ARE NOT COLLECTING HIV TEST RESULTS, HISTORY OF DRUG OR ALCOHOL ABUSE, OR MENTAL HEALTH INFORMATION INCLUDES A STATEMENT THAT THE PROJECT DOES NOT INVOLVE COLLECTING HEALTH INFORMATION THAT MAY BE CONSIDERED SENSITIVE.**] [**REVISE AS NECESSARY IF IDENTIFIERS WILL BE SHARED OUTSIDE OF CUMC/NYP**] Any research information that is shared with people outside of Columbia University Medical Center and NewYork-Presbyterian Hospital will not include your name, address, telephone number or any other direct identifiers unless disclosure of the information is required by law or you have authorized the disclosure. [**DESCRIBE PROCEDURES FOR MAINTAINING CONFIDENTIALITY, SUCH AS THE FOLLOWING STATEMENTS**] Your **[INSERT AS APPLICABLE:** data, biological samples, questionnaire responses, health	Confidentiality protections (To be used when a waiver of written documentation of consent is requested and the study involves Protected Health Information.) (This text should be incorporated into the Information Sheet or verbal consent script.)

information, etc.] will be assigned a code number, and separated from your name or any other information that could identify you. The research file that links your name to the code number will be kept in **[SELECT AS APPLICABLE:** a locked file cabinet, an encrypted data file, a password-protected computer] and only the investigator and authorized study staff will have access to the file. The following individuals and/or agencies will be able to look at, copy, use, and share your research information: - The investigator, study staff, Columbia University staff, **[INSERT IF APPLICABLE:** NewYork-Presbyterian Hospital staff] and medical professionals who may be evaluating the study or providing services for the study - Authorities from Columbia University **[INSERT IF APPLICABLE:** and NewYork-Presbyterian Hospital], including the Institutional Review Board ('IRB') - The Federal Office of Human Research Protections ('OHRP') **[INSERT IF APPLICABLE***:* and the United States Food and Drug Administration ('FDA')**]** [**ADD IF THIS STUDY IS SPONSORED (MONEY OR SUPPLIES ARE BEING PROVIDED)]** - The sponsor of this study, [**NAME SPONSOR**], including persons or organizations working with or owned by the sponsor - Other government regulatory agencies (including agencies in other countries) if the sponsor is seeking marketing approval for new products resulting from this research. [**IF APPLICABLE**] - [**LIST OTHER ENTITIES THAT MAY RECEIVE AND PROCESS PHI, I.E. DATA COORDINATING CENTER, DATA SAFETY AND MONITORING BOARD/COMMITTEE …]** [**CHOOSE ONE OF THE FOLLOWING STATEMENTS:**] Your authorization to use and share the information collected for this research purpose does not have an expiration (ending) date. [**OR**] Your authorization to use and share the information collected for this research purpose will expire when the research is completed. Once your research information has been disclosed to a third party (for example, a pharmaceutical company participating in a study), federal privacy laws may no longer protect it from further disclosure. Also, even if you revoke (take back) this consent and authorization, the researchers and the sponsor (if applicable) may continue to use and disclose the information they have already collected.	
WHAT ABOUT CONFIDENTIALITY?	Sub-header
Certificate of Confidentiality To help us protect your privacy, we received a Certificate of Confidentiality from the National Institutes of Health (NIH). With this Certificate, we cannot be forced to provide information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. We will use the Certificate to resist any demands for information that would identify you, except as explained below. The Certificate of Confidentiality does not stop you or a member of your family from telling others about yourself or your involvement in this research. If an insurer, employer, or other person gets your written consent to receive research information, then we cannot use the Certificate to withhold that information. The Certificate cannot be used to resist a demand for information from representatives of the United States Government that is used for auditing or evaluation of projects they are responsible for overseeing or for information	Certificate of Confidentiality has been obtained

that must be provided in order to meet the requirements of the federal Food and Drug Administration (FDA). You should also know that this Certificate does not protect you from our responsibility to report certain communicable diseases, suspected child abuse, or danger of physical or mental harm, to appropriate agencies or authorities.	
What about your privacy?	Sub-header from 12-17 year old assent form template
To protect you, the information collected in this study will not be shared with anyone unless required by law**. [BE SURE THIS IS ACCURATE, E.G., IF PARENTS WILL HAVE ACCESS, IT SHOULD BE SO NOTED.]** The researchers in this study will need to talk about you and the study **[INSERT AS RELEVANT: WITH YOUR PARENT/GUARDIAN AND WITH OTHER RESEARCHERS]** but will not talk about you with anyone else except the people working on the study. If the researcher(s) need(s) to talk to anyone else about you he/she/they will ask you and your parent/guardian if it is okay to do so.	Confidentiality (from 12-17 year old assent form template)
What about my privacy?	Sub-header from minimal risk consent form template; includes HIPAA authorization language
Every effort will be made to keep your personal information confidential. However, we cannot guarantee total privacy. **DESCRIBE THE STEPS THAT WILL BE TAKEN TO MAINTAIN CONFIDENTIALITY OF SUBJECT DATA:** **SUGGESTED PROCEDURES/TEXT:** The data collected [and/or specimens] will be given a code number, and separated from your name or any other information that could identify you. The research file that links your name to the code number will be kept in a **[CHOOSE AS APPROPRIATE: PASSWORD PROTECTED DATABASE OR LOCKED FILE CABINET]**. Only the Principal Investigator and the study staff will be able to see this file. If information from this study is published or presented at scientific meetings, your name and other personal information about you will not be used. Access to your health information is required to be part of this study. If you choose to take part in this study, you are giving us the authorization (i.e. your permission) to use the protected health information and information collected during the research that can identify you. The health information that we may collect and use for this research may include medical history that may be considered sensitive. **[IF YOU ARE COLLECTING HIV TEST RESULTS, HISTORY OF DRUG OR ALCOHOL ABUSE, OR MENTAL HEALTH INFORMATION IT MUST BE STATED HERE. IF YOU ARE NOT COLLECTING HIV TEST RESULTS, HISTORY OF DRUG OR ALCOHOL ABUSE, OR MENTAL HEALTH INFORMATION, INCLUDE A STATEMENT THAT THE PROJECT DOES NOT INVOLVE COLLECTING HEALTH INFORMATION THAT MAY BE CONSIDERED SENSITIVE.]** Information about you may be obtained from any hospital, doctor, and other health care provider involved in your care that is needed for this research purpose, including **[INSERT LIST IF NECESSARY]**. **[REVISE AS NECESSARY IF IDENTIFIERS WILL BE SHARED OUTSIDE OF CUMC/NYP]**	Confidentiality (from minimal risk consent form template)

The research information that is shared with people outside of Columbia University Medical Center and NewYork-Presbyterian Hospital will not include your name, address, telephone number or any other direct identifier unless disclosure of the information is required by law or you have authorized the disclosure. The following individuals and/or agencies will be able to look at, copy, use and share your research information: - The investigator, study staff, Columbia University staff, **[INSERT IF APPLICABLE:** NewYork-Presbyterian Hospital staff] and medical professionals who may be evaluating the study or providing services for the study - Authorities from Columbia University and NewYork-Presbyterian Hospital, including the Institutional Review Board ('IRB'). An IRB is a committee organized to protect the rights and welfare of people involved in research. - The Federal Office of Human Research Protections ('OHRP') and/or the [add FDA if applicable] United States Food and Drug Administration ('FDA'); - **[IF THIS STUDY IS SPONSORED (MONEY OR SUPPLIES ARE BEING PROVIDED)]** The sponsor of this study, **[NAME SPONSOR]**, including persons or organizations working with or owned by the sponsor may review your data for accuracy but may not copy information with your name on it. - **[LIST OTHER ENTITIES THAT MAY RECEIVE AND PROCESS PHI, I.E. DATA COORDINATING CENTER, DATA SAFETY AND MONITORING BOARD/COMMITTEE …]** **[CHOOSE ONE OF THE FOLLOWING STATEMENTS:]** Your authorization to use and share your health information does not have an expiration (ending) date. **[OR]** Your authorization to use and share your health information will expire when the research is completed. Once your health information has been disclosed to a third party (for example, a pharmaceutical company participating in a study), federal privacy laws may no longer protect it from further disclosure. You may change your mind and revoke (take back) this consent and authorization at any time and for any reason. To revoke this consent and authorization, you must contact the Principal Investigator**, [INSERT CONTACT INFORMATION]**. However, if you revoke your consent and authorization, you will not be allowed to continue taking part in the Research. Also, even if you revoke this consent and authorization, the Researchers and the Sponsor (if applicable) may continue to use and disclose the information they have already collected. **[FOR BLINDED STUDIES, PLEASE ADD:]** To maintain the integrity of this research study, you generally will not have access to your protected health information related to this research until the study is complete. At the conclusion of the research and at your request, you generally will have access to this information.	
What about privacy and confidentiality?	Sub-header from genetic testing consent form template
Every effort will be made to keep your personal information confidential. However, we cannot guarantee total confidentiality. **[DESCRIBE THE STEPS THAT WILL BE TAKEN TO MAINTAIN CONFIDENTIALITY OF SUBJECT DATA; SEE ALSO SECTION 10:]** If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.	Privacy and confidentiality (from genetic testing consent form template)

The following individuals and/or agencies will be able to look at and copy your research records: - The researchers, study staff and other professionals who are conducting the study or analyzing study results; - If necessary for monitoring purposes: ---Authorities from Columbia University, including the Institutional Review Board ('IRB'). An IRB is a committee organized to review, approve and oversee research involving human subjects. ---The U.S. Office for Human Research Protections **[ADD, IF APPLICABLE: AND/OR THE U. S. FOOD AND DRUG ADMINISTRATION];** **---[ADD, IF THIS STUDY IS SPONSORED.]** The sponsor of this study, **[ADD: SPONSOR NAME]**, including persons or organizations working with or owned by the sponsor may review your data for accuracy, but may not copy information with your name on it. **[IF THE STUDY WILL USE PROTECTED HEALTH INFORMATION AND A STAND-ALONE HIPAA AUTHORIZATION FORM WILL BE USED, INSERT THE FOLLOWING STATEMENT:]** You will be asked to sign a separate form to allow the use and disclosure of your protected health information. **[IF HIPAA AUTHORIZATION WILL BE COMBINED WITH THIS CONSENT FORM, ADD THE AUTHORIZATION LANGUAGE HERE:]**	

Injuries

Text	Topic and explanations
WHAT IF I GET HURT WHILE I AM ON THE STUDY?	Sub-header
Taking part in this research study may result in injury or harm to you. In the event of an injury resulting from your participation in this study, you should seek appropriate medical care and inform the study doctor. In the event of an emergency you should go to an emergency room. If you are injured or harmed as a result of participating in the study and receive medical care through the NewYork-Presbyterian Hospital (NYPH), a Columbia doctor, or any other health provider, you will be sent a bill for whatever medical care you receive. All or part of your bill may be paid by your health insurance. If this medical care is provided by NYPH or by a Columbia doctor, the study sponsor may pay these providers for any reasonable medical expenses to treat your injury. The study sponsor, however, is not offering to pay for medical expenses that are covered by your insurance provider or if your injury was not caused by the study drug/device or a study procedure. Columbia University and NewYork-Presbyterian Hospital (NYPH) are not offering to provide you the drug/device after the termination of the study or to pay you for pain, worry, lost income, the cost of your medical care or non-medical care costs that might occur as a result of your taking part in this study. However, you do not waive any of your legal rights in signing this form.	Industry-sponsored initiated studies (Phases I-III) involving investigational drugs or devices
Taking part in this research study may result in injury or harm to you. In the event of an injury resulting from your participation in this study, you should seek appropriate medical care and inform the study doctor. In the event of an emergency you should go to an emergency room. If you are injured or harmed as a result of participating in the study and receive medical care through the NewYork-Presbyterian Hospital (NYPH), a Columbia doctor, or any other health provider, you will be sent a bill for whatever	All other studies that are greater than minimal risk [e.g., Investigator initiated, NIH, non-profit sponsor/research collaborator (other universities or foundations) or industry-supported Phase IV studies involving

medical care you receive. All or part of your bill may be paid by your health insurance. Columbia University and NewYork-Presbyterian Hospital (NYPH) are not offering to provide you the drug/device after the termination of the study or to pay you for pain, worry, lost income, the cost of your medical care or non-medical care costs that might occur as a result of your taking part in this study. However, you do not waive any of your legal rights in signing this form.	drugs or devices; if studies involve interventions other than drugs or devices, insert "study intervention" for "drug/device"]
What are my rights if I take part in this study?	Sub-header from genetic testing consent form template
Taking part in this study is your choice. You can decide not to take part or stop being in the study at any time. Your choice will not involve any penalty or loss of benefits to which you are entitled and will not affect your access to health care at CUMC or NYPH. You will need to notify in writing one of the researchers listed in the Contact section of this consent form if you decide to withdraw from the study before it is finished and no longer want to be contacted by the researchers. You will need to specify in your written notice if you want your unused biological samples destroyed and your identifying information removed from all CUMC databases so that your samples and/or data will not be included in any future analyses. However, there are limitations on our ability to exclude your information or remove your biological samples after they have been de-linked from identifying information or deposited in scientific databases, and, if you have given your permission to do so, used or shared with other researchers.	Rights (from genetic testing consent form template)

Compensation

Text	Topic and explanation
WILL I GET COMPENSATED?	Sub-header
No Payment You will not receive any payment or other compensation for taking part in this study.	No payment
Payment **[INCLUDE THE AMOUNT, SCHEDULE AND TERMS OF COMPENSATION (INCLUDING GIFT CARDS, PARKING REIMBURSEMENT, ETC.) OFFERED TO SUBJECTS FOR PARTICIPATION. IF TAKING PART IN THIS STUDY INVOLVES MORE THAN ONE SESSION, DESCRIBE HOW PAYMENTS WILL BE PRO-RATED IF THE PARTICIPANT WITHDRAWS PRIOR TO COMPLETING THE STUDY. (I.E. YOU WILL RECEIVE A TOTAL OF $100 FOR 10 STUDY VISITS. IF YOU CHOOSE TO WITHDRAW FROM THE STUDY BEFORE ALL VISITS ARE COMPLETED, COMPENSATION WILL BE PRORATED TO INCLUDE ONLY COMPLETED VISITS. FOR INSTANCE, IF YOU COMPLETED 2 VISITS AND DECIDED TO WITHDRAW, YOU WOULD BE PAID $20.00.).]**	Payment terms
Reportable payments According to IRS regulations, compensation payments totaling more than $600 in a calendar year must be reported to the Internal Revenue Service (IRS). We will need to obtain your Social Security Number for this purpose.	Payments reportable to IRS

Reimbursement for travel or other study-related expenses are not considered compensation for tax purposes.	
Will I get paid or be given anything to take part in this study?	Sub-header from minimal risk consent form template
[CHOOSE AS APPROPRIATE:] You will not receive any payment or other reward for taking part in this study. **OR** **[IF COMPENSATED:]** We will give you **[INSERT SPECIFICS I.E. AMOUNT GIVEN IN CASH OR GIFT CARDS]** to pay you for your time. **[IF MORE THAN ONE STUDY VISIT]** You will receive **[INSERT SPECIFICS**] at each visit. **[IF PAYMENT WILL BE BY CHECK:]** A check will be mailed to you about **[INSERT NUMBER]** weeks after your participation in the study has ended. You will need to provide your Social Security Number for payment. **[IF APPLICABLE, I.E., A SERIES OF SUBJECT PAYMENTS WILL RESULT IN TOTAL COMPENSATION GREATER THAN $600, PLEASE ADD:]** According to the rules of the IRS, compensation payments totaling more than $600 in a calendar year are considered taxable income and will be reported to the Internal Revenue Service (IRS). **[OR]** **[IF REIMBURSED FOR TRAVEL EXPENSES:]** We will reimburse you up to $ **[INSERT AMOUNT]** per visit for reasonable travel and parking expenses. **[IF BY CHECK]** You will need to provide the original receipt and your Social Security Number for reimbursement.	Compensation (from minimal risk consent form template)
Will I get paid or be given anything for taking part in this study?	Sub-header from genetic testing consent form template
[SELECT:] You will not receive any payment or other compensation for taking part in this study. **[OR, IF THERE WILL BE COMPENSATION TO THE PARTICIPANT:]** You will receive **[INSERT DETAILS OF THE COMPENSATION THAT WILL BE PROVIDED]** for taking part in this study. **[ADD, IF TOTAL REIMBURSEMENT WITHIN A CALENDAR YEAR WILL EXCEED $600:]** According to U.S. Internal Revenue Service (IRS) regulations, compensation payments totaling more than $600 in a calendar year must be reported to the IRS. We will need to obtain your Social Security Number for this purpose. Reimbursement for travel or other study-related expenses are not considered compensation for tax purposes. **[ADD, IF REIMBURSED FOR TRAVEL EXPENSES:]** We will reimburse you up to $ **[INSERT AMOUNT]** per visit for reasonable travel and parking expenses. **[ADD, IF REIMBURSEMENT IS BY CHECK:]** You will need to provide the original receipt and your Social Security Number for reimbursement.	Compensation (from genetic testing consent form template)

Additional Costs

Text	Topic and explanations
WHAT ARE THE COSTS?	Sub-header
No cost There are no costs to you for taking part in this study.	No costs
No added costs The study procedures in this study will not involve additional costs to you. All study drugs will be given free of charge by the sponsor company or the drug makers. You and/or your insurance company will have to pay for any costs that are part of your regular medical care. You will remain responsible for all insurance premiums, deductibles, copayments and coinsurance.	Medical - no added costs
Added costs **[DESCRIBE ANY COSTS (INCLUDING TRANSPORTATION, EXCESS PROCEDURES, COSTS OF CO-PAYMENTS/DEDUCTIBLES, ETC.) THAT SUBJECTS WILL INCUR AS A RESULT OF PARTICIPATING IN THIS RESEARCH STUDY. IF THE SUBJECT IS RESPONSIBLE FOR RESEARCH COSTS, WHETHER PERSONALLY OR THROUGH THEIR INSURANCE COVERAGE, THIS SHOULD BE EXPLAINED.]**	Medical - added costs
What will it cost you to be in this study?	Sub-header from 12-17 year old assent form template
There is **[CHOOSE ONE: SOME/NO COST]** to you or your parents for being in this research study. Add one of the following statements: You will not get paid to participate in this study. **[OR]** You will receive **[ADD AMOUNT OF GIFT CARDS]** for your participation in this study.	Cost and compensation (from 12-17 year old assent form template)
Will I incur costs if I take part in this study?	Sub-header from minimal risk consent form template
There will be no costs to you for being in this study. **[OR]** **[IF THERE WILL BE COSTS TO THE PARTICIPANT:]** The study will pay for services that you will receive only if you are in the study **[LIST WHAT WILL BE PAID FOR, E.G. BLOOD TESTS, STUDY DRUG]**.	Costs (from minimal risk consent form template)
Will I incur costs if I take part in this study?	Sub-header from genetic testing consent form template
[SELECT:]	Costs

There will be no costs to you for being in this study. ***[OR, IF THERE WILL BE COSTS TO THE PARTICIPANT:]*** The study will pay for services that you receive because you are in the study such as [list what will be paid for, e.g. blood tests]. The study will not cover the costs of procedures or tests that you would have even if you were not in the study. ***[ADD, IF RESULTS MAY BE RETURNED:]*** You will not be charged for the costs of confirming in a clinical laboratory any findings to be used in research. However, you or your insurance company will be responsible for any additional clinical test, including genetic tests that may be recommended by your physician as a result of information received from the study.	(from genetic testing consent form template)

Participation

Text	Topic and explanations
DO I HAVE TO BE IN THE STUDY?	Sub-header
Voluntary participation Taking part in this study is your choice. You can decide not to take part in or stop being in the study at any time. Your choice will not affect the treatment you receive from doctors and staff at Columbia University Medical Center **[ADD, IF APPLICABLE]** and NewYork-Presbyterian Hospital.	Voluntary participation – CUMC
Supplement for safety follow up (drug study) For your safety, you should tell us if you want to stop being in the study. You may be asked to give back any study drug that you have not used and/or come back for a final visit.	Safety follow-up if withdrawal
Termination of participation by investigator You should know that we will not let you participate in the study any more if **[INDICATE THE CIRCUMSTANCES IN WHICH THE INVESTIGATOR OR STUDY SPONSOR WILL REMOVE A PARTICIPANT]**. In addition, your participation will end if the investigator or study sponsor stops the study earlier than expected.	Termination by investigator
Voluntary Participation Taking part in this study is your choice. You may refuse to take part in the study or withdraw from the study at any time without jeopardizing your employment, student status, or any other rights. The investigator may withdraw you at his/her discretion **[INDICATE THE CIRCUMSTANCES IN WHICH THE INVESTIGATOR OR STUDY SPONSOR WILL REMOVE A PARTICIPANT]**.	Voluntary participation - Morningside
Voluntary Participation Participation in this study is voluntary. Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled. You may discontinue participation at any time without penalty or loss of benefits to which you	Voluntary participation – generic

are otherwise entitled.	
Do you have to be in this study?	Sub-header from 7-11 year old assent form template
No, you do not have to be in this study. No one will be mad at you if you say **no**. You can also say yes now and change your mind later. Just tell the doctor or your parent/guardian that you want to stop. If you say yes, you can ask as many questions as you want, at any time. No one else will know what you tell us **[INSERT AS RELEVANT:]** besides your parents/guardian. Please talk this over with your parents before you decide if you want to be in the research study. Your parents have said that it is ok with them if you are in the research study. You can still say **no** even if your parents said that it is ok with them if you are in this research study.	Voluntary participation (from 7-11 year old assent form template)
Do you have to be in this study?	Sub-header from 12-17 year old assent form template
No, you do not have to be in this study. We are asking you if you would like to be in the study but if you say **no**, no one will be upset with you. You can also say yes now and if you change your mind later, you can quit the study at any time. **[ADD, IF THIS IS AN INTERVENTION STUDY:]** If you choose not to be in this study, you can: **[LIST ALTERNATIVES TO PARTICIPATION, E.G., ALTERNATIVE TREATMENTS, IF ANY]**. Please talk this over with your parents/guardians before you decide whether or not to participate. Even though your parents/guardians have said it is all right with them if you want to be in the study, you can still say **no**. If you do agree to be in the study but later decide you would rather not be in the study, you may stop your participation at any time. Your decision will not affect your care or that of your parents or family members in any way. If you sign this paper, it means that you want to be in this study. **If you do not want to be in the study, do not sign this paper.**	Voluntary participation (from 12-17 year old assent form template)

Additional Information

Text	Topic and explanations
Some Background on Genes	Sub-header from genetic testing consent form template
We would like you to be well informed about genetic research, and for that reason we have, next, a few brief explanations. Please let us know, at any point, if you want or need more information in order to understand. DNA is the material that governs the inheritance of many human traits, such as hair and eye color or the risk of some diseases. DNA is contained in most of the cells that make up the body's tissues. DNA carries the instructions for your body's development and functions. A piece of DNA that determines a specific function of a cell is called a "gene." Abnormalities in the information in a gene can lead to disease.	Basic genetic information (from genetic testing consent form template)

Your entire unique genetic material, made up of DNA, is known as a "genome." An "exome" is the portion of the genome that includes only the DNA that is directly responsible for telling cells how to make the correct parts, or proteins, to function properly.	
What are Whole Exome Sequencing and Whole Genome Sequencing?	Sub-header from genetic testing consent form template
We are requesting your permission to perform genetic testing on your biological samples to identify variants and consider their relationship to the Study Medical Condition. Genetic research is evolving rapidly. We expect that we will perform whole **[INSERT, AS APPLICABLE: (A) GENOME AND/OR (B) EXOME]** sequencing but other genetic tests in addition to, or in place of, whole exome sequencing (WES) or whole genome sequencing (WGS) may be performed, including new genetic tests that may be developed in the future. WES and WGS are very detailed types of genetic tests. WES searches through the exome for DNA variations that can cause disease. WGS searches through all of the genome, including areas outside of the exome. Because WES and WGS examine a larger portion of the genetic material than traditional tests, they may be able to find causes of disease where other tests did not. WES and WGS may also reveal information about unexpected diseases. Because WES and WGS are more comprehensive than other genetic tests, it is particularly important that you understand what is involved. **[INSERT, AS APPLICABLE: (A) THE RESEARCHER CONDUCTING THIS STUDY OR (B) YOUR PHYSICIAN] [INCLUDE, IF APPLICABLE: AND A GENETIC COUNSELOR]** will tell you more about WES and WGS. You may also wish to obtain professional genetic counseling prior to signing this consent form. **[ADD A STATEMENT ABOUT WHETHER GENETIC COUNSELING IS PROVIDED, AND WHETHER IT IS PROVIDED WITHOUT COST OR WOULD BE BILLABLE TO THE PARTICIPANT.]**	Explanation of Whole Genome Sequencing and Whole Exome Sequencing (from genetic testing consent form template)
What results will be returned to me?	Sub-header from genetic testing consent form template
[SELECT ONE OF THE FOLLOWING ALTERNATIVES:] **[ALTERNATIVE NO. 1, NO PLANS TO RETURN RESULTS:]** No results of the genetic testing will be reported to you as this is a research study. **[IF ALTERNATIVE NO. 1 IS SELECTED, OMIT THE REMAINDER OF SECTION 8. IF ALTERNATIVE NO. 2 IS SELECTED, THE REMAINDER OF THIS SECTION HAS AN UNDERLYING PREMISE THAT RESULTS MAY BE RETURNED.]** **[ALTERNATIVE NO. 2, POSSIBILITY OF RETURNING RESULTS:]** If you are known to have the Study Medical Condition, results may be reported to you if the study team determines that a variant in your genome or exome is possibly, likely or definitely responsible for some or all features of the Study Medical Condition. **[IF SECONDARY FINDINGS MAY BE RETURNED, WHETHER OR NOT THE SUBJECT HAS THE STUDY MEDICAL CONDITION INCLUDE THE FOLLOWING PARAGRAPH:]** Whether you have the Study Medical Condition or not, you may choose, at the end of this form, if you want to be provided with findings about conditions other than the Study Medical Condition that may be relevant to your health. These are generally called "secondary findings". The nature of WES and WGS and other detailed genetic tests makes it possible that we may identify information about you that was not previously known, such as disease status or risk. The study team may return genetic results to you if they determine that you have gene(s) or variant(s) that are probably or definitely associated with a medical condion. That condition may have been previously undiagnosed, or	Return of results options (from genetic testing consent form template)

or you may be at risk of developing it in the future. Knowing this information might help to prevent development of medical conditions. The absence of a reportable secondary finding does not mean that you have no disease-causing genetic changes, so if you have symptoms or features of a genetic disease in the future, clinical genetic testing should be considered. Coverage of specific genes through WES/WGS may not be as comprehensive as individual tests designed to investigate them. **[END OF SECONDARY FINDINGS SECTION.]** **[INCLUDE THE FOLLOWING INFORMATION IF ANY RESULTS, PRIMARY OR SECONDARY, MAY BE RETURNED:]** Before any test results can be returned to you, they must be confirmed by a laboratory that is certified to provide clinical genetic testing. **[ADD, IF PART OF THE INITIAL SAMPLE WAS NOT STORED IN A CLIA-COMPLIANT ENVIRONMENT FOR THIS PURPOSE: YOU WILL BE CONTACTED TO PROVIDE AN ADDITIONAL SAMPLE FOR THIS TESTING.]** The purpose of additional testing in this laboratory is to confirm whether the variant is present. If the finding is confirmed, the results will be provided to your physician who will make a determination with the research team as to whether those results may have clinical importance to you. If they do, you will be notified and an appointment with your physician **[ADD, IF APPLICABLE: AND ONE OR MORE MEMBERS OF THE RESEARCH TEAM]** will be arranged to discuss the results. If you are not known to have the Study Medical Condition, a positive test result can mean that you may be predisposed to (i.e., more likely to develop) or have the Study Medical Condition. If this is the case, you may wish to consider further independent testing, consult your physician or pursue genetic counseling. If you are known to have the Study Medical Condition, it is important for you to understand that this study may not identify a cause for the Study Medical Condition because: • The Study Medical Condition is not due to a genetic cause or • A genetic change exists, but based on current knowledge, it cannot be determined whether it is related to the Study Medical Condition. In these situations, you will be informed that the research analysis did not identify a genetic cause for the Study Medical Condition.	
What will happen to my biological samples and/or data?	Sub-header from genetic testing consent form template
As indicated above, if you agree to be in this study, you will provide biological samples that contain your DNA. The genetic tests will be performed on the DNA that is in these samples and such tests will produce genetic data about you. Your samples and/or data may be retained for the life of this study. After the study is concluded, we will **[INSERT, AS APPLICABLE: (A) DESTROY THE SAMPLES AND/OR DATA OR (B) WITH YOUR PERMISSION, RETAIN AND USE THE SAMPLES AND/OR DATA INDEFINITELY.]** Whether or not your samples are destroyed at the end of the study, **[SELECT THE APPLICABLE OPTION:]**	Plans for biological samples and options for uploading of data to federal or other repositories (from genetic testing consent form template)

[IF THE RESEARCH IS FUNDED BY NIH, INCLUDE:]
because our research study is funded by the U.S. National Institutes of Health (NIH), we are required to submit your genetic and/or clinical data in coded form to one or more databases managed by the NIH.

[IF IT IS A REQUIREMENT OF PARTICIPATION IN THE STUDY TO ALLOW THE DATA OF THE PARTICIPANT TO BE INCLUDED IN ANOTHER GOVERNMENT OR PRIVATE DATABASE FOR RESEARCH PURPOSES, INCLUDE:]
because our research study is funded by a sponsor that makes it a condition of participation to store your data, we will submit your genetic and/or clinical data in coded form to one or more *[if the research is funded by NIH, add "other"]* government or private databases developed to make data accessible to researchers. **[IF THE RESEARCH IS NOT FUNDED BY NIH, ADD "SOME OF THESE ARE MANAGED BY THE NATIONAL INSTITUTES OF HEALTH."] [IF STORAGE OF DATA IS NOT REQUIRED BY THE SPONSOR, ADD: WE WILL REQUEST YOUR PERMISSION LATER IN THIS CONSENT FORM TO STORE AND PERMIT ACCESS TO YOUR DATA.]]**

[IF THE DATA WILL BE UPLOADED AS UNRESTRICTED ACCESS DATA, INCLUDE:]
Some of these databases permit public unrestricted access to the data.

[IF THE DATA WILL BE UPLOADED AS CONTROLLED ACCESS DATA, INCLUDE:]
Some of these databases permit only controlled access to the data. Researchers who request access to data must promise that they will protect the data, only share data as permitted by the database rules, report any data breaches and not seek to identify any individual from the data.

[IN EITHER CASE, ADD:]
The data may be the combined or individual data of many people. Any data that is submitted will not be labeled with your name or other information that could be used to easily identify you. However, it is possible that the information from your genome, when combined with information from other public sources, could be used to identify you. We believe that this is unlikely to happen.

If you agree that we may retain and use your samples and/or data indefinitely, they will be stored at CUMC either with the researchers on this study or in a central storage facility called a repository in identifiable form in a coded manner. This means that your samples and/or data will be identified by a unique code number that is linked to your name. The key to the code will be stored securely **[SELECT, AS APPLICABLE: (A) ON THE RESEARCHERS' OR REPOSITORY'S DATA SERVERS, (B) ON AN ENCRYPTED ELECTRONIC DEVICE OR (C) IN A LOCKED FILE CABINET.]**

Also with your permission, your samples and/or data may be used by other Columbia researchers or researchers at other institutions, including commercial companies, for research on the Study Medical Condition or other medical conditions. If they are given to researchers who are not researchers on this study, they will only be given in deidentified form. This means that your name and other identifying information have been removed from your samples and/or data or that your samples and/or data are coded and the researchers who will use them will not have the key that links your name to the code number.

Any future testing or research using your samples and/or data may lead to the development and use of information, products, tests and/or treatments having commercial value. You will not receive any compensation that may result from these tests or treatments.

Can I select someone to act for me in the future if I cannot act for myself?	Sub-header from genetic testing consent form template
You have the option to designate someone who can, if you lose the capacity to consent for yourself or die, make choices for you with respect to your data and/or biological samples.	Designation of proxy (from genetic testing consent form template)
Whom may I call if I have questions?	Sub-header from genetic testing consent form template
You may call **[INSERT NAME OF PRINCIPAL INVESTIGATOR OR STUDY CONTACT]** at telephone # **[INSERT PHONE NUMBER]** if you have any questions or concerns about this research study. If you have any questions about your rights as a research participant, or if you have a concern about this study, you may contact the office below. Human Research Protection Office Institutional Review Board Columbia University Medical Center 154 Haven Avenue, 1st Floor New York, NY 10032 Telephone: (212) 305-5883 irboffice@columbia.edu	Contact information (from genetic testing consent form template)
WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?	Sub-header
If you are receiving research credit for participating in this study, you still have the right to withdraw from this study at any time without penalty. If you want to withdraw from the study, tell the interviewer and leave the room. You will still receive research credit for the study.	Right to Withdraw without Penalty - Course Credit
If you have any questions or concerns about the study, you may contact **[Insert the investigator name(s) or other contact person, and their telephone number(s). If the researcher is a student, include the advisor's name and telephone number.]** If you have any questions about your rights as a subject, you may contact: Institutional Review Board Columbia University Medical Center 154 Haven Avenue, 1st Floor New York, NY 10032 Telephone: (212) 305-5883 Email: irboffice@columbia.edu An Institutional Review Board is a committee organized to protect the rights and welfare of human subjects involved in research.	Contact Specifics – CUMC researcher

Questions If you have any questions or are hurt while taking part in this research study, you should contact **[INSERT THE INVESTIGATOR NAME AND CONTACT INFORMATION, E.G., TELEPHONE NUMBER(S), EMAIL ADDRESS, MAILING ADDRESS.]** If you have any questions about your rights as a research subject, you should contact the Columbia University Institutional Review Board by phone at (212) 305-5883 or by email at irboffice@columbia.edu. More information about taking part in a research study can be found on the Columbia University IRB website at: http://www.cumc.columbia.edu/dept/irb.	Contact information - CUMC IRB
Questions If you have any questions or are hurt while taking part in this research study, you should contact **[INSERT THE INVESTIGATOR NAME AND CONTACT INFORMATION, E.G., TELEPHONE NUMBER(S), EMAIL ADDRESS, MAILING ADDRESS. IF THE RESEARCHER IS A STUDENT, INCLUDE THE ADVISOR'S NAME AND CONTACT INFORMATION.]** If you have any questions about your rights as a research subject, you should contact the Institutional Review Board by phone at (212) 851-7040 or by email at askirb@columbia.edu. More information about taking part in a research study can be found on the IRB website at http://www.columbia.edu/cu/irb	Contact information - Morningside IRB
What if you have questions?	Sub-header from 7-11 year old assent form template
You may ask questions at any time. You can ask now or later. You may talk to the researcher or someone else. Your parents/guardians have the information on who to call if you have questions after you go home.	Contact information (from 7-11 year old assent form template)
What if you have questions?	Sub-header from 12-17 year old assent form template
You may ask questions at any time. You can ask now or later. You may talk to the researcher or someone else. If you have any questions about this study you can call **[INSERT PI NAME]** at telephone # **[INSERT PHONE NUMBER]**. If you have any questions about your rights when you are in a research study, you may contact the Institutional Review Board by mail, telephone, or email at: Institutional Review Board Columbia University 154 Haven Avenue, 1st Floor New York, NY 10032	Contact information (from 12-17 year old assent form template)

Telephone: (212) 305-5883 Email: irboffice@columbia.edu An Institutional Review Board is a committee organized to protect the rights and welfare of human subjects involved in research.	
What are my rights if I take part in this study?	Sub-header from minimal risk consent form template
Taking part in this study is your choice. You can decide not to take part in or stop being in the study at any time. Your choice will not change the treatment you receive from doctors and staff at Columbia University Medical Center **[ADD, IF APPLICABLE]** and New York-Presbyterian Hospital. **[IF APPLICABLE, PLEASE ADD:]** Please tell one of the Researchers listed at the beginning of this consent form if you decide to leave the study before it is finished. **[IF APPLICABLE, PLEASE ADD:]** Your participation will also end if the Researchers or the study Sponsor stops the study earlier than expected or if you do not follow the study procedures.	Rights (from minimal risk consent form template)
Who can I call if I have questions?	Sub-header from minimal risk consent form template
You may call **[INSERT NAME OF PRINCIPAL INVESTIGATOR OR STUDY CONTACT]** at telephone # **[INSERT PHONE NUMBER]** if you have any questions or concerns about this research study. If you have any questions about your rights as a research participant, or if you have a concern about this study, you may contact the Institutional Review Board listed below. Institutional Review Board Columbia University Medical Center 154 Haven Avenue, 1st Floor New York, NY 10032 Telephone: (212) 305-5883 irboffice@columbia.edu	Rights (from minimal risk consent form template)
Why might researchers want to contact me in the future?	Sub-header from genetic testing consent form template
[INCLUDE THIS SECTION IF PERMISSION FOR FUTURE CONTACT WILL BE REQUESTED.] We may want to contact you for additional information or to get a new sample of your **[SELECT (A) BLOOD AND/OR (B) TISSUE]** in order to learn more about the research findings from this study. We may contact you directly or through your physician. We may ask you to provide a new sample or additional medical information, participate in other research studies or allow us to use your samples and/or data in identifiable form for other studies. If a biological sample, your participation in future research or use of your samples in identifiable form is requested, you may be asked to sign an additional form to agree to this.	Future contact (from genetic testing consent form template)

In addition, in the future, we may want to contact you if we learn more about the genetic basis for the Study Medical Condition or other medical conditions or if we are more certain about identifying the genetic cause of such conditions that might give you the opportunity to obtain treatment or better treatment for such conditions.	
Selection of options (initials required for each decision)	Sub-header from genetic testing consent form template
Please initial your choice for each option. Your choices will not affect your status in this research study or your access to health care at CUMC or NYPH. **<u>[INCLUDE ONLY IF RESULTS MAY BE RETURNED:] Section 9: Reporting of Results</u>**: **[_____ I agree] [_____ I do not agree]** that you may notify me about the results of the genetic testing to be conducted as part of this study. **[ADD, IF LABORATORY CONSENT FOR CONFIRMATORY TESTING WILL BE OBTAINED:]** I will be asked to sign a separate consent form for additional testing to confirm the results before information about them is given to me. --- **<u>Section 16: Designation of a Proxy:</u>** **[_____ I do] [_____ I do not]** wish to designate a proxy if I lose the capacity to consent for myself or die to: ***[INCLUDE OPTION (A) ONLY IF RESULTS WILL BE RETURNED]*** (a) receive the results of genetic testing that is done on my biological samples; (b) request that my biological samples no longer be used for this study; and/or (c) have the authority to have my biological samples transferred to another medical or research institution. If applicable, please provide the name of the proxy: _____ --- **<u>Section 18: Storage and Future Use of Biological Samples and/or Data:</u>** **[_____ I agree] [____ do not agree]** to the **storage** of my samples and/or data at CUMC in identifiable form after completion of this study and the **use** of my samples and/or data in deidentified form for future research and/or testing, including for commercial purposes, that may or may not be related to this study. You can change your mind regarding storage and future use of your samples, DNA and/or data at any time. Please see Section 15 of the consent form for further information. --- **<u>Section 19: Future Contact</u>** **[_____I agree] [____I do not agree]** to being contacted in the future to provide an additional biological sample or medical information, to receive information about other research studies, with a request to use samples, DNA and/or data with my identifying information attached, or to receive additional information for the treatment of the Study Medical Condition or other medical conditions.	Options (from genetic testing consent form template)
Statement of Consent	Sub-header from genetic testing consent form template
[WHEN FINALIZING THIS DOCUMENT, PLEASE MAKE SURE THE STATEMENT OF CONSENT AND SIGNATURES ARE ON THE SAME PAGE. IF THERE ARE ANY LARGE AREAS OF BLANK SPACE AS A RESULT,	Statement of consent (from genetic testing consent form

ADD THE STATEMENT, "THIS SECTION INTENTIONALLY LEFT BLANK."] **Statement of Consent** I have read this consent form and the research study has been explained to me. I agree to be in the research study described above. A copy of this consent form will be provided to me after I sign it. By signing this consent form, I have not given up any of the legal rights that I would have if I were not a participant in the study.	template)
STATEMENT OF CONSENT **[A STATEMENT OF CONSENT ADDRESSES THE ELEMENT OF VOLUNTARY PARTICIPATION THAT IS ARTICULATED IN THE FEDERAL REGULATIONS FOR THE PROTECTION OF HUMAN SUBJECTS AS A REQUIRED ELEMENT FOR INFORMED CONSENT. INCLUDING INFORMATION ABOUT THE VOLUNTARY NATURE OF PARTICIPATION IN A FORMAL "STATEMENT OF CONSENT" IS NOT REQUIRED BUT MAY BE DESIRABLE TO INCREASE UNDERSTANDING. OTHER SAMPLES IN THIS CONSENT FORM BUILDER ADEQUATELY ADDRESS THE VOLUNTARY PARTICIPATION ELEMENT AND MAY BE USED IN ADDITION TO OR INSTEAD OF A STATEMENT OF CONSENT.]**	Statement of consent
Statement of Consent **[IN TERMS OF LOCATION, THE STATEMENT OF CONSENT SHOULD BE THE LAST SECTION DIRECTLY ABOVE THE SIGNATURE LINES.]** I have read the consent form and talked about this research study, including the purpose, procedures, risks, benefits and alternatives with the researcher. Any questions I had were answered to my satisfaction. I am aware that by signing below, I am agreeing to take part in this research study and that I can stop being in the study at any time. I am not waiving (giving up) any of my legal rights by signing this consent form. I will be given a copy of this consent form to keep for my records.	Statement of consent option 1
Statement of Consent and HIPAA Authorization **[IN TERMS OF LOCATION, THE STATEMENT OF CONSENT SHOULD BE THE LAST SECTION DIRECTLY ABOVE THE SIGNATURE LINES.]** Statement of consent and HIPAA Authorization I have read the consent and HIPAA authorization form and talked about this research study, including the purpose, procedures, risks, benefits and alternatives with the researcher. Any questions I had were answered to my satisfaction. I am aware that by signing below, I am agreeing to take part in this research study and that I can stop being in the study at any time. I am not waiving (giving up) any of my legal rights by signing this consent form. I will be given a copy of this consent and HIPAA authorization form to keep for my records.	Statement of consent option 1 (for use when the consent form and HIPAA authorization form will be combined)

Statement of Consent **[IN TERMS OF LOCATION, THE STATEMENT OF CONSENT SHOULD BE THE LAST SECTION DIRECTLY ABOVE THE SIGNATURE LINES.]** I voluntarily consent to participate in the study. I have read this consent form which includes information about the nature and the purpose of the study, as well as a description of study procedures. I have discussed the study with the investigator or study staff, have had the opportunity to ask questions and have received satisfactory answers. The explanation I have been given has mentioned both the possible risks and benefits to participating in the study and the alternatives to participation. I understand that I am free to not participate in the study or to withdraw at any time. My decision to not participate, or to withdraw from the study will not affect my future care or status with this investigator. **[INSERT THE FOLLOWING PARAGRAPH IF APPLICABLE TO YOUR STUDY]** I confirm that I have informed the investigator or study staff to the best of my knowledge of: any medication/drug that I have taken in the month before the start of the study; and any medication/drug that I am taking or plan to take, whether prescribed or not. I agree to cooperate with the study investigator/staff and will report any unexpected or unusual symptoms. I understand that I will receive a copy of this signed and dated consent form. By signing and dating this consent form, I have not waived any of the legal rights that I would have if I were not a participant in the study.	Statement of consent option 2
Statement of Consent and HIPAA authorization **[IN TERMS OF LOCATION, THE STATEMENT OF CONSENT SHOULD BE THE LAST SECTION DIRECTLY ABOVE THE SIGNATURE LINES.]** I voluntarily consent to participate in the study. I have read this consent and HIPAA authorization form which includes information about the nature and the purpose of the study, as well as a description of study procedures. I have discussed the study with the investigator or study staff, have had the opportunity to ask questions and have received satisfactory answers. The explanation I have been given has mentioned both the possible risks and benefits to participating in the study and the alternatives to participation. I understand that I am free to not participate in the study or to withdraw at any time. My decision to not participate, or to withdraw from the study will not affect my future care or status with this investigator. **[INSERT THE FOLLOWING PARAGRAPH IF APPLICABLE TO YOUR STUDY]** I confirm that I have informed the investigator or study staff to the best of my knowledge of: any medication/drug that I have taken in the month before the start of the study; and any medication/drug that I am taking or plan to take, whether prescribed or not. I agree to cooperate with the study investigator/staff and will report any unexpected or unusual symptoms. I understand that I will receive a copy of this signed and dated consent form. By signing and dating this consent form,	Statement of consent option 2 (for use when the consent form and HIPAA authorization form will be combined)

I have not waived any of the legal rights that I would have if I were not a participant in the study.	
Statement of Consent **[IN TERMS OF LOCATION, THE STATEMENT OF CONSENT SHOULD BE THE LAST SECTION DIRECTLY ABOVE THE SIGNATURE LINES.]** PARTICIPANT'S STATEMENT I have read the above purpose of the study, and understand my role in taking part in the research. I volunteer to take part in this research. I have had a chance to ask questions. If I have questions later, about the research, I can ask the investigator listed above. I understand that I may refuse to participate or withdraw from participation at any time without jeopardizing my employment, student status or other rights to which I am entitled. The investigator may withdraw me at his/her professional discretion. If I have questions about my rights as a research participant, I can call the Institutional Review Board office at **[INSERT APPROPRIATE NUMBER FOR CUMC OR MORNINGSIDE, RESPECTIVELY]** (212) 305-5883 **[OR]** (212) 851-7040. I certify that I am 18 years of age or older and freely give my consent to participate in this study. I will receive a copy of this document for my records.	Statement of consent option 3
Statement of Consent and HIPAA authorization **[IN TERMS OF LOCATION, THE STATEMENT OF CONSENT SHOULD BE THE LAST SECTION DIRECTLY ABOVE THE SIGNATURE LINES.]** PARTICIPANT'S STATEMENT I have read the above purpose of the study, and understand my role in taking part in the research. I volunteer to take part in this research and give my authorization to use the protected health information and information collected during the research. If I have questions later, about the research, I can ask the investigator listed above. I understand that I may refuse to participate or withdraw from participation at any time without jeopardizing my employment, student status or other rights to which I am entitled. The investigator may withdraw me at his/her professional discretion. If I have questions about my rights as a research participant, I can call the Institutional Review Board office at **[INSERT APPROPRIATE NUMBER FOR CUMC OR MORNINGSIDE, RESPECTIVELY]** (212) 305-5883 **[OR]** (212) 851-7040. I certify that I am 18 years of age or older and freely give my consent to participate in this study. I will receive a copy of this document for my records.	Statement of consent option 3 (for use when the Consent form and HIPAA authorization form will be combined)
Statement of Consent and HIPAA authorization **[IN TERMS OF LOCATION, THIS PARAGRAPH SHOULD BE THE LAST SECTION]** I have read the consent and HIPAA authorization form and fully understand the purpose, procedures, risks, benefits and alternatives. I am aware that any questions I have can be answered prior to choosing to participate. I am not waiving (giving up) any of my legal rights by agreeing to take part in this research study and I am aware that I can stop being in the study at any time. I will be given a copy of this form to keep for my records.	Statement of consent for Information Sheet (for use when a waiver of written documentation of consent is requested and the study involves Protected Health Information) (This section can be incorporated into the Information Sheet or verbal consent script)
Statement of Consent and Signatures	Sub-header from minimal risk consent

	form template
[WHEN FINALIZING THIS DOCUMENT, PLEASE MAKE SURE THE STATEMENT OF CONSENT AND SIGNATURES ARE ON THE SAME PAGE.] **Statement of consent and HIPAA authorization** I have read this consent form and HIPAA authorization. The research study has been explained to me. I agree to be in the research study described above. A copy of this consent form will be provided to me after I sign it. [Add, if an inpatient] Another copy will be placed in my medical record. By signing this consent and HIPAA authorization form, I have not given up any of the legal rights that I would have if I were not a participant in the study. **Signatures** **[OMIT SIGNATURE LINES THAT DO NOT APPLY TO YOUR STUDY. IF THE SIGNATURE LINE REMAINS, THE EXPECTATION IS THAT IT WILL BE USED AT THE TIME OF EACH ENROLLMENT.]** _____ **Research Participant** Date _____ Print Name of Research Participant --- If this consent also serves as the parental permission, please include a parent/Guardian signature line. _____ **Parent/Guardian** Date _____ Print name of Parent/Legal Guardian --- **[IF THIS CONSENT ALSO SERVES AS THE PERMISSION FROM A SURROGATE, PLEASE INCLUDE A "LEGALLY-AUTHORIZED REPRESENTATIVE" SIGNATURE LINE.]** _____	Statement of consent (from minimal risk consent form template)

Legally Authorized Representative Date _____ Print name of Legally Authorized Representative --- _____ **Person Obtaining Consent** Date _____ Print Name of Person Obtaining Consent --- _____ **Witness** Date _____ Print name of Witness **[THE SIGNATURE OF A WITNESS IS ONLY REQUIRED FOR MINIMAL RISK STUDIES WHEN OBTAINING CONSENT FROM:** ➢ **A NON-ENGLISH SPEAKING RESEARCH PARTICIPANT USING THE SHORT FORM PROCESS, OR** ➢ **A PERSON WHO IS PHYSICALLY NOT ABLE TO READ, TALK OR WRITE.]**	
[THIS TEXT BOX ONLY APPLIES IF YOU WILL OBTAIN THE ASSENT VERBALLY, IN WHICH CASE THE SIGNATURE LINES THAT APPEAR LATER IN THE FORM SHOULD BE DELETED. **IF YOU WILL OBTAIN THE CHILD'S SIGNATURE, THE "ACKNOWLEDGMENT OF VERBAL ASSENT" TEXT BOX SHOULD BE DELETED AND THE SIGNATURE LINES SHOULD BE RETAINED.]** _____ **Acknowledgment of verbal assent** Print name of Child: _____	Documentation of verbal assent from 7-11 year old consent form template

Print name of parent(s)/guardian(s) present: _____ Do you want to be in this study? Child's response: ☐ Yes ☐ No _____ Signature of Person conducting the assent process Date _____ Print name of Person conducting the assent process	
If you sign this paper, it means that you want to be in this study. **If you do not want to be in the study, do not sign this paper.** **Signatures** **[OMIT SIGNATURE LINES THAT DO NOT APPLY TO YOUR STUDY. IF THE SIGNATURE LINE REMAINS, THE EXPECTATION IS THAT IT WILL BE USED AT THE TIME OF EACH ENROLLMENT.]** _____ **Signature of Child** Date _____ Print name of Child _____ **Signature of Person Obtaining Assent** Date _____ Print name of person obtaining Assent _____ **Signature of Witness** Date _____ Print name of witness **[THE SIGNATURE OF A WITNESS IS ONLY REQUIRED WHEN OBTAINING ASSENT FROM:**	Signature block from 7-11 year old assent form template (may utilize the Rascal signature line options in lieu of editing these lines)

➢ **A NON-ENGLISH SPEAKING RESEARCH PARTICIPANT USING THE SHORT FORM PROCESS, OR** ➢ **A PERSON WHO IS PHYSICALLY NOT ABLE TO READ, TALK OR WRITE.]**	
Signatures **[OMIT SIGNATURE LINES THAT DO NOT APPLY TO YOUR STUDY. IF THE SIGNATURE LINE REMAINS, THE EXPECTATION IS THAT IT WILL BE USED AT THE TIME OF EACH ENROLLMENT.]** _____ **Signature of Minor** Date _____ Print name of minor _____ **Signature of Person Obtaining Assent** Date _____ Print name of person obtaining assent _____ **Witness** Date _____ Print name of witness **[THE SIGNATURE OF A WITNESS IS ONLY REQUIRED WHEN OBTAINING ASSENT FROM:** ➢ **A NON-ENGLISH SPEAKING RESEARCH PARTICIPANT USING THE SHORT FORM PROCESS, OR** ➢ **A PERSON WHO IS PHYSICALLY NOT ABLE TO READ, TALK OR WRITE.]**	Signature block from 12-17 year old assent form template (may utilize the Rascal signature line options in lieu of editing these lines)
Signature block	Sub-header from genetic testing consent form template
Signatures **[OMIT SIGNATURE LINES THAT DO NOT APPLY TO YOUR STUDY. IF THE SIGNATURE LINE REMAINS, THE EXPECTATION IS THAT IT WILL BE USED AT THE TIME OF EACH ENROLLMENT OR THAT "N/A" WILL BE ENTERED ON THE LINE AT THE TIME OF ENROLLMENT.]** _____ **Research Participant** Date	Signature block (from genetic testing consent form template) (may utilize the Rascal signature line options in lieu of editing these lines)

_____ Print Name of Research Participant --- **[IF THIS CONSENT ALSO SERVES AS THE PERMISSION FROM A PARENT, LEGAL GUARDIAN OR LEGALLY AUTHOHRIZED REPRESENTATIVE, PLEASE INCLUDE THE FOLLOWING SIGNATURE LINE.]** _____ _____ **Parent, Legal Guardian or Legally Authorized Representative** Date _____ Print name of Parent, Legal Guardian or Legally Authorized Representative --- _____ **Person Obtaining Consent** Date _____ Print Name of Person Obtaining Consent --- **[INCLUDE A WITNESS SIGNATURE LINE IF CONSENT WILL BE OBTAINED FROM A NON-ENGLISH SPEAKING INDIVIDUAL USING THE SHORT FORM PROCESS, OR A PERSON WHO IS PHYSICALLY NOT ABLE TO READ, TALK OR WRITE.)]** _____ **Witness** Date _____ Print name of Witness	