Consent to Participate in a Research Study

Title: Coriell Personalized Medicine Collaborative

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A. INTRODUCTION

This is a research study. Your doctor or a representative from a research program will explain this study to you. Research studies include only people who choose to take part. Please take your time to make your decision about taking part in this study.

The sponsor of this study is the Coriell Institute for Medical Research (Coriell).

This research study is called the Coriell Personalized Medicine Collaborative (CPMC). The purpose of this research is to learn whether giving people personal information about their genes causes them to make changes that can help reduce their risk for certain diseases. The CPMC study team will give 10,000 people information about their own genes. The CPMC study team will then see what people do with this information and whether it changes their health behaviors.

This consent form will give you details about the CPMC study. It tells you why the study is being done, what happens if you decide to take part and how to get answers to your questions. First, we will give you some background about genes.

Genes are the instructions for how our bodies work. We inherit our genes from our parents. We each have between 20,000 and 25,000 genes in each cell of our body. Genes are made up of DNA or deoxyribonucleic acid. Although we are all more than 99% identical, there are lots of differences in the DNA when comparing person to person. These differences are called genetic variants. Differences in genetic variants may make some people more likely and others less likely to get certain complex diseases. Cancer, heart disease and diabetes are complex diseases. They are caused by the interaction between multiple genetic variants and the environment. In addition, differences in genetic variants may make some people have a bad reaction to a medication or may mean that some people need a higher or lower dose of a medication than other people.

The study of a person’s entire DNA and their genetic variants is called “genomics”. Genomics can be used to make medicine more personal. That means medical care can be based on a person’s very own genetic variants. For example, your doctor may use genomic medicine to tell you about your risk of a certain disease.

This study will NOT give you results on all genetic variants. The study team will only give you results on genetic variants for which you may be able to do something to improve your health. We will call these “genetic variants of interest”. Genetic variants of interest are those which:

- Are believed by scientists to be related to a specific health condition.
• Have actions you can take to reduce the health risk linked to that variant.
• Affect how your body responds to medications.

Actions to reduce risk may include but are not limited to increased screening, use of medication and changes in lifestyle. An external review committee called the Informed Cohort Oversight Board (ICOB) will review genetic variants that CPMC scientists identify from current scientific literature to determine which genetic variants are potentially “variants of interest.” Examples of diseases that are believed to have “variants of interest” include iron storage disease, heart disease and type 2 diabetes.

In this study, we hope to learn how personal genomic medicine may improve health outcomes.

Participants will control access to their genetic variant information through a secure web portal, a website similar to those of banks and online vendors, with security features to protect your privacy. For each genetic variant, participants will be able to decide for themselves whether or not to view the information and whether they would like to share the information with their healthcare provider or family/friends.

Your participation in this study is expected to last a minimum of 5 years.

This study is completely voluntary. In order to take part in this study, you must:
• Be at least 18 years of age or older
• Have a valid email address
• Be willing to provide a saliva sample for genetic testing
• Be willing to complete a questionnaire regarding your medical history, family history and lifestyle
• Be willing to complete follow-up questionnaires about what you did with the information you learned through your participation in this study

B. WHY IS THE STUDY BEING DONE?

There are three purposes of this study. To see if learning about your personal genetic variants related to certain diseases changes your behavior or perception of your risk of these diseases. To find genes and gene variants which increase the risk of certain diseases We will also look at cases where more than one gene variant may interact with your environment or factors in your medical history to play a role in increasing the risk of disease. We will also study how your genetic variants may affect the way certain medicines work in your body. To share your de-identified data with researchers outside Coriell Institute “De-identified” means we will remove your name and other personal information that would link the data to you. You do not have to share your data. You can tell us at the end of this consent form if you wish to share your data.

C. WHAT IS INVOLVED IN THE STUDY?

1. Learning about the Research Study
Prior to enrolling in this study you will be asked to listen to a presentation about this study. If you decide to participate in this study you will be asked to complete and sign this consent form.

2. Providing Saliva
After signing this consent form you will be asked to provide about one-half teaspoon (2 ml) of saliva. You will not be required to take medications nor to undergo an experimental procedure to participate in this study.

3. Laboratory Processing
A barcode will be assigned to your saliva sample and your consent form. This is to protect your privacy. Participants will get their own barcode number. This is the link between your identity and your sample. Your name and contact information will be stored separately from your sample and your results. Your saliva is a source of your DNA. The DNA from your saliva is used to look for genetic variants. Genetic
testing will be performed in a CLIA-certified laboratory. Laboratories with this certification have met standards established by the federal government for reporting results to be used as part of clinical care. In accordance with the laws of New Jersey, genetic testing performed as part of this research study is ordered by a licensed physician who has volunteered to serve as the CPMC physician of record.

4. How Variants of Interest Are Selected
This study has an Informed Cohort Oversight Board (ICOB). This is a group of doctors, scientists and community members who will decide which variants of interest will be shared with participants. The ICOB will also decide which results are potentially actionable (there may be something you can do to reduce your risk or improve the disease outcome) and which results are actionable (there is a specific medical action that is typically recommended in response to a particular result). The ICOB will meet at least twice a year to make these decisions. When the ICOB approves the sharing of information about a variant, the information will be available to you through the study web site. Also, a copy of your results will go to the physician of record.

5. How to Set Up and Use Your Account on the Study Web Site and Complete Surveys
We will send you an email using the address you gave us on this consent form to tell you how to set up your account. This takes about 5 minutes. This is a secure web site. You will use your account to view your genetic test results and to complete the study surveys. We will ask you to complete a number of questionnaires including: medical history, family history and lifestyle. You can complete these all at one time or you may complete them over time. This takes about 1 – 2 hours, depending on the size of your family. You can choose the option to answer “don’t know.” However, you must complete the medical history, family history and lifestyle questionnaires before you view your genetic variant results. You will have 45 days to complete the required surveys from the time that you receive your CPMC account information. If you do not complete the required surveys within 45 days you may be withdrawn from the study.

We will ask you for “protected health information” (PHI). This includes things like your name, address, birth date and medical information. We may ask you to get your medical record from your health care provider to share with us. Your medical record is also protected health information. We must have your permission to use your protected health information.

You must agree to the Terms and Conditions listed on the CPMC web site. You may request a paper copy of the Terms and Conditions. Under these Terms and Conditions, you must obey all applicable Federal and State laws to protect your privacy and the privacy of other participants. You must tell us if anyone uses your study password or account without your permission. Coriell takes the unlawful use of your account seriously. If you do not obey these Terms and Conditions, Coriell will block your access to the web site and you may be removed from the study.

6. Informing You about Your Personal Genetic Variant Information
We will send you emails when a new result for an ICOB approved genetic variant is ready. You can then decide if you would like to visit the web site to view your results.

7. Sharing your Personal Genetic Variant Information (optional)
You may want to share your results with your doctor, friend or family members. Results can be printed from your “My Account” page, or using the Print tab within your results. The CPMC may develop a way to share your results electronically in the future. If this becomes available you will be given instructions on how to share your results electronically. You are not required to share your results with anyone, however it is recommended that you consider sharing your results with your doctor.

8. Completing Study Surveys about Personal Genetic Variant Information
We will ask you to complete another survey about three months after you view your personal genetic variant information. This takes about 20 minutes. This survey will ask what you did with your genetic variant results, for example:
• Did you share the results with your healthcare provider, family, or friend?
• Did you visit your healthcare provider?
• Did you have any medical tests because of the results?
• Did you change your behavior in any way?
• Did the information make you anxious or worried?
You may choose the “do not want to answer” option for any question.

9. Re-Consenting and Updating Information
You will be asked to re-consent to the study if there are significant changes to the study which might affect your decision to continue with your participation.

You will be asked to update your contact information, complete a new lifestyle questionnaire, and update your medical history, family history, and medication information periodically. We will not ask you to do this more often than one time per year.

You must re-consent (when asked) and complete updates to required questionnaires if you want to continue to receive updated information about genetic variants of interest.

10. Completing Other Surveys (optional)
We may notify you about other surveys that you may participate in while you are in the study. You will be notified through the CPMC web portal or by email. These surveys are about your knowledge of genetics, your health, behavior, or feelings. These surveys are voluntary. You do not have to complete them to stay in the study.

11. Learning about Other Studies for Which You May Be Eligible (optional)
We may tell you about other studies you may be eligible for while you are taking part in this study. You may be eligible for other studies based on your personal genetic variant results or information in your medical history, family history or lifestyle surveys. These other studies are optional. You may choose whether you want to join.

12. Granting Release of De-identified Data to Biomedical Researchers (optional)
If you give your permission, your DNA and/or the genetic data may be shared with other researchers. We would remove any information that could identify you, such as your name and address before we shared your DNA or genetic data. You may choose whether you want to join.

13. Releasing Medical Records (optional)
We may request your recent medical records. This will help us confirm the medical information you gave us and will allow us to learn more about your medical health. You do not have to allow us to see your medical records. It will not affect your participation in this study. If you allow us to have a copy of your medical records, we will ask you to sign a form to let your doctor give us a copy.

If you make an appointment with one of the CPMC genetic counselors, you may be asked to share your medical record to help review your medical risks. You may agree to share your medical records with the genetic counselor, the CPMC study team, or both.

D. HOW WILL I FIND OUT ABOUT THE RESULTS OF THIS STUDY?

1. Your Access to Limited Genetic Information
Results of testing for ICOB-approved genetic variants will be reported back to you through our secure web portal (see Section C4 for description of the ICOB). You will have the option to share your results with others, including your healthcare provider.
2. Limitations on Release of Genetic Information to You
You WILL NOT receive results for all genetic variants. Some genetic variants are related to medical conditions for which there is no treatment and no way to reduce the risk of the disease. Results of these variants will NOT be reported back to you. This study will not test for rare disorders such as cystic fibrosis and Duchenne muscular dystrophy. These are not very likely to be found and reported to you, even if they are there.

3. Releasing Genetic Information to You During the Study
Results of genetic testing will be released over time as genetic variants are approved by the ICOB. The ICOB meets at least every 6 months. We will give you your personal results from testing for all ICOB approved variants no matter what your result is. Sometimes, for technical reasons, a sample may not be able to give a result for one or more variants. If this happens with your sample, we will tell you.

4. Your Access to Genetic Counseling
You will be able to speak with a CPMC genetic counselor about your results. You will not have to pay to speak with a CPMC genetic counselor while you are in the study. Genetic counseling may help you understand your genetic risk based on your CPMC results. However, the genetic counselors cannot give you a medical diagnosis. For a medical evaluation please see your regular healthcare provider.

You will be able to contact a CPMC genetic counselor through the study web site. You must share your genetic variant results with the CPMC genetic counselor to schedule an appointment. The genetic counselor is required to keep all of your information confidential. The genetic counselor may ask you to release some portion of your medical records to help assess your health risk.

5. Your Access to Education Regarding Genetic Variants and Health Conditions
The study web site will have written information and videos to help you learn more about genetic variants and health. There will be meetings at Coriell and other places to discuss the genes and diseases being studied. These meetings will be led by study doctors and genetic counselors. You may attend these meetings.

6. Access to Results of Studying Groups of Participants
One of the goals of the study is to study genetic variation in groups of participants to see if they play a role in disease. We will share what we learn with other health professionals by publishing our results in medical and/or scientific journals. We will not identify you in these publications.

E. WHAT ARE THE RISKS, DISCOMFORTS AND LIMITATIONS OF THE STUDY?

1. Risk of Providing Saliva
There are no physical risks associated with providing a saliva sample.

2. Risk of Awkwardness and Anxiety
Some of the questions included in the surveys may embarrass you or make you feel awkward. You may choose the “do not want to answer” option for any question that makes you feel uncomfortable. Your risk of a certain disease may make you anxious. If you feel you may have less anxiety by NOT viewing your results for the variant related to that disease, you do not have to view it. Also, you may speak to a study genetic counselor about your anxiety related to your health risk.

3. Risk of Not Understanding Your Genetic Results
You may over estimate or under estimate your risk of a particular condition based on the results of this study. It is not possible to tell you whether you will definitely get a disease. We will not diagnose disease in this study. Right now, the best way to predict whether you will get a disease is what your family history and medical history shows. You should share your family history and medical history with your healthcare provider. You could also share the information you learn about your genetic variants. This
could help you and your healthcare provider talk about the best ways to lower your risks of certain diseases.

4. Risks Related to Your Family
The results of this study may give information helpful for your children and other family members. If you learn you have a higher risk for a certain disease, other blood relatives in your family may also have a higher risk for that disease. CPMC genetic counselors can discuss this with you at no cost. If you choose to share your results with your family members or they give you permission to see their results, you may learn information that you did not expect. For example, you could learn that someone you believed to be a blood relative is not actually related to you by blood.

5. Risk of Learning about Other Disease Risk
In this study, we will only look at diseases for which you can do something to lower your risk.

We do not plan to include diseases for which we do not have good information about things you can do to lower your risk. However, in the future, scientists may learn new information about the genetic variants for which we have already given you information. For example, we may give you information about a variant linked to diabetes, and later someone may discover that same variant is also linked to Alzheimer’s disease. If this happens, the variant will be reviewed by the ICOB and handled in the same way as other genetic variants. If you learn about this on your own and have questions, you may call the study’s genetic counselors. Taking part in this study does not take the place of any genetic testing requested by your healthcare provider.

As part of the quality control process by the genetic testing laboratory, the CPMC will look at a small number of genetic variants on the X and Y chromosome (the pieces of your genome that determine your sex). If a genetic variant is found during this quality control process that could have a serious affect your health, this will be discussed with the ordering physician. If the ordering physician believes it is important for you to be informed about this variant for your health a CPMC genetic counselor will contact you to discuss the situation. You will be given the option to decide whether or not you want this information.

6. Risk that Your Risk Assessment is Wrong or Not Complete
Genetic information given to you in this study is based on research done in one or more groups of people and performed by different scientists. The results of these studies have been reported in scientific journals. This study or other studies may find that information already reported to you has since been found to be wrong or not complete. The ICOB can withdraw a genetic variant that they had approved in the past. Or they can have your results re-assessed based on the new information. Also, when more than one genetic variant is linked to a single disease, it may not be possible to accurately estimate the role of each genetic variant. We will explain how we calculate your risk and the limits of our calculations.

7. Risk of Genetic Results that are Wrong
The gene chip used for testing your DNA has greater than 99% reproducibility. This means that if your DNA was tested a second time with a similar test, more than 99% of the data would be the same.

Although rare, it is possible that you could get a wrong result. Therefore, 100% accuracy of reported results cannot be guaranteed. Also, sometimes, we will not be able to read or understand the results of a particular variant on a lab test. You will not receive a result for that variant if this happens. We expect that you will receive a result for 95% of the approved variants of interest.

8. Risk of Missed Opportunity for Medical Benefit
Some of the information provided through the CPMC is actionable information, that is, there is a current medical treatment or intervention, like changing the dose of a medication, which applies to individuals with a specific genetic result. If you choose not to view results that are actionable and share them with your doctor you may miss the opportunity for medical treatment or intervention.
9. Other Risks
You should not make any changes to your medication without talking to your doctor. Stopping, starting or changing your medication without the advice of your doctor may cause significant health problems.

F. ARE THERE BENEFITS TO TAKING PART IN THE STUDY?
You will receive information about your personal risk for certain diseases or conditions. You may or may not personally benefit from receiving this information. The information and results from this study may help improve human health in the future.

You will be able to speak to CPMC genetic counselors to discuss your personal genetic variant information. This service is free.

If you release a copy of your medical records to the CPMC, neither you nor your physician will be able to obtain a copy of these records or any compendium of these records from the CPMC study.

Participation in this study does not take the place of any genetic testing requested by your healthcare provider.

G. ARE THERE ALTERNATIVES TO PARTICIPATION?
You may choose not to participate in this study.

H. HOW WILL INFORMATION ABOUT ME BE KEPT PRIVATE?

1. Confidentiality Protections Through the Coriell Institute for Medical Research
We will give your saliva and DNA sample a barcode to keep your information confidential. We will not use your personal information to label your samples or the genetic data we get from your DNA sample.

Your samples with the barcode will be stored securely, away from files which link your name to the barcode. Files with names linked to barcodes will be kept locked and only the Coriell Personalized Medicine Collaborative data managers who are located at the Coriell Institute will have access to them.

Only you can release any personal study information that can identify you to others. If you choose to release your personal genetic variant information to others, Coriell cannot guarantee its confidentiality.

If you agree to share your data or samples with other researchers, we will remove any information that can identify you. We will give your data and samples a sample code number (not your barcode number). We will not release any personal information that could identify you to anyone outside of the CPMC study without your okay. However, since there is a slight chance of identification, all researchers who have access to your information will sign legal papers requiring them to protect your privacy.

Your sample will be kept indefinitely, unless you withdraw consent. If you withdraw consent, we will destroy any sample that has not yet been studied or given to approved biomedical researchers with your permission. You may withdraw consent at any time and do not need to give a reason. If you withdraw, you will be ending your authorization to use or share future protected health information (PHI). It is not practical to withdraw the information which has already had your identification removed from it. Therefore, the researchers may still use this information.

2. Risks Related to Privacy
We will make every effort to keep the results of your genetic testing private; however, we cannot give you a 100% guarantee. To protect your information, we will not keep your name and address with your sample. Instead, we will give your sample a code number. We will keep files that link your name to the code number separate and secure. Only the study staff will be allowed to look at them. Coriell cannot
guarantee the confidentiality of your personal variant information you choose to share with others. We do not know how your sharing of this information may affect your confidentiality. New Jersey and some other states have laws to reduce these risks. You may allow the release of some of your medical records to us while you are in the study. If you do, we cannot send you or your doctor copies of these medical records, or a summary of these medical records.

3. Confidentiality Protections Through the State of New Jersey
Because your study sample and information are stored in New Jersey, we will follow state laws to treat your information as confidential. New Jersey state law protects you against discrimination by employers and insurance companies based on genetic information. New Jersey state law may offer added protection in addition to any Federal laws that may be in place.

4. Confidentiality Protections Through the Federal Government
a. Records that identify you in this study are strictly private. Only study staff can ever look at them unless you agree to it. This is because Coriell Institute has been granted a Certificate of Confidentiality under a federal law (Section 301(d) of the Public Health Service Act). This means that the records of this study may not be shared, under federal, state or local court order, without your written approval. Data that are protected by a Certificate of Confidentiality may be released to the Department of Health and Human Services, if required for audits of research records. If, however, you choose to release your personal genetic variant information to others (see Section C7), Coriell cannot guarantee the confidentiality of this information.

b. A new Federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:
   - Health insurance companies and group health plans may not request your genetic information that we get from this research.
   - Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
   - Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

All health insurance companies and group health plans must follow this law by May 21, 2010. All employers within 15 or more employees must follow this law as of November 21, 2009.

Be aware that this new Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

I. AUTHORIZATION TO USE YOUR HEALTH INFORMATION FOR RESEARCH PURPOSES

1. Authorizing Use of Questionnaire Information You Supply
You have rights regarding the privacy of your protected health information (PHI) collected prior to and in the course of this research. PHI is defined in Section C5. You have the right to limit the use and sharing of your PHI. By signing this consent form, you are allowing CPMC to have access to your name, address, telephone number, email address and survey information regarding your medical history, family history and lifestyle information obtained through questionnaires that are part of the CPMC study.

You do not have to give permission for use of your PHI. If you do not want to provide permission for use of your PHI obtained through questionnaires, you will not be able to participate in the CPMC study.

2. Authorizing Use of Medical Information Others May Supply (optional)
In some instances, the CPMC may request that you release some part of your medical records to the study. This request may be made to you if you have requested counseling by a CPMC genetic counselor.
and the genetic counselor feels specific medical records are necessary to provide counseling. The CPMC may request that you release some part of your medical records based on answers to questions you supplied as part of the required questionnaires. If you release medical records to Coriell as part of this study, your PHI may include results of physical exams, blood tests, and other diagnostic and medical procedures. This information will be used to study the health benefits of receiving personal genetic variant information. If the CPMC requests that you release some part of your medical record for either purpose (genetic counseling or research), you will be asked to sign a form permitting your doctor to release specific records to the CPMC. Release of medical records is voluntary and is not required for your participation in the study. If you authorize release of your medical records, these records may include data that you have chosen not to share with the study through questionnaires (see Section C).

3. Use of Your Protected Health Information (PHI)
PHI that includes your identity will be used only for the study purposes described in this research consent form. Your identifiable PHI may be shared with the Institutional Review Board (IRB), the National Institutes of Health, the Department of Health and Human Services and with any person or agency as described in Section H3. All of these people or groups are obligated by law to protect your PHI.

If all information that identifies you is removed from your health information, the remaining information is no longer subject to the limits of this Authorization or to the HIPAA privacy laws. Therefore, de-identified and anonymized information may be used and released by the researchers (as permitted by law) for other purposes, such as other research projects. At this point, there is no plan to end the study, so your information may be kept and used indefinitely.

The information from this study may be published in scientific journals or presented at scientific meetings but your identity will be kept strictly confidential.

4. Withdrawing Your Authorization
If you decide to participate, you are free to withdraw your authorization regarding the use and disclosure of your health information (and to discontinue any other participation in the study) at any time. After any revocation, your health information will no longer be used or disclosed in the study, except to the extent that the law allows us to continue using your information (e.g., necessary to maintain integrity of research). If you wish to revoke your authorization for the research use or disclosure of your health information in this study, you must contact Coriell Institute’s Director of Communications with your request in writing at 403 Haddon Avenue, Camden, NJ 08103.

If you have questions or concerns regarding your privacy rights under HIPAA, you should contact the Coriell Institute’s Regulatory Affairs Officer at phone number: (856) 757-9716.

J. ARE ANY COSTS OR PAYMENTS INVOLVED?
There will be no cost to you for participating in this research study. If you choose to share your results with your healthcare provider, you will be responsible for the costs of seeing your healthcare provider and the costs of any testing that he/she may order.

You will not be paid for your participation in this research study.

If you think that you have been physically injured as a result of your participation in this study, we will help you get medical care through your usual healthcare provider. You will be responsible for the cost of any care you receive.

Saliva samples obtained from you and DNA samples derived from your saliva may be used to make a discovery that could be patented by or licensed to a company. If this happens, neither you nor your heirs will receive any financial benefit. Further, you will have no responsibility or liability for any use that may be made of your samples.
K. WHAT WILL HAPPEN TO MY SAMPLE AFTER THE STUDY IS OVER?

At this point there is no plan to end the study, so your sample and information may be kept and used indefinitely. We will store your sample under a code number and we will keep the file that links the code number to your name private. An Institutional Review Board (IRB), like the one that helps protect you during this research project, will review and approve all future projects. By federal law, every IRB must protect you and ensure the privacy of your information. Should the study end, we will tell you how we will dispose of your data and samples. Transfer of the samples to a third party could only be done with your consent.

L. WHAT ARE MY RIGHTS AS A PARTICIPANT?

1. You Have the Right to Withdraw From the Study at Any Time.
Taking part in this research study is your choice. You may choose either to take part or not to take part in the research study. If you decide to take part in the study, you may leave the study at any time. You may choose to withdraw your saliva sample and DNA from your saliva sample at a future date and your sample(s) will be destroyed. We may have already removed your identity from your sample and shared your sample with other researchers. If this has already happened, we will not be able to destroy these samples. Therefore, the researchers may still use these samples.

2. Participation by Coriell Employees is Voluntary
If you are a Coriell Institute for Medical Research employee, your participation in this study is completely voluntary and you are free to choose not to participate in this protocol for any reason. If you elect not to participate, it will not affect your employment with Coriell Institute. If you do elect to participate in this study, you may withdraw from the study at any time without affecting your relationship with Coriell Institute, its staff or your employment status.

3. Participation by Members of the Public
Your decision whether or not to participate will not affect your current or future ability to participate in other research studies at Coriell Institute for Medical Research.

4. Participation by Patients of Physicians and Hospitals in Partnership with Coriell
Your decision whether or not to participate will not affect your ability to receive care at any of our partner hospitals.

M. WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

If you have questions about this study, contact Coriell Institute’s Director of Communications at 856-757-9752. If you have any concerns about your rights as a study participant, please contact the Institutional Review Board (IRB) Office at Coriell Institute for Medical Research at 856-757-9719.
N. WHAT DO I DO TO COMPLETE THIS CONSENT FORM?

If you would like to participate, you must agree to the following statements.
Please initial each statement:

_________ I am over 18 years of age.

_________ I agree to provide a saliva sample which will be given a unique barcode. My DNA from my saliva will be used for genetic testing.

_________ I understand that this genetic testing on my sample was ordered by a licensed physician in the State of New Jersey. I also understand that I WILL NOT be billed by the physician or Coriell for this test.

(As a note, in accordance with the laws of New Jersey, genetic testing performed as a part of this research study is ordered by a licensed physician who serves as the CPMC physician of record. This CPMC physician of record is known as the “ordering physician”.)

_________ I authorize Coriell Institute to report my ICOB-approved genetic variant of interest results to the ordering physician.

_________ I agree that I will be able to access information about my genetic risk factors and understand that I may choose to view or not to view my personal genetic variant information for each ICOB-approved genetic variant.

_________ I understand that I MAY or MAY NOT benefit from learning about genetic risk information.

_________ I accept that the Informed Cohort Oversight Board (ICOB) will decide those variants that will be made available for me to view as part of this study. My physician and I will not receive information about a variant unless there are ways to reduce the risk of the condition or disease that might result from that variant.

_________ I agree to complete medical history, family history, and lifestyle surveys as part of this study and understand that I will have the option to choose “do not want to answer” for many of the questions.

_________ I agree to complete follow-up surveys about what I did with the results of this study after I have received results.

_________ I understand that if I choose to share information from the study with others (healthcare provider, family or friends), Coriell Institute is no longer responsible for the confidentiality of this information.
O. AUTHORIZATION OF TRANSFER AND ACCESS OF YOUR DNA AND DATA TO ADDITIONAL THIRD PARTIES

Your DNA will not be given or sold to anyone else, nor will it be used for purposes other than the genetic research described in this document unless you authorize the transfer of your DNA and data by checking the YES boxes below.

YES NO
☐ ☐ I agree to allow biomedical researchers from NON-PROFIT organizations to have access to my saliva, DNA, genetic data and data from my medical history, family history and lifestyle surveys as long as it is de-identified. That means all information that could identify me is removed and a code number is used instead.

Non-profit organizations will use de-identified saliva, DNA, genetic data and data from your medical history, family history and lifestyle surveys for research that may include finding genetic links to disease. They may also use it to help develop lab tests or medicines. Note that as detailed in Section J, neither you nor your heirs will benefit financially from this. Examples of non-profit organizations include the Coriell Institute and the University of Medicine and Dentistry of New Jersey.

YES NO
☐ ☐ I agree to allow biomedical researchers from FOR-PROFIT companies to have access to my saliva, DNA, genetic data and data from my medical history, family history and lifestyle surveys as long as it is de-identified. That means all information that could identify me is removed and a code number is used instead.

For-profit companies will use de-identified research results to pursue company objectives. This may include the development of lab tests or medicines that could benefit many people. The for-profit companies may profit from the use of your de-identified saliva, DNA, genetic data and data from your medical history, family history and lifestyle surveys. Note that as detailed in Section J, you or your heirs will not benefit financially from this. Examples of for-profit companies include Merck and Johnson & Johnson.
CONTACT INFORMATION AND SIGNATURES:
Participation in this research study is voluntary and requires that you provide information about your health by filling out questionnaires. You cannot be involved in the study unless you are willing to provide this information and agree to its use as outlined in this document. To show your agreement, you are required to sign this form. Your signature below indicates that you are providing both consent to participate in the research study and authorization for the researcher to use your de-identified health information for this research study.

SIGNATURE: __________________________________________________________

PRINT NAME: _________________________________________________________

DATE: ______________________

TIME: ______________________

EMAIL ADDRESS: ______________________________________________________
(PLEASE WRITE CLEARLY)
Note: It is strongly suggested that you list a personal email account, as most employers do not guarantee the confidentiality of private information.

MAILING ADDRESS: _____________________________________________________
_______________________________________________________________________
_______________________________________________________________________

PHONE NUMBER: _______________________________________________________

FOR STAFF USE ONLY:

Signature __________________________ Name of Investigator/Desigee ___________ Date __________