

Print Name: _____



Coriell Institute for Medical Research

PARTICIPANT COPY
KEEP FOR YOUR RECORDS

Consent to Participate in a Research Study

Title: *Coriell Personalized Medicine Collaborative*

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A. INTRODUCTION:

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.

Common diseases, such as diabetes, cancer, and heart disease, are known as complex diseases. These conditions are caused by the interaction of genetic variants in multiple genes in combination with the environment. The study of the entire genetic sequence, including the 20,000-25,000 genes at one time is called genomics. Genomics can be used in personalized medicine, which is medical care based on the genetic make up of a specific person.

The Coriell Personalized Medicine Collaborative (CPMC) will recruit 10,000 participants who are over the age of 18 into this study to investigate the impact of receiving personal genetic variant information on health and health behavior of the participants.

This study will only report back to participants those genetic variants that are potentially “medically actionable.” Potentially medically actionable genetic variants are those for which 1) there is a scientifically valid association between the variant and a specific health condition, 2) there are actions or interventions that can be taken to reduce the risk of the health condition, and 3) the risk of adverse events from these possible intervention(s) is likely small in relation to the risk associated with the genetic variant if no medical action is taken. 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 “medically actionable.” Examples of diseases that are believed to be “medically actionable” include iron storage disease, heart disease and type 2 diabetes.

By performing this study, we hope to gain a better understanding of the potential uses of genomic/personalized medicine to 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. Each is described below:

- 1) To determine the effectiveness of receiving information about personal genetic variants that may influence your risk of “medically actionable” conditions, such as diabetes, heart disease, and cancer. You will be given the opportunity to learn your personal genetic variant information after which time you will be asked to complete online surveys. These surveys will help us determine how this information may have influenced your behavior and your healthcare and whether it has been a useful predictor of your health.
- 2) To identify and validate genes and gene variants which elevate the risk of common complex diseases and alter your response to particular medications. In addition, we will examine how multiple genetic variants and non-genetic risk factors interact in order to better assess someone’s risk of disease. You will be asked to complete online surveys annually that assess your medical history, your family history, your medication history and your lifestyle.
- 3) To make de-identified genetic, medical history, lifestyle and family history information available to biomedical researchers outside Coriell Institute. The release of samples and data to researchers outside of Coriell is optional. You are asked to indicate your preference at the end of this consent form.

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. The number attached to this barcode is unique to you and 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. DNA will be extracted from your saliva and used to look for genetic variants

throughout your genome. 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. Potentially Medically Actionable Genetic Variants Approved by ICOB

At least twice per year, the Informed Cohort Oversight Board (ICOB) will meet to vote on potentially medically actionable genetic variants. Once a genetic variant is approved by the ICOB for release to study participants, your personal genetic variant information will be available to you through the CPMC web portal. In addition, a copy of your results will be reported back to the CPMC physician of record.

5. Establishing Account at CPMC Web Portal and Completing Required Information

You will be contacted via the email address you supply on this consent form and asked to create an account on our secure web portal. At that time you will be asked 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. However, you must complete the medical history, family history and lifestyle questionnaires prior to viewing your personal genetic variant information. Protected health information (PHI) includes demographic information as well as your medical history and family history, both self-reported by questionnaire and supplied through voluntary release of medical records from healthcare providers. As the information you supply about past or present health information is a form of PHI, you are required to authorize the use of this information in order to participate in this study (See Section I). Participants must abide by the Terms and Conditions for use of the CPMC web portal (hard copy available upon request). Under these Terms and Conditions, we require you to comply with all applicable Federal and State laws, regulations and ordinances so as to protect your privacy and the privacy of other participants. We require you to report any unauthorized use of your password or account. Coriell takes such breeches seriously. If you fail to comply with these Terms and Conditions, Coriell will block your access to the web portal and you may be removed from the study.

6. Receiving Notification of Personal Genetic Variant Information

When the results of your genetic testing for ICOB-approved genetic variants are available you will be contacted via email and directed to log into the secure web portal to view your results. Viewing your results is optional. You will only be invited to view your genetic results for variants that contribute to complex diseases and that are determined to be potentially “medically actionable” by the ICOB. We will not report results back to you that are not medically actionable.

7. Granting Access to your Personal Genetic Variant Information (optional)

Through the web portal you will be given the option to share your results with your healthcare provider and anyone else you would like to share the results with. To access the results, individuals designated by you will need to set up their own account on the web portal. These designated individuals will only be able to view the specific genetic variants that you authorize them to see. If another participant invites you to view their personal genetic variant information, you will receive an email with instructions on how to accept the invitation and view these results.

8. Completing Questionnaires Regarding Personal Genetic Variant Information

Approximately 3 months after you view personal genetic variant information, you will be sent an email requesting that you complete a questionnaire to assess what you did with your genetic variant results (e.g., whether you shared them with your healthcare provider or your family/friends, whether you saw your healthcare provider or had any medical tests because of your genetic results, whether you changed your behavior in any way, and whether or not the results made you feel anxious).

9. Re-Registering for the Study Annually

You must re-register on a yearly basis to remain in this study. Re-registration will occur through the web portal and involves updating contact information, verifying previously indicated authorized viewers (healthcare providers, others), verifying medical history, family history, demographic, and medication information and completing a new lifestyle questionnaire. It is necessary to re-register if you want to continue to receive updated information about medically actionable variants. Otherwise you will not receive any further notifications.

10. Completing Additional Questionnaires (optional)

Throughout your enrollment in the CPMC we may send you additional questionnaires about your knowledge of genetics, your health, behavior, or feelings. Completion of these additional questionnaires is voluntary.

11. Learning About Other Studies For Which You May Be Eligible (optional)

Throughout your enrollment in the CPMC we may notify you of other studies for which you may be eligible based on your personal genetic variant results or information in your medical history, family history or lifestyle questionnaire. Participation on these additional studies is voluntary.

12. Granting Release of De-identified Data to Biomedical Researchers (optional)

With your permission (indicated at the end of this form) your DNA and/or the genetic data generated from it may be de-identified (stripped of personal identifiers such as your name and address and assigned a new barcode using a series of numbers and letters) and shared with other biomedical researchers.

13. Releasing Medical Records (optional)

In order for us to verify some of your medical history information and/or your responses to surveys regarding particular genetic variant information, and for use in scientific research to discover genetic risk factors for disease and treatment outcomes, we may request your recent medical records. Releasing your medical records for use in this study is optional and will not affect your participation in this study. If you are willing to release your medical records, we will ask you to sign a form to let your doctor give us a copy of your medical record. In addition, if you schedule an appointment with one of the CPMC genetic counselors, you may be asked to release your medical records for use in assessing your risk. You will have the option to release your medical records to be used in research OR to the genetic counselor OR to 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. Genetic variants associated with medical conditions for which there is no treatment or intervention to reduce the risk of disease WILL NOT be reported back to participants. The technology employed by the CPMC is not designed to detect single gene mutations that cause rare Mendelian disorders such as cystic fibrosis and Duchenne muscular dystrophy; therefore, these are very unlikely to be detected and reported to you.

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. Personal genetic variant information regarding ICOB-approved variants will be made available to all participants, regardless of genetic variant status. However, occasionally, for technical reasons, a sample may not yield a result for one or more genetic variants.

4. Your Access to Genetic Counseling

You will be able to speak with a CPMC genetic counselor about your results at no cost to you during your participation in the study. Genetic counseling can help clarify your genetic risk based on your CPMC results but can not provide 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 web portal. In order to schedule an appointment with a CPMC genetic counselor you will be prompted to release your personal genetic variant results to the CPMC genetic counselor who is ethically bound to treat all of your information confidentially. The genetic counselor may ask you to release some portion of your medical records to help in assessing your overall risk of the condition for which you seek counseling.

5. Your Access to Education Regarding Genetic Variants and Health Conditions

You will be able to view educational material on the CPMC web portal both in written form and streaming video. In addition, you will be notified of upcoming seminars held at Coriell and other regional locations where the diseases and genetic contribution to the diseases studied as part of the CPMC will be discussed. Seminars will be hosted by partner physicians and CPMC genetic counselors.

6. Access to Results of Studying Groups of Participants

One of the goals of the study is to examine genetic variation in groups of participants to identify or validate associations of genetic variants with disease. We will share what we learn with other health professionals through medical and/or scientific publications. In these publications, your identity will be kept strictly confidential.

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 questionnaires 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. Some individuals have increased anxiety about results of genetic testing that may show that you and your family members may have an increased risk for disease. You have the option to view or NOT to view each genetic variant individually. Thus, you may choose NOT to view your personal genetic variant information that relates to your risk of diseases about which you may be anxious. In addition, you will have the opportunity to meet with or speak with a genetic counselor to discuss any questions or concerns you may have regarding your genetic variant information.

3. Risk of Misinterpretation of 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 rule out your risk of diseases by participating in this study. It is also not possible to diagnose a condition by participating in this study. Currently, family and medical history are the best predictors of your risk of complex diseases. Obtaining personal genetic variant information through this study does not substitute for discussing with your healthcare provider your

medical history and family history. Receiving personal genetic variant information by participating in this study may enable you and your healthcare provider to have more informed discussions aimed at lowering your risk of complex diseases.

4. Risks Related to Your Family

Results of this study may provide information about the risk for your children or other family members to develop certain diseases. CPMC genetic counselors are available to discuss these potential risks with you at no cost. If you choose to share your results with your family members and/or are granted access to other family members' results, you may learn information that you did not expect. For example it may be possible to determine that someone believed to be a blood relative is not actually related to you.

5. Risk of Learning about Non-medically Actionable Disease Risk

Although we will not select any "non-medically actionable" disease variants for inclusion in this study, there may be future advances in genetic research that we cannot predict now. These advances may identify new disease associations for genetic variants that we have released to you. It is possible that new associations may link a genetic variant that we have already informed you about to a "non-medically actionable" condition (for example a variant reported to be associated with diabetes may later be found to ALSO be associated with Alzheimer's disease). If this occurs, we will not contact you with this additional information. However, if you learn of any new associations with variants that have been released to you through the CPMC, you may contact the CPMC genetic counselors to discuss these new associations.

6. Risk of Inaccurate and Incomplete Risk Assessment

Genetic information provided in this study is based on findings of one or more population studies conducted by different scientists published in the scientific literature. It is possible that this study or additional studies may find that associations that have already been reported to you are invalid or incomplete. The ICOB can approve withdrawal of previously approved genetic variants or approve a reassessment of risk based on these new findings. Also, when more than one genetic variant is shared as a risk factor for a single health condition, it may not be possible to accurately assess the combination of these independent genetic variants. We will explain how we calculate your risk and what the limitations of these calculations are.

7. Risk of Inaccurate Genetic Results

The gene chip used for testing your DNA has greater than 99% reproducibility. This means that if your DNA was tested a second time on a new gene chip, more than 99% of the data would be the same compared to the results of the first test. Although rare, it is possible that you may receive an incorrect result; 100% accuracy of reported results cannot be guaranteed. In addition, occasionally there is a specific variant on a gene chip that is not able to be read or interpreted. In this case you will not receive a result for that variant. It is expected that you will receive results for about 95% of variants approved by the ICOB.

8. Risks Related to Privacy

Although every effort is made to keep the results of your genetic testing confidential, breeches in confidentiality may occur. To protect your information, we will not keep your name and address with your sample, only a code number. Files that link your name to the code number will be kept separate and secure and only the study staff will be allowed to look at them (Please see Section H for more information). If you choose to release your personal genetic variant information to others, Coriell cannot guarantee the confidentiality of this information. The effect of your decision to release this information to third parties is unknowable. New Jersey and some other states have laws to minimize these risks.

F. ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

You will receive personalized information about your risk of complex genetic conditions. You may or may not personally benefit from receiving this information. Still, the information and results from genetic variant studies may help improve human health in the future.

You will have access to CPMC genetic counselors to discuss your personal genetic variant information at no cost to you during your participation in the study.

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

To ensure confidentiality, a barcode will be assigned to your saliva and DNA samples. No personal identifying information will be used to label your samples or the genetic data generated from your DNA sample.

The barcoded specimens will be stored securely, separated from files which link your name to the code numbers. Files linking names to samples will be kept locked and accessible only to the Coriell Personalized Medicine Collaborative data managers who are located at the Coriell Institute.

Only you can release any identifiable study-related information about you to others. If you choose to release your personal genetic variant information to others, Coriell cannot guarantee the confidentiality of this information.

If you agree to share your de-identified medical/family history/lifestyle data, genetic data and/or DNA samples with other biomedical researchers, a sample code number (not your barcode number) will be used to identify the sample. No personal identifying information about you will be released to anyone outside of the CPMC study without your authorization. However, since there is a remote chance of identification, all qualified investigators who have access to your data will sign legal documents requiring them to protect the privacy of your information.

Your sample may be kept indefinitely, unless you withdraw consent. If you withdraw, any sample that has not yet been analyzed or given to affiliated biomedical researchers with your permission will be destroyed. You may withdraw consent at any time and need not provide a reason. If you withdraw, you will revoke your authorization and use or sharing of future protected health information (PHI) will be stopped. It is not practical to withdraw the de-identified protected health information (PHI) which has already been collected. Therefore, these data may still be used by biomedical researchers.

2. Confidentiality Protections Through the State of New Jersey

Any information we obtain about you during this study will be treated as confidential to the full extent permitted by applicable law. New Jersey state law provides protection against discrimination on the

basis of genetic information by employers and health insurance companies. New Jersey state law may offer added protection in addition to any Federal laws that may be in place.

3. Confidentiality Protections Through the Federal Government

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 disclosed, under federal, state or local court order, without your written approval. Data that are protected by a Certificate of Confidentiality may be disclosed 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.

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. Should this occur, 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, participants will be informed of the planned disposition of the 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.

You are free to withdraw your consent and discontinue participation for any of the procedures in the Coriell Personalized Medicine Collaborative at any time. You may choose to withdraw your saliva sample and DNA derived from it at a future date and your sample(s) will be destroyed at that time. However, if you had previously given permission for your saliva sample and/or DNA sample derived

from it to be de-identified and provided to other biomedical researchers, and this has already occurred at the time you withdraw, we will not be able to destroy these de-identified sample(s). Any data generated from testing your sample or supplied by you until the point that you withdraw will remain part of the research study.

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.

**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 will be extracted from it and used for genetic analysis.

_____ I understand that this genome profile test 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.

_____ I authorize Coriell Institute to report my ICOB-approved genetic variant information to the ordering physician.

_____ I agree that I will be able to access information about genetic risk factors and understand that I will have the option 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 for conditions which are considered medically actionable.

_____ I accept that the Informed Cohort Oversight Board (ICOB) will decide those variants I may view for purposes of this study and that risk factors for diseases for which there is no

effective medical intervention WILL NOT be made available to me or my physician(s) through this study.

_____ I agree to complete medical history, family history, and lifestyle questionnaires 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 questionnaires about what I did with the results of this study after I have received results.

_____ I understand that if I choose to share information generated by the study with others (healthcare provider, family or friends), Coriell Institute is no longer responsible for the confidentiality of this information.

Please answer YES or NO (These questions address an OPTIONAL part of the study, and your answers will not affect enrollment into the main part of the study):

If you agree to either of the questions below, your DNA will not be sold to anyone; however, a shipping and handling fee may be charged to the requesting institution. You do not pay. Materials are requested through a standard, scientific proposal application which must be approved prior to release of materials.

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 questionnaires provided all personally identifying information has been removed and a de-identified coded 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 questionnaires for research purposes, which may include determining genetic associations to disease. It is also possible that research for diagnostic lab tests or pharmaceutical therapies would be pursued. 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 questionnaires provided all personally identifying information has been removed and a de-identified coded number is used instead.

For-profit companies will use de-identified research results to pursue company objectives, which may include development of diagnostic lab tests, or pharmaceutical therapies that could benefit many people. The for-profit companies may profit from the receipt of your de-identified saliva, DNA, genetic data and data from your medical history, family history and lifestyle questionnaires. 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 and TIME

EMAIL ADDRESS
(PLEASE WRITE CLEARLY)

MAILING ADDRESS:

PHONE NUMBER:

FOR STAFF USE ONLY:

Signature

Name of Investigator/Designee

Date