

CONSENT TO PARTICIPATE IN RESEARCH

The Scripps Genomic Health Initiative

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Research Sites: Scripps Health Locations throughout San Diego County, CA
Scripps Translational Science Institute (STSI) and Scripps Genomic
Medicine

Sponsor: Scripps Translational Science Institute (STSI)

Co-Sponsors: Navigenics, Affymetrix, and Microsoft

Before you start reading about this research, please read the California Experimental Subjects' Bill of Rights, which is located on page 7 of this form.

Why is this research being done?

The purpose of this research is to find out whether knowing about your risk for certain diseases will encourage lifestyle changes. By providing a sample of your saliva, you can have your DNA examined and receive a report of your estimated risk for developing common diseases such as diabetes, Alzheimer's, obesity and some forms of cancer. This test does not look for rare genetic mutations in single genes that are associated with a very high likelihood of having the disease. For example, genes for cystic fibrosis, familial breast and ovarian cancer (BRCA1 and BRCA2) will not be looked for in this scan.

Genes are made of DNA and are the basic "instruction book" for people.

Genes are made of DNA. DNA is a major part of what carries our personal information of what we are made of. The DNA of a person is about 99.5% the same as the DNA of any other person. However, no two people have exactly the same DNA except identical twins. Differences in DNA are known as genetic variations. These variations explain some of the differences among people, like eye color and blood types. They also partly explain why some people get diseases like cancer, diabetes, asthma, and depression, while others do not. Diseases such as these are also affected by environmental factors and lifestyle choices such as diet, exercise, smoking

and pollution.

Genomics is the study of an individual's entire inherited information (your genes). Recent discoveries in the area of genomics have led to the development of companies that offer genetic testing to consumers. This research is being done to find out if participating in consumer genetic testing influences changes in lifestyle and leads to early diagnosis and treatment of diseases. The results of this research may lead to better understanding of the relationship between what we are born with and the influences from our environment.

Navigenics is the company that provides genetic testing services.

Affymetrix is the laboratory that examines the DNA from your saliva for 1.8 million DNA markers.

Microsoft is the computer software company that will provide a secure web "vault" where you can store your personal health information, including the genomic results from this study.

Up to 10,000 people, mostly Scripps employees, their families and friends, will participate in this study.

How long is the study?

If you agree to participate, you will be in the study for about 15 months.

You must complete self-reported health assessment questionnaires when you sign this form, and again at three and twelve months after receiving the results of your gene scan. In addition, you may be contacted periodically for up to 20 years to complete brief questionnaires about your health and lifestyle.

What will happen to me?

If you agree to participate, you will be required to read and agree to this informed consent form.

Health Questionnaires: You will be asked to complete self-reported health assessment questionnaires at the time of registration and at three and twelve months after receiving the results of your gene scan. These questionnaires will include items relating to your age, ethnic background, health history,

medications, lifestyle and family history. You may be contacted periodically for up to 20 years to complete additional brief questionnaires.

Saliva Sample: You will be asked to provide a sample (about ½ teaspoon) of your saliva. This could take 5 minutes to 30 minutes to collect in the provided container. There are two options available for the collection of your saliva sample:

1. You can choose to have the saliva collection kit mailed to your home where you will be responsible for collecting and mailing the sample back. You will be charged an additional fee for shipping the sample. If for some reason your saliva sample amount is not enough or is damaged during shipping, you will be sent a replacement kit free of charge.

OR

2. You may attend one of the scheduled events where the study staff will assist you with your saliva collection. There will be no additional charge for this option.

How will the samples be used?

Your genetic material will be separated from the sample of saliva and examined for differences that can increase your risk of developing certain health conditions. Researchers will list the genetic variations they find in your sample. You will be able to access these results on a secure website.

Researchers will store the genetic variations found and use them as a tool to continue to study genes linked to many diseases. The database that is created to store the information will be used for research to understand ways to prevent, diagnose, and treat disease.

The samples, the database, and the genetic variants will also be used to study other questions, such as the biology of DNA, how new differences come about, the genetic history of human groups, and how people from different parts of the world are related to each other. By including people and families from several ethnic and geographic groups, researchers will find the genes that affect diseases in different groups.

Coding of Saliva Samples and Questionnaire Information

* Your saliva sample and self-reported health assessment questionnaire will be identified by a unique number.

* The Scripps Translational Science Institute and Navigenics will have the information that links this unique number to identifying information, such as your name, email, gender and date of birth. This information will be stored without the links in an encrypted, secure database. No other researchers, including those who will be working with your sample and self-reported health assessment questionnaire information, will have access to any of your identifying information.

Storage and release of saliva samples and questionnaire information

* Your coded saliva sample will be examined for 1.8 million DNA markers at Affymetrix. Affymetrix will not have any information that can identify you. This company will scan your whole genome, but will only report on your risk of developing health conditions that you can influence with lifestyle changes. Three months after your DNA is extracted your saliva sample will be destroyed by Affymetrix.

* The results of over 20 health conditions will be made available to you on the websites for Navigenics Health Compass™ and Microsoft's HealthVault™.

* Remaining results will be stored at The Scripps Translational Science Institute and used for future research related to diseases or in other research projects.

Will I be given the results of my genetic scan?

Yes. You can review the results of your genetic scan that will be stored on the websites for Navigenics Health Compass™ and Microsoft's HealthVault™. The remaining results will not be interpreted or made available to you.

Additional health conditions may be added to the Navigenics Health Compass™ periodically. If additional health conditions are added during your one-year subscription, your genetic information may be re-examined for these new health conditions. You will be notified by e-mail if new information is added to your Navigenics Health Compass™ account and Microsoft HealthVault™ for you to review at your convenience. In addition, your genetic information will be examined to determine the part of the world that you and your ancestors originated from and you will be notified by e-mail that this information is available.

Can I ask to have my saliva sample or genetic scan information destroyed?

Yes. If you change your mind and want your saliva sample or genetic scan information destroyed, you must make your request by calling Navigenics member services at (866) 522-1585 from 9 a.m. to 5 p.m. Pacific Standard Time. It is your responsibility to tell the customer service agent that you want your genetic scan information destroyed and removed from all applicable databases. If, at the time of your request, your genetic data and health information is being used in a current study/publication we will not be able to destroy it. However, your data will not be used in any future research.

What are the Risks of Participating in the Study?

Saliva Sampling: The only known risk of saliva sampling is the possibility of a dry mouth during collecting the sample. Dry mouth symptoms will go away after drinking fluids.

Psychological or Social Risks: While we believe that the risks to you and your family are very low, we are unable to tell you exactly what all of the risks are. We believe that the benefits of learning more about diseases outweigh the following potential risks.

- * Some genetic variations can help to predict potential increased risk for future health problems for you and your relatives. Knowing your genetic information could cause you or your family distress if it re-vealed that you or a blood relative carries a genetic disease.

- * The ability to collect your genetic information is fairly new. The information may not be completely accurate for certain ethnic groups for whom less information is currently available.

- * Your privacy is very important to us and we will use every possible safety and security measure to protect your privacy. However, in spite of all of the safety measures that we will use, we cannot guarantee that your unique number will not be linked to your identifying information. Although your genetic information is unique to you, you do share some genetic information with your children, parents, brothers, sisters, and other blood relatives. It may be possible that genetic information from your blood relatives could be used to help identify you. Similarly, it may be possible that genetic information from you could be used to help identify them.

Patterns of genetic variation can be used by law enforcement agencies to identify a person or his/her blood relatives.

- * A recently passed Federal law, Genetic Information Non-discrimination

Act (GINA), protects you from discrimination by employers and health insurance providers. Currently there are no Federal laws protecting you from discrimination by life and disability insurance providers.

* Genetic Counseling: Scripps cannot provide genetic counseling. Your personal physician may not be able to provide guidance about the results of your genetic scan. If you have concerns about your gene scan results, you may contact Navigenics genetic counseling at 1-888-694-2546 or 1-650-585-7744. There will be a fee charged to you for these services. Costs of genetic counseling will be your responsibility.

By participating in this study, you may be giving up your right to sue Navigenics if Navigenics releases your personal information and test results in error. If you have agreed to Indemnify Navigenics, you are also agreeing to defend Navigenics in a lawsuit if Navigenics is sued. (Please refer to the Navigenics Consent Form, which Navigenics has requested that you sign as a condition of your participation in this study.)

By participating in this study, you will receive test results which you may be required to disclose in future applications for life insurance, medical insurance, and other requests for personal information. Failure to disclose such information could result in denial of payment of a claim by the insurer.

Are there any risks to my community or group?

Information on your ethnic and geographical background will be included with other information about you in the database. In future studies, researchers may find that certain genetic variations appear more often in people from your ethnic group than in people from other ethnic groups, and that these variations are more common in people with a certain disease.

Some individuals may use this information to call attention to these differences in a negative way.

Will I benefit from this research?

We cannot promise that you will benefit personally. Participation in this study provides you with the latest state-of-the art information on your DNA.

You will receive a one-year subscription at a greatly discounted rate to Navigenics Health Compass™. Navigenics Health Compass™ helps you understand what your genes have to say about the future of your health, and gives you action steps to take control of your health today.

For the entire year membership, Navigenics provides ongoing, secure and

personalized updates to your Health Compass™ account. These updates include new discoveries relating to your gene scan and wellness strategies.

It is your responsibility to take action by making lifestyle changes and seeking medical evaluation. An additional benefit you will receive in 2009 is information about your family origin. Once you join the study, you will be registered for Microsoft's HealthVault™. This online service provides secure storage for your health information and provides access to your genetic scan results free of charge.

Will I be paid?

No, you will not be paid.

Will it cost anything to be in the study?

Yes. A non-refundable fee will be charged at the time of enrollment into the study. Payment will be made directly through Navigenics Health Compass™ website at the time of consent and registration.

Through November 7, 2008: \$250 (\$150 for Scripps Employees and families)

November 8-November 30, 2008: \$300 (\$200 for Scripps Employees and families)

December 1-December 31, 2008: \$350 (\$250 for Scripps Employees and families)

If at the end of the one-year study, you decide to continue your membership with Navigenics, the cost will be \$250 per year.

What if I end the study early?

You can change your mind and quit at any time. You must make this request by calling Navigenics member services at (866) 522-1585 from 9 a.m. to 5 p.m. Pacific Standard Time.

What other options do I have?

You could obtain your genetic scan without being in this study, but the cost would be much higher.

What are my rights?

* You may e-mail the research staff at STSI to ask any questions about this study. They can be contacted at: SGHI@scrippshealth.org. You can expect

response within 3 business days.

- * Participation in this study is voluntary. You still have all your legal rights whether you join the study or not.

- * You can decide not to be in this study or you can quit after starting

- * Being in this study will not change your insurance or employment status nor affect your medical care.

- * If you have any questions about your rights, call the Scripps Office for the Protection of Research Subjects at (858) 652-5500. You should also read the Experimental Subject's Bill of Rights, which is page 7 of this form.

What are my responsibilities if I participate?

If you are in this study, you are expected to:

- * Follow the instructions of the research staff.

- * Sign an informed consent and fill out the self-reported health assessment questionnaires.

- * Provide a sample of saliva and return the sample to Navigenics or the research staff

What about confidentiality?

We will make every attempt to protect your confidentiality and to make sure that your personal identity is kept private. Neither your employer nor your health insurance provider will have access to any information specific to this study unless you provide it to them. A recently passed Federal law, Genetic Information Non-discrimination Act (GINA), protects you from discrimination by employers and health insurance providers. Currently there are no Federal laws protecting you from discrimination by life and disability insurance providers. Please familiarize yourself with your legal rights before sharing your gene scan results with anyone.

We will follow the plan explained in the "Storage and Release of saliva samples and questionnaire information" section on page 3 of this document.

For more information, see the Authorization to use your Private Health Information at the end of this consent form.

What if I get hurt in the study?

There are no anticipated injuries that would require medical or urgent care. Other risks are described on page 3-4 of this form.

Will Scripps Translational Science Institute, Scripps Genomic Medicine, the investigators or co-sponsors benefit from this study?

Scripps Translational Science Institute, Scripps Genomic Medicine, the investigators or co-sponsors might benefit financially from your participation in this study. If any of these parties make a profitable product from your participation, there is no plan to share any profits with you. The possible financial benefit to the re-searcher and the institutions involved in the research will not affect the scientific quality of the study.

I agree to participate.

I have read and understood the explanation of the study. I have had a chance to ask questions and have them answered to my satisfaction. I agree to take part in this study. I have not been forced or made to feel obli-gated to take part. I have read the attached Experimental Subject’s Bill of Rights and the Authorization to use your Private Health Information, which contain important information about research studies.

I must sign this consent form, the Experimental Subject's Bill of Rights and the Authorization to use your Private Health Information. I have been given the opportunity to print a signed copy of this consent form.

EXPERIMENTAL SUBJECT’S BILL OF RIGHTS

If I am asked to consent to be a subject in a research study involving a medical experiment, or if I am asked to consent for someone else, I have the right to:

1. Learn the nature and purpose of the experiment (also called “study” or “clinical trial”).
2. Receive an explanation of the procedures to be followed in the study, and any drug or device to be used.
3. Receive a description of any discomforts and risks that I could experience from the study.
4. Receive an explanation of any benefits I might expect from the study.
5. Learn about the risks and benefits of any other available procedures, drugs or devices that might be help-ful to me.
6. Learn what medical treatment will be made available to me if I should be injured because of the study.
7. Ask any questions about the study or the procedures involved.
8. Quit the study at any time, and my decision will not be used as an excuse

to withhold necessary medical treatment.

9. Receive a copy of the signed and dated consent form.

10. Decide to consent or not to consent to a study without feeling forced or obligated.

If I have questions about this research study, I can contact the STSI staff at SGHI@scrippshealth.org. If I have concerns about the research staff, or need more information about my rights as a subject, I can contact the Scripps Office for the Protection of Research Subjects, which protects volunteers in research studies. I may telephone the Office at (858) 652-5500, 8:00 a.m. to 4:00 p.m. weekdays, or I may write to the Scripps Office for the Protection of Research Subjects c/o Scripps Clinic, Mail Stop SCRC200, 11025 North Torrey Pines Road, La Jolla, CA, 92037.

*California Health & Safety Code, Section 24172

Authorization to use your Private Health Information

Name of Study: The Scripps Genomic Health Initiative

Principal Investigator: Eric Topol, M.D. IRB Study Number: 08-5069

What is private health information?

Private health information is any information that can be traced back to you.

We need your authorization (permission) to use your private health information in this research study. The private health information that we will use and share for this study includes:

- * your past and present health information
- * information that can be used to contact you, such as your name, e-mail address, gender and date of birth
- * Your age, ethnic background and related family history

Who else will see my information?

In addition to the Principal Investigator, this information may be shared with:

- * STSI, Scripps Genomic Medicine, and co-sponsors Navigenics, Affymetrix and Microsoft
- * Government agencies, such as the US Food and Drug Administration,

the National Institute of Health, the Department of Health and Human Services, and agencies like these in other countries

* Scripps committees that review research to help protect people who join research studies

Once we have shared your information we cannot be sure that it will stay private. If you share your information with people outside the research team, it will no longer be private. Your name will not be used in any report that is written.

How long will STSI use and share my information?

* Your information will be stored and used through 2028. At that time, the code that links you to the sample will be destroyed. The de-identified sample and related health and trait information may be kept indefinitely

What if I change my mind about sharing my research information?

If you decide not to share your information anymore:

* The sponsors and the researchers can continue to use any of the private information that they already have.

* You will no longer be a part of the research study.

* You will still get the same medical care that you have always had.

* You must call Navigenics Member Services at 1-866-522-1585 and notify them that you no longer want to share your information.

Do I have the right to see my research information?

You will have access to your genetic scan results on Navigenics Health Compass™ and Microsoft's HealthVault™.

If you agree to share your information, you should sign this form below.

You will be able to print a copy of this form.

Navigenics™ Informed Consent

This is Navigenics, the genetic test service, informed consent that in addition to Scripps informed consent form needs to be re-viewed and understood by you before you agree to proceed with receiving Navigenics' services and being a part of this study.

Description and purpose of the service

The Navigenics Health Compass service is intended to help you learn more about your genes and what they mean for your health. Using a sample of your DNA, our service scans more than 900,000 SNPs (pronounced "snips") across your genome. SNPs, or single nucleotide polymorphisms, are common, one-letter variations in the genetic code. Navigenics compares your results to reputable scientific and medical research and provides you with a personalized genetic risk estimate for specific, common health conditions and traits.

Your genes, along with your environment and lifestyle choices, play a role in the likelihood of developing certain health conditions over your lifetime. Current research in genetics is attempting to answer how DNA variations such as SNPs may be linked to various traits and health conditions. While our service does not diagnose whether you have, or will develop, any specific condition, knowing about genetic risk factors can serve as a tool to help you focus your health-care needs. The information and services provided by Navigenics do not establish a doctor-patient relationship and are not intended as medical advice. As with any health-related decision, we encourage you to work with your physician or other qualified health-care provider to develop the best-personalized health program.

Conditions included in the service

The Navigenics Health Compass service is dynamic; as new genetic and medical research emerges and satisfies our strict scientific standards, Navigenics will add new conditions, traits or information about your ancestry to your Navigenics Health Compass report. You will receive email notifications when such updates are available. Updates may also include new genetic and health information relevant to information you have already received.

The number of health conditions included in the Navigenics Health Compass probably will continue to increase. For more information on conditions that are currently included, please contact Member Services at (866) 522-1585 or +1 (650) 585-7743.

Your results

Based on the results of your whole-genome scan, you will receive your specific results (genotype) at each SNP that Navigenics includes in its risk estimates. The risk estimates will be based on information from scientific research, population studies and general population statistics to calculate the following:

- * Your estimated lifetime risk for each condition currently included within the service and whether you have an above-average, average or below-average risk of developing a specific condition during your lifetime based on your genetic data

- * How your genetic risk for each condition compares to other people in the general population

The Navigenics Health Compass service is not a diagnostic test. Your results will not tell you whether you currently have or will develop any of the conditions included in the service. A result indicating that you have an increased estimated lifetime risk for a specific condition is merely an indication that you may be genetically prone to that condition. In this instance you may wish to consider further independent testing, consult your physician or pursue genetic counseling. If you are concerned that you have, or may develop, a specific condition, additional testing through a qualified health-care provider will be required to confirm whether or not you have the condition, or any signs or symptoms of that condition.

Likewise, a result indicating that you have an average or below-average chance of developing a specific condition during your lifetime is not an indication or guarantee that you do not have or will not develop the condition. Our risk estimates do not account for environmental influences. With common, complex health conditions such as those included in our service, both genetic and environmental factors (such as your behavior and lifestyle) contribute to your overall risk of developing the condition. It is important that you continue to maintain a healthy lifestyle and continue regular medical check-ups with your physician or other qualified health-care provider.

Limitations of the genome-wide scan

The genome-wide scan performed by the testing laboratory that will process your sample is considered greater than 99 percent accurate in identifying SNPs across your genome. (This does not mean that a genome-wide scan is

necessarily an accurate predictor of your risk for any health condition or trait.) However, there remains a small chance of laboratory error, such as your sample being misidentified by the laboratory or an error in the testing process. Accuracy of the genome-wide scan also depends on several factors outside of the laboratory's control, including how carefully you follow the saliva collection instructions provided by Navigenics. Following these instructions carefully helps to ensure that your sample will arrive at the lab in a timely manner in good condition, that your sample can be identified by the unique anonymous ID number assigned by Navigenics, that your sample provides enough DNA, and that it is not mixed with the DNA of others.

Occasionally, the test will not be able to determine your result at a particular SNP even in the absence of any laboratory or sample collection errors. Navigenics will work with the testing laboratory to repeat the analysis, but in some cases, the repeat testing will not provide additional data, in which case the SNP will not be included in your risk estimate.

It is important to realize that although your genome-wide scan will analyze approximately 900,000 SNPs in your DNA, information about clinical significance is not yet available for most of these SNPs. Additional markers from your genome-wide scan will be incorporated into your Navigenics Health Compass report over time as new scientific and medical research emerges. Further, in some cases, SNPs that researchers have found to be associated with a specific health condition are not included on the testing platform used by the laboratory. In some of the cases Navigenics is able to identify a SNP included in the test that closely represents it (called a tag SNP), but in other cases no such substitute is available.

Finally, there are many types of genetic variations that the genome-wide scan does not test for. The genome-wide scan does not test for rare mutations in single genes in which having one or two specific mutations are associated with a very high likelihood of having the disease. For example, the test does not look for genetic mutations for cystic fibrosis (CFTR), or familial breast and ovarian cancer (BRCA1 and BRCA2). If you are interested in testing for these types of conditions, Navigenics recommends you speak with a qualified health-care provider. A Navigenics Genetic Counselor can help you identify how to seek out such testing services, if needed. This service is provided at an additional charge to you.

If we incorporate one or more additional technologies to collect or analyze

genetic data in the future, we may, at our discretion, re-process your DNA sample using any such additional technology and include the results within your updated risk estimate report. However, your purchase of the Navigenics Health Compass service does not automatically include any such additional technology. You may be notified that such additional testing is available for an additional fee.

You may also need to submit a new saliva sample or other biological sample for processing on such additional technology.

Limitations of our risk estimates

The risk information provided by the Navigenics Health Compass service is based on current scientific knowledge. It is important to realize that there are many aspects of the interpretation that may improve over time as the field of genetic research advances.

* Your estimated risk for certain conditions may change over time as new SNP associations, environmental influences, population studies and general population statistics are published in peer-reviewed scientific and medical literature. In some cases, previously published SNP associations used in our risk estimates may be revised or challenged by new studies.

* The availability of genetic information representative among and across different populations will improve over time. Current risk estimates may be limited by the populations studied. For example, most of the published genome-wide association studies have focused predominantly on people of Western European descent. We do not yet have enough information to know if, or to what extent, these results can be accurately applied to people of non-Western European ancestry.

* Our risk estimates do not account for environmental influences. With common, complex health conditions such as those included in our service, both genetic and environmental factors (such as your behavior and lifestyle) contribute to your overall risk of developing the condition.

Possible drawbacks

There are possible drawbacks related to your use of the Navigenics Health Compass service. You may experience a variety of emotions after receiving information about your genetic predisposition to certain conditions. Not everyone has an emotional reaction, but some do. It may be difficult to

know in advance how you may react to the testing process and your results. If you have been diagnosed by a health-care professional with depression, anxiety or another mental health disorder, we recommend that you consult with your health-care provider before proceeding with testing. You may choose not to proceed with testing, or you may choose to do so under the close care and supervision of a qualified health-care provider. If you elect to proceed with testing, you acknowledge that you have either consulted with a qualified health-care provider or you are proceeding knowing the possible drawbacks and consequences of testing.

- * For more information on genetic discrimination,
- * For more information on recent efforts to enact federal legislation,
- * For more information on laws in your state.

Confidentiality

Navigenics will never, without your explicit consent, reveal Your Account Information, Your Genetic Data or Your Phenotype Information to a third party except as required to provide services you have requested, or as required by law.

* "Your Account Information" means the information that you provide to us when creating or updating your Navigenics account, or purchasing our services, that can be used to uniquely identify you, such as your name, telephone number, e-mail address, billing/shipping address or credit card number.

* "Your Genetic Data" means the genotyping results that we generate for you through our services (namely, the set of A's, G's, T's and C's at particular locations in your genome) to the extent such results are sufficient in quantity to uniquely identify you.

* "Your Phenotype Information" means the personal information that you voluntarily provide to us, which may include your gender, your birth date, your ethnicity/ancestry, the geographic regions where you or your ancestors have lived, any diseases or other health conditions that run in your family and personal traits such as height and weight.

For more details on our privacy and security policies and practices, please see our Privacy Policy on our website.

No compensation

You understand that you will not receive any compensation as a result of having your whole genome scanned; Your Genetic Data or Your Phenotype Information analyzed or from any other research performed using Your Genetic Data or Your Phenotype Information.

Alternatives

Your participation with Navigenics is entirely voluntary. The Navigenics Health Compass service is one of many types of genetic testing currently available. If you are interested in additional types of tests not provided by the Navigenics Health Compass service, you can speak with your physician or other qualified health-care provider as to what may or may not be appropriate for you.

Questions? (866) 522-1585 / +1 (650) 585-7743

Navigenics does not provide medical advice, diagnosis or treatment. You should consult your doctor if you have questions regarding any medical condition, before starting any new treatment, and before stopping any treatment that has been prescribed for you. Your use of the site indicates your agreement to be bound by the Terms and Conditions; please review them before using the site. We recommend that you also review our Privacy Policy.

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