

SPECTRUM BIOBANK CONSENT FORM FOR RESEARCH PROGRAM

Spectrum Biobank (Spectrum) is asking you to participate in a research program. The purpose of this consent form is to help you decide if you want to participate in this research program. Please take your time to read the following consent form. You may discuss with your friends, family, and doctor.

This consent form will explain:

1. The purpose of this research program.
2. What will happen if I decide to participate.
3. How your data will be used.
4. How we will protect your data and keep it private.
5. The possible benefits and risks of participation.
6. Costs associated with participating and payment for participation.
7. Other options and how to withdraw if you decide to participate.
8. If you will be contacted by Spectrum or Spectrum Collaborators.
9. If you can be discriminated against based on your genetic data.
10. Who to contact if you have questions.

It is important that you read and understand the information in this consent form before you agree to participate in the research program. If you have questions, please email the Spectrum staff at support@spectrumbiobank.org.

You should not join this research program until all your questions are answered.

Things to know before deciding to take part in this research program:

- Taking part in this research program is completely voluntary. Whether you take part is up to you.
- You can choose not to take part in this research program.
- You can agree to take part and later change your mind at any time for any reason.
- There will be no penalty or loss of benefits to which you are otherwise entitled if you choose not to participate or if you choose to participate and later decide to withdraw.
- If you do not understand something in this form, ask questions.
- Ask all the questions you want before you decide.

1. What is the purpose of this research program?

A biobank is a collection of biological samples, such as blood, saliva, urine or any other material from the human body and associated health information from the donor of the sample(s). Samples stored in a biobank could be used for a variety of research purposes, including but not limited to biological and biomedical or genetic research or research on a particular disease or illness.

One of Spectrum's missions is to make and support meaningful scientific discoveries by increasing diversity in genomics research. Spectrum Biobank aims to:

- Provide quality data, both DNA and survey data from consented participants, to investigators for research.
- Discover genetic factors behind diseases and traits.
- Uncover connections among diseases and traits.
- Learn about human migration and population history through genetics.
- Create new or improved diagnostic tools and therapies to treat diseases or other conditions.

Spectrum is asking you to use your samples for research conducted by Spectrum and Spectrum Collaborators as described in this consent form.

2. What will happen if I decide to participate?

You have already signed up for Spectrum's Personal Genome Service and have provided (or will provide) a saliva sample(s) via a collection kit that was mailed to you as a part of the Personal Genome Service. We are asking you to give us permission to use these saliva sample(s) that you have provided (or will provide) as a part of the Personal Genome Service for the purposes of future research. This research will be conducted by Spectrum and our research collaborators and will be approved by an ethics committee/Institutional Review Board (IRB).

If you agree to participate in the research program, you agree to let Spectrum Biobank and its research collaborators use your Genetic & Self-Reported Information for research purposes. "Genetic & Self-Reported Information" refers to:

- Your genetic data (i.e. DNA genome sequencing data) obtained from your saliva sample(s) via Spectrum's Personal Genome Service that you purchased.
- Information you enter via Spectrum's secure online portal into Spectrum surveys, forms and other features, and any other information you submit after giving consent to participate in this research.
- Your age and ethnicity.

Your Genetic & Self-Reported Information will not include any identifying registration information you provided when you purchased the Personal Genome Service or created an account (such as name, address, email address, user ID, password, or credit card information).

You will not get reports or other information related to the results from research done through the research program. Spectrum and our research collaborators will study samples and information from many people; it may take many more years before we know if the results have any meaning. Research results are not the same as clinical test results. It is possible that the research performed on your samples could detect incidental findings that are unrelated to

the purpose of the research. The researchers conducting the research will have the discretion to determine and disclose to you if the research procedures uncover incidental findings and undertake no duty to inform you of incidental findings. Any additional testing or care decisions on the basis of any incidental findings that researchers may share with you will be decisions between you and your doctor. We are not responsible for any testing or care costs associated with incidental findings. If you do not wish to be notified of incidental findings, please contact us at support@spectrumbiobank.org.

Participation in the research program consists of (1) entering information about yourself into Spectrum features on Spectrum's secure online portal, and (2) allowing Spectrum and its research collaborators to use your Genetic & Self-Reported Information for research.

The Spectrum online portal's features include surveys, individual questions, and other features where you will be asked to enter information about yourself and your relatives, such as "What is the color of your eyes?" or "Does your family have a history of heart disease". If you do not feel comfortable providing a piece of information, you may choose not to answer that question. You may choose to take all, some, or none of the surveys, forms or other features.

New surveys, forms and other features may be added to the Spectrum portal on a continuing basis. If new surveys, forms, or other features are added, we may ask you to complete these activities. We may also notify you of your potential eligibility to participate in a separate research study if your Genetic & Self-Reported Information matches the area of interest of a research collaborator. We will let you know by using routine communication methods, such as email, push notifications or announcements when you sign in to your account, and only if you provide consent to this communication as outlined in our Privacy Policy and Terms of Service.

Your participation in the Spectrum research program is completely voluntary. You can choose to not take part or to withdraw your participation at any time and for any reason without any penalty or loss of benefits to which you are otherwise entitled.

3. How will my data be used?

Your Genetic & Self-Reported Information may be used to discover links between genetic markers, non-genetic markers, traits, diseases, behaviors and other characteristics, to study human migrations and population history, or to assess how people respond to personal genetic information. Discoveries made as a result of this research could be used to help us understand the basic causes of disease, develop drugs or other treatments and/or preventive measures, or predict a person's risk of disease.

The topics to be studied span a wide range of traits and conditions, from common to rare. The topics include simple traits such as eye color or height, or diseases such as cardiovascular disease, asthma, etc. Some of these studies may be sponsored by or conducted on behalf of Spectrum or by our research collaborators, such as non-profit foundations, academic institutions or pharmaceutical companies.

Your data may be used for future studies conducted by or on behalf of Spectrum or its third-party collaborators. These studies may cover potentially sensitive topics such as sexual orientation, illicit drug use or other illegal behavior, or HIV/AIDS status. When Spectrum conducts studies on such sensitive topics, you will be provided additional information to help you decide whether you want to participate in research on these topics.

We will protect the privacy of participants in this research program.

Both your sample(s) and Genetic & Self-Reported Information may be accessible to the following entities:

- The sponsor of this research program (Spectrum) and their agents
- The sponsor of any future research studies and their agents (Spectrum or third-party research collaborators)
- People who work for or with the sponsor of this research program and future research studies
- Regulatory authorities including the US Food and Drug Administration (FDA) or foreign regulatory authorities
- Monitors, auditors, the IRB and research oversight staff
- The U.S. Dept. of Health and Human Services

Data from this study, including information about you could be sent to the National Institute of Mental Health Data Archive (NDA), to other data repositories at the National Institutes of Health (NIH) or may be shared with other repositories that allow researchers to collect and share de-identified (coded) information with each other.

There are risks associated with sharing your data with a federal repository. There is a possibility that someone who is not authorized could get access to your data, including genetic information that is unique to you. Because the data is in electronic format, it could be accessed due to a computer security breach. It could be released to members of the public, insurers, employers, or law enforcement agencies. However, we and the agencies with which we share data have strict protections in place, as discussed below, to reduce the chances that this will happen. If you withdraw from the research the data that has already been distributed cannot be removed.

4. How do you keep my data protected and private?

The collection and the storage of saliva samples and Genetic & Self-Reported Information, as well as the preparation for future use will be done by Spectrum staff, third party collaborators, and our sequencing partner labs. All samples will only be labeled with a participant ID number. Your sample(s) will be stored at our secure biobank after sequencing at our biobank facility in the United States as stated in our Terms of Service.

Spectrum will use a range of physical, technical, and administrative procedures to protect

the privacy of your personal information as much as possible, including your Genetic & Self-Reported Information.

If you agree to participate in the research program, Spectrum and our research collaborators can use your data for research purposes described in this consent form. This may include research that will be published in scientific journals, or that is sponsored by the National Institutes of Health and certain other organizations. However, the data that will be used will be deidentified and will not contain your personal identifiable information. There is an information management system that will link your participant ID number to your Genetic & Self-Reported Information and identifiable information. Just as Spectrum aims to minimize the chances of a privacy breach while conducting its business, Spectrum researchers aim to minimize the chances of a privacy breach while conducting research. Here are the main ways we do that:

- The Spectrum researchers who conduct the statistical analyses involving participant data do not have access to your Personal Genome Service Registration Information (name, address, email address, user ID, password, and credit card).
- Spectrum researchers who have access to your name and contact information, only have access to very limited genetic and other personal information.
- To minimize the chance that an external person can determine that you are part of a research program, Spectrum researchers and Spectrum collaborators will either:
 - publish only data aggregated across multiple participants such that any one participant cannot be identified, or
 - publish only very limited, non-identifying information of a single participant.
- All Spectrum employees are trained on how to work with human research participants. In addition, all Spectrum researchers are trained on how to conduct research responsibly.
- Genetic & Self-Reported Information and other related data is kept for as long as the research program is active and will be deleted within 30 days of your withdrawal from or termination of the Spectrum research program. All data obtained, including from samples and your Genetic & Self-Reported Information, is required to be stored on an encrypted server and will only be accessed by researchers that have been granted permission.

To further protect the confidentiality of your data, we have obtained a Certificate of Confidentiality from the Department of Health and Human Services (DHHS). This means the investigators cannot be forced by the police or others (for example by court subpoena) to release research information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings.

You should also know that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others. The Certificate of Confidentiality will not be used to prevent disclosure to local authorities of child abuse and neglect, or intent to harm yourself or others.

5. What are the possible benefits and risks of participation?

Possible Benefits:

There are no direct benefits to you for participating in this research program. One of Spectrum's missions is to make meaningful scientific contributions. Information gained from the samples and information you provide during the research program may help improve the care for others as scientific knowledge increases and/or new drugs or tests are developed.

There may be additional benefits to participation that are currently unforeseeable.

Possible Risks:

There are some potential non-physical risks and discomforts to participating in the Spectrum research program, as described below.

- Some survey questions or data comparisons may make you uncomfortable.
- Your sample(s), genetic sequencing data, survey responses, and/or personally identifying information may be stolen in the event of a security breach. In the event of such a breach, if your data are associated with your identity, they may be made public or released to insurance companies, which could have a negative effect on your ability to obtain insurance coverage. In addition, if you or a family member has genetic data linked to your name or your family member's name in a public database, someone who has access to your genetic data provided by Spectrum might be able to link that data to your name or your family member's name through the publicly available genetic data. Although Spectrum cannot provide a 100% guarantee that your data will be safe, Spectrum has strong policies and procedures in place to minimize the possibility of a breach.
- Collaborators will sign a Data User Agreement to gain access to your data. The data will be transferred in an encrypted manner. If Spectrum researchers publish or present results from this research program, they may include your Genetic & Self-Reported Information but only as part of an aggregate summary across enough people to minimize the chance that your personal information will be exposed. Identification of your individual-level data from those summaries would be extremely difficult, but it is possible that a third party that has obtained some of your genetic data could compare that partial data to the published results and infer some of your other personal information.
- There is a risk that taking part in genetic research may influence insurance companies and/or employers. Although, there are laws against the misuse of genetic information, they may not give full protection (see Section 9 below).
- As with any online service, if you disclose your account password to others, they may be able to access your account and your Genetic & Self-Reported Information.
- There may be additional risks to participation that are currently unforeseeable.

None of the surveys or other procedures used by the researchers in the Spectrum study are invasive or experimental.

6. What does it cost to participate? Will I be paid for participating?

You will not be charged for participation in the research program. You will not receive any additional compensation for participating in the research program.

Based on the results obtained from this research program, Spectrum or its research collaborators may develop intellectual property, including but not limited to patents, copyrights and trademarks. Spectrum and its research collaborators may commercialize products or services, directly or indirectly from this research. In such cases, you will not be eligible to benefit financially from this, nor would you obtain legal rights in the future as a result of your participation in this research. There are no plans to compensate you for any patents or discoveries that may result from your participation in this research.

7. What are my options? Can I withdraw from the research program?

Taking part in this research program is completely voluntary. Your alternative is not to participate in the Spectrum research program. If you do not consent to participate, there will be no penalty or loss of benefits to which you are otherwise entitled.

At any time, you may choose to change your consent status to either take part in the Spectrum research program or to withdraw your participation in the program. Your consent status is located in the Spectrum Biobank "Profile" page. This page also allows you to withdraw your consent at any time. You will have access to your own Genetic & Self-Reported Information as long as you are a participant of Spectrum's research program. If you withdraw your participation or, after the research program is terminated, you will no longer have access to this information. If you withdraw your participation, you can decide whether some or all of your Genetic & Self-Reported Information continues to be used in the Spectrum research program. If you decide to withdraw all or some of your Genetic & Self-Reported Information, Spectrum will prevent that information from being used in new Spectrum Research initiated after 30 days from receipt of your request (it may take up to 30 days to withdraw your information after you withdraw your consent). Any research on your data that has been performed or published prior to this date will not be reversed, undone, or withdrawn.

In addition, your participation in the Spectrum research program may be terminated without your consent for any reason, such as the termination of the Spectrum research program.

8. Will I be contacted by Spectrum or Spectrum Research Collaborators?

Spectrum may potentially contact you occasionally to request additional information such as survey questions or to provide additional saliva samples to perform additional DNA sequencing. You have no obligation to respond to any requests from us, and in the case that

you do not respond, your data and samples may continue to be used for purposes that are outlined in this consent form.

We will also contact you if Spectrum or a research collaborator wishes to use your data that is beyond the scope of what is described in this consent form.

Based on your Genetic & Self-Reported Information, Spectrum may contact you with information relating to specific research studies conducted by our research collaborators that you may be eligible for. Spectrum will contact you to see whether you are interested in learning more about these research studies and your potential eligibility to participate. If you are interested in these additional research opportunities, Spectrum will put you directly in contact with its research collaborators to discuss these opportunities.

9. Can I be discriminated against based on my genetic data?

A 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. See - <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-genetic-information-nondiscrimination-act/index.html#fn2>
- 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 and employers with 15 or more employees must follow this law.

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

10. Who do I contact if I have questions?

If you have general questions about the Spectrum research program, please contact: support@spectrumbiobank.org.

If you have any questions or concerns about the Spectrum research program or if you have a question about your rights as a research participant, or to offer input, please contact the following:

- Spectrum Support
- Email: support@spectrumbiobank.org

If you have any questions or concerns about the research that you do not wish to discuss with Spectrum, contact the independent, impartial research review board for this study.

Ethical and Independent Review Services (E&I) Institutional Review Board (IRB)

- 800-472-3241
- Email: subject@eandireview.com

Reference E&I Study 21120

By checking the appropriate box below, you agree to participate in the Spectrum research program and to let Spectrum Biobank and its research collaborators use your Genetic & Self-Reported Information for research purposes as described in this consent form.

[[Hyperlink will be added to print a copy for their files](#)]

[[Checkboxes will be available electronically on our website](#)]