

RESEARCH PARTICIPANT CONSENT INFORMATION SHEET

TITLE: Helix DNA Discovery Project

PROTOCOL NO.: 0002-0001
WIRB® Protocol #20170748

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**STUDY-RELATED
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KEY DETAILS

You have the opportunity to take part in “Helix DNA Discovery Project.” To keep things simple, we’ll refer to it as “the Project” here. The Project consists of a data repository and the studies that use it. The repository holds some information about Helix customers who volunteer to take part. The purpose of the Project is to support the exploration of the human genome. That support could lead to major breakthroughs in science and medicine.

Here are some key details you should know if you choose to take part:

- Helix will store your “Genetic Information” in the repository. Helix will also store your “Self-Reported Information.” These terms are defined below.
- Helix will carry out studies using the repository. Qualified researchers with studies that Helix approves may also do so.
- The Project will use only your Genetic and Self-Reported Information. Your information will not be attached to your name or contact details. In other words, it will be de-identified.
- There is no cost to take part. You also likely will not be paid to do so.
- Taking part involves minimal risks. One of these is that the privacy of your information may be harmed. This could happen during a security breach.
- You likely will not receive any direct benefits from the Project.
- You or your family may receive indirect benefits from the Project. This is because of breakthroughs that may come from studies that use the repository.
- You can still use the Helix Platform if you don’t take part. Taking part is voluntary.

If you have any questions, concerns, or complaints about the Project, you can contact Helix Customer Care at support@helix.com or 1-844-211-2070. You can also contact the group that approved the Project, WIRB, at help@wirb.com or 1-800-562-4789.

FULL DETAILS

Key terms

- **Account Information:** Any sensitive details about you (like your password) or details that can identify you with ease. These include your name, email, and shipping address.
- **De-identified:** Data that are not attached to your Account Information. De-identification is a method that makes it hard (but not impossible) to connect data back to its source. Any of your information used for the Project will be de-identified.
- **Genetic Information:** Your DNA data. These data are the same as the data you can use for Helix Store products. These data come from a file you upload and/or a saliva sample that you send us.
- **IRBs:** Institutional Review Boards. These groups review and approve research projects. They do so to make sure that those projects are ethical.
- **Re-contact:** Getting a notification (like an email) that you might be able to take part in a certain study that's part of the Project.
- **The Project:** The Helix DNA Discovery Project, described here. If you wish, you can choose to take part.
- **Self-Reported Information:** Other details about you that aren't a part of your DNA. It may include details about your health, family tree, lifestyle, and behaviors. We collect these details for the Project through surveys, tools, and other sources.

Purpose of the Project

Our mission is to empower every person to improve their life through DNA. That is what led us to create our Platform. Helix also believes in a world where every person is able to help all of humanity lead better lives. That is what led us to create the Project.

The Project will involve a data repository. The repository will hold digital samples for future research. These samples will include the Genetic and Self-Reported Information of people who take part. The Project could improve our knowledge of genetics. It could lead to breakthroughs in knowledge about whole populations. It could also teach us more about medicine, history, and many other fields. The Project could look at topics like these:

- How genetic changes do (or don't) affect certain health conditions
- How lifestyle and environment do (or don't) affect the genes behind certain health conditions
- How genetics affects health differently across racial or ethnic groups
- How humans of the past moved out of Africa and settled around the globe

The Project will look at these topics through research studies. These studies will look at data from the Project's repository. Some of them may be run by Helix. Some of them could be run by researchers outside of Helix. In either case, studies will need to be approved by Helix to use data from the Project. In many cases, they will also need to be approved by an IRB.

As a Helix customer, you are in a unique position to take part in the Project. To do so, you would share your Genetic Information for the Project. You can also share some of your Self-Reported Information. You can do so by sharing Self-Reported Information that you have used for the Helix Platform. You can also do so by filling out the Project's surveys.

You can also choose not to take part at all. Taking part in the Project is voluntary. Your choice will have no effect on your use of the Helix Platform. You can also change your mind at any time.

Helix may re-contact you on behalf of some studies that are part of the Project. You may be re-contacted to give more details about yourself. We would collect these details through surveys, tools, or other sources. Some studies may want these details from you to compare against people who have a certain health condition. They may want those details to compare against people who are healthy. You may not know if you are being compared to sick or healthy people. You may also be re-contacted to take part in other research studies that are not part of the Project. You have the option to opt out of being re-contacted. We will also work to protect your privacy if we re-contact you.

Information you would share with the Project

To help you access the Helix Platform, Helix asks you for some of your information. This information has three types. The first is your Account Information. The second is your Genetic Information. The third is your Self-Reported Information. If you choose to take part, only the last two types will be part of the Project.

The Project would use your Genetic Information for studies. You will not be asked to send us a saliva sample just for the Project. Helix will not need to sequence a sample that you've sent again. If you choose to take part in the Project, you must share your Genetic Information.

The Project would use your Self-Reported Information for studies. Helix may also seek other details about you through surveys. These details would focus on areas beyond those that the Helix Platform deals with. If you choose to take part in the Project, you can choose whether to share your Self-Reported Information. Doing so is helpful, but not required.

Any of your information that is shared for the Project will be de-identified.

Requirements for participation

In order to participate in the Project, you must

- Be at least 18 years old,
- Have Genetic Information stored by Helix,
- Understand English, and
- Consent to take part based on what is described here.

If you do not meet these requirements, you will not be able to take part in the Project. If you have used a Helix Store product before, you have Genetic Information stored by Helix.

As a Helix customer, you do not need to do anything more to take part. During the course of the Project, you can choose to share more details about yourself. We may also send you some surveys to do so. Some of these surveys may only be sent to you if you have allowed us to re-contact you.

Procedures

As described above, Helix will store your information for the Project. When we do, we will follow our standards for keeping data private and secure. Your information will be de-identified.

The Project data may be used in two ways. The first way is by Helix researchers for our research studies. The second way is by researchers outside of Helix. They may approach Helix with research studies that could use the Project data. Helix will review these studies to make sure they meet our standards for ethics and science. Helix will also make sure that they meet our research, privacy, and security policies. Approved studies will be able to use the Project data.

Many of the studies that use these data will also need to be approved by an IRB. Even so, studies that just use data from the Project repository may not need to do so.

Some breakthroughs based on the Project data may be published or shared outside of Helix. If they are, they will not be able to share your information alone. They will only be able to share pooled data.

This Project is seeking a Certificate of Confidentiality (CoC) from the National Institutes of Health. This CoC would protect the information you allow the Project to use from being disclosed for most legal proceedings. For instance, your data could not be used as evidence, even if there is a court subpoena. While you are taking part in the Project, Helix would not share your identifiable information outside the Project without your consent.

The CoC could not protect your information from being shared if Helix is required by law to report something (like child abuse). Also, you could still consent to share your information beyond the Project (like with DNA Products or other research).

You can always choose to use or share your own data outside of the Project.

Ending participation

You will continue to take part in the Project until you choose to stop. You can choose to stop taking part at any time. Choosing to stop taking part will involve no penalty. Refusal to participate will involve no penalty. You can do so through your Account Settings. After you choose to stop taking part, we will remove your information from the Project. Any research study that starts after that point will not be able to use your information. Your information will still be used in studies that started before you stopped taking part. These studies will not be able to stop using the data.

You can also stop taking part if you close your Helix account. At that point, you will have the option to donate your information to the Project. If you do so, you would not be able to change your mind later on. If you choose not to do so, we will remove your information from the Project.

Choosing to stop taking part will not hurt you in any way. You will still be able to use the Helix Platform. You will also still be able to use products that use the Helix Platform.

You can change your mind about stopping at any time. To start taking part again, you can change your Account Settings. You may need to give your consent again to take part.

While not likely, there is a small chance that Helix may stop the Project. If so, your participation will end when the Project does.

Costs, payment, and funding

You will not need to pay to take part in the Project.

You likely will not be paid for taking part in the Project. It's not likely that any study that's part of the Project will pay you to take part. There is a chance that Helix could profit from breakthroughs made through the Project. Some researchers could also profit from those breakthroughs. In either case, you will not receive a portion of those profits. This includes any rights to intellectual property that comes from their breakthroughs.

The main funding for the Project will come from Helix. Helix may charge researchers for access to the Project's data.

Risks, benefits, and alternatives

Taking part in the Project involves minimal risk. This means that it will not be more risky than what you could expect in your daily life. You should still weigh the risks and benefits of taking part.

The main risks of taking part come from a security event. In such an event, someone could access and use your information without your consent. Since your information is de-identified, there is a low risk that it could be connected to you. But because your DNA is unique to you, it could still happen.

You likely will not receive any direct benefits from the Project. This is because the Project will not lead to knowledge that applies just to you. But, your participation may lead to crucial breakthroughs in science and medicine. These breakthroughs could benefit people all over the world. They may even affect you. You may see this as an indirect benefit of the Project.

The alternative to taking part in the Project is choosing not to take part. You can make this choice at any time. To do so, go to your Account Settings.

Data security

When we store your information, we will follow our standards for keeping data private and secure. We do so to reduce the risk that someone could connect your information back to you.

We de-identify your information. The Project will not include any of your Account Information. It will also not include any other data that could identify you with ease.

The Project uses several data safeguards. These include encrypting sensitive data. They also include applying strict authentication requirements for any access to the data. From time to time, Helix also tests how secure our systems are. Doing so helps us find points of weakness before they become problems.

Whom to contact with questions

You may have questions, concerns, or complaint about the Project or your participation. You may also feel you have had an issue related to the Project. If you do, you can contact Helix Customer Care:

Email: support@helix.com

Phone: 1-844-211-2070

You may have questions, concerns, or complaints that you do not want to discuss with Helix. If so, you can contact the IRB that approved the Project. IRBs work to keep participants like you from being exposed to too many risks. The Project was approved by Western IRB (WIRB). You can contact WIRB:

Western Institutional Review Board® (WIRB®)
1019 39th Avenue SE Suite 120
Puyallup, Washington 98374-2115
Telephone: 1-800-562-4789 or 360-252-2500
E-mail: Help@wirb.com

WIRB is a group of people who perform independent review of research.

WIRB will not be able to answer some study-specific questions, such as questions about how to access your Helix account. However, you may contact WIRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.