IRB APPROVED
AS MODIFIED
Mar 01, 2022

Updated February 17, 2022

PROJECT
SINGULAR

RESEARCH SUBJECT CONSENT FORM (FOR ADULT SELF-ENROLLMENT)

TITLE:	Project Singular
PROTOCOL NO:	None IRB Protocol #20211655
SPONSOR:	Additional Ventures Foundation
INVESTIGATOR:	Kirstie E Keller, BS, PhD 314 Lytton Ave Palo Alto, CA 94301 United States
STUDY-RELATED PHONE NUMBER(S):	(650) 561-6750 (24 hours; messages returned within 48 hours) contact@projectsingular.org

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PROJECT SINGULAR
RESEARCH CONSENT FORM

Affected Adults and Adults Who Are Immediate Family Members of Affected Individuals

Title:	Project Singular
Principal Investigator:	Kirstie E Keller, PhD
Study Staff:	Diane Pickles and Taylor MacLean
Contact:	contact@projectsingular.org

Please carefully read the consent form below. If you have questions about Project Singular or this form, please ask us. You can call us at (650) 561-6750 or email us at contact@projectsingular.org.

We encourage you to download a PDF version of the consent form and read it carefully.

Available on each page with progress bar*

Updated February 17, 2022

RESEARCH CONSENT SUMMARY

In this consent form, "you" always refers to the person participating in the study. If you are a legally authorized representative/guardian of an adult unable to consent for themselves, please remember that "you" refers to the study participant.

We are asking you to take part in a research study. We are asking for one of two reasons:
(1) You have a single ventricle heart defect; or
(2) You are a close family member (birth child, sibling, or parent) of someone with a single ventricle heart defect.

Taking part in the study is all your choice. You can choose if you want to take part or not, and you can quit the study at any time.

The goal of this study is to learn more about people with single ventricle heart disease. To do this, we need to collect genetic and health information from them. We also need to collect this information from their close family, including birth parents, siblings, and children.

We will ask you to answer questions about your health. If you have a single ventricle heart defect, we will ask you to sign a medical record release form. We will also ask you to send us a sample of your saliva (spit), which we will use for genetic testing (studying your genes).

Your privacy is very important to us. We will store your information securely. Researchers can use the information to study single ventricle heart defects. They can also use it to study many other diseases.

Researchers around the world can use the information, but the information will be "de-identified." This means we will take out details such as your name and birth date. This makes it hard to identify you from the information. We will protect your privacy the best we can, but there is a small risk someone may see information that identifies you.

The research may lead to ways to prevent and treat single ventricle heart disease and other diseases.

Full Research Consent Form

Introduction

Project Singular is a research study on single ventricle heart disease. We want to learn why some children are born with single ventricle heart defects. To do this, we need to collect genetic and health information from these people and their close family members, which includes birth parents, siblings, and children.

Project Singular is paid for by Additional Ventures, a nonprofit foundation. The foundation's goal is to learn about single ventricle heart disease to develop better treatments and improve care and outcomes.

We are asking you to take part in Project Singular for one of two reasons:
(1) You have a single ventricle heart defect; or

(2) You are a close family member (birth parent, sibling, or child) of someone with a single ventricle heart defect.

This form will help you choose if you want to take part in the study. It will tell you what you will need to do if you choose to participate, as well as the risks and benefits of taking part.

Let us know if you have any questions. If you do not understand something on this form, ask us. You can call us at (650) 561-6750 or you can email us at contact@projectsingular.org.

You may talk about Project Singular with anyone. You may choose to take part in the study or not. It is important to know that it is your choice. You should know what your choice means for you. Do not sign this form until you are sure you want to take part in the study.

What is the goal of Project Singular?

Right now, we don't know how and why some children are born with single ventricle heart defects. We also don't know why some people with this disease end up with other health problems.

Project Singular is a research project with the goal of collecting genetic and health information from people with different kinds of single ventricle heart defects and their close family. This information will help us learn what may cause the defects and possibly other related health problems.

Those who take part in Project Singular will need to send us a few things. We will need a saliva (spit) sample. If you have a single ventricle heart defect, we will ask for information from your medical records. We will ask you to fill out a survey that will ask health questions. We will securely store all this information, and saliva samples will be kept in a secure gene bank. The samples will be processed at the Broad Institute of MIT and Harvard, which is a nonprofit biomedical research institute.

We will share this information with researchers around the world, but the information will be "de-identified." This means we will take out details like name and birth date, which makes it hard to link information back to a person.

Who is paying for this study?

Additional Ventures, a nonprofit foundation, is paying for Project Singular. Additional Ventures does not make money (a profit) for its work on Project Singular. The lead researcher for Project Singular works for Additional Ventures.

If you have questions or concerns, ask the study staff. You can call us at (650) 561-6750 or you can email us at contact@projectsingular.org.

How long will Project Singular last?

Project Singular does not have an end date. Our goal is for at least 5,000 people with single ventricle heart disease and many of their family members to take part in the study, and we don't know how long that will take. Researchers will be able to access information from the study for a long time. We're not sure how long yet.

You can quit the study at any time. Please see the section "Can I quit Project Singular?" to learn more.

Who can take part in Project Singular?

Any person diagnosed with a single ventricle heart defect can take part as long as they live in the United States or Canada.

A close family member of a person with a single ventricle heart defect can take part as long as they live in the United States or Canada. This includes birth mother, father, brother, sister, son, or daughter.

Any child that is a minor must have adult consent to take part in the study. The child's birth parent or legally authorized representative (such as a guardian) must give consent.

Any adults with a single ventricle heart defect who are not able to give consent themselves must have consent from a legally authorized representative/guardian to join the study.

What will I need to do if I take part in Project Singular?

If you choose to participate in the study, you will need to set up a secure account on www.projectsingular.org. You will need to fill out a survey that asks about your age, race, and gender. If you have a single ventricle heart defect, we will also ask about your diagnosis and other health information.

You will need to send us a sample of your spit. We will mail you a kit to use to collect the sample and send back to us, free of charge.

If you have a single ventricle heart defect, we will ask you to send us contact information for your doctor and sign a medical release form. This will allow your doctor to send us your medical records and will give us the ability to collect and store your medical records now and in the future. That way, we can update your health information, which will be useful for researchers doing studies.

We can contact your doctor to ask for the medical records or you can ask your doctor for the records and send them to us via fax or through our secure website.

We may call or email you if we need more information or if your doctor needs you to sign more forms. We may send you reminders to complete surveys or we may tell you if there has been a major change to the study. We also may contact you in the future and ask if you want to take part in other research studies.

What will you do with my saliva (spit) sample?

When we receive your saliva (spit) sample, we will do what is called "whole genome sequencing." This will give us a detailed look at your genes.

Genes are parts of your DNA. Genes have instructions for how cells in your body should work and grow. We will study your DNA through "gene sequencing", a way to read DNA. Gene sequencing lets us look for information in genes that may change the way your cells work. These changes may lead to different diseases. The goal of genetic research is to learn more about these diseases. We also want to find better ways to prevent, diagnose, and treat diseases.

Sometimes researchers will only study a small part of DNA the part they know can cause a disease. We don't know much about single ventricle heart disease, so we will look at all or most of your genes. This is called whole genome sequencing. This way, researchers can try to find which genes may play a role in single ventricle heart disease.

What will you do with my information?

We will carefully store your information using a secure online system. We will control access to the system, which means only doctors and researchers can view the information. The information will also be "de-identified." This means we will take out details such as your name and birth date, which makes it hard to identify you from the information.

How long will you keep my information?

Research is an ongoing process. We may want to use your information for future research. For this reason, we can't set an exact time limit on how long we will store your information.

Who will have access to my information? What will they do with it?

We may share your information with other researchers, but the information will be "de-identified." This means the researchers won't be able to identify you. This also means they can't ask you if they can use your information in future studies, so you won't get to choose if your information is used in these studies. These future research studies may be on diseases other than single ventricle heart disease. Some researchers may study ways to measure health or how health might change with certain treatments or care. Some of these studies may be with for-profit companies for commercial uses so the companies can try to develop new treatments.

What choices will I have for sharing my information?

If you take part in Project Singular, we will share your information with researchers. The information will

be de-identified, and researchers who want to access the information will be approved by a scientific review committee. You won't get to choose if you want to share your information with specific researchers, and you can't choose whether or not to take part in specific studies.

We may also need to share your information for business and legal reasons. We may share your health information with:

- A limited number of Project Singular staff and contractors who need the information to do their jobs.
- Federal regulatory or oversight authorities. [For example, the U.S. Department of Health & Human Services and the U.S. Food and Drug Administration (FDA)].
- An Institutional Review Board (IRB). This board makes sure we comply with your consent. The board also makes sure we do the study in the ways we said we would.

If you do not want us to share your information in these ways, you may quit the study at any time. To do this, you must tell us in writing. You can email us at contact@projectsingular.org.

Will you contact me if it looks like I might be eligible for a clinical trial?

No. We do not plan to contact you about clinical trials.

Will I benefit from taking part in Project Singular?

You are not likely to directly benefit from taking part in Project Singular. However, the information we collect from you may help research. The research may lead to better ways to prevent and treat single ventricle heart disease in the future.

How much does it cost to take part in Project Singular?

There is no cost to take part in Project Singular.

Will I be paid for taking part in Project Singular?

No. You will not be paid for taking part in Project Singular. You will not be paid if research using your information results in new treatments, tests, or commercial products.

Will I find out the results of the research?

You will most likely not get back any results specific to you or your family member with single ventricle heart disease. Also, your doctor will not get your results. In addition, you will not get any data files such as your genetic sequence.

Right now, we don't know which parts of DNA cause single ventricle heart defects. That is why we're doing this study. This means we don't know which parts of your (or your family member's) DNA may cause single ventricle heart disease, so we cannot give you any information about your (or your family

member's) genetic cause. In the future, we may make those discoveries and if we do, we may contact you. We may ask if you want information about your genetics specific to single ventricle heart disease, but we don't know if or when this might be possible.

Project Singular may provide a summary of research results. We may email you the summary or put it on our website. Single ventricle heart disease likely comes from many causes, which means not all results will apply to all patients - not even major discoveries. We may publish results, but the results may not be specific to your (or your family member's) single ventricle heart defect.

If we provide a summary of research results, we can't answer questions about who specifically has which genetic cause due to patient privacy.

Will I find out any other genetic results of the research?

We want to understand the causes of single ventricle heart disease. To do this, we will look at every piece of your DNA. When we do, we may find changes in your DNA that may be linked to some other disease that is **not** single ventricle heart disease. These results are called "secondary findings." This type of result is not common, and most people in this study will not have a result like this.

You have a choice as to whether or not you would want to know about a result like this. At the end of this consent form, we will ask if you would want to know about this kind of result if we find one. If you tell us you would want to know and we find one of these results, we will contact you and connect you with a genetic counselor in your state.

The counselor can do a second genetic test to confirm the finding, free of charge. If the finding is confirmed, the genetic counselor will work with you. They will help you understand what the finding means and what the next steps are.

Currently, these secondary findings are not able to be returned to participants who live in Canada because of local and country guidelines. If guidelines change in the future and make it possible to return secondary results to Canadian participants, these results will be returned.

How will information about me be kept private?

Your privacy is very important to us, and we will take many steps to protect it. We will remove details from your information that could identify you. For example, we will take out your name and birth date. We will replace these details with a unique code number before we share your information with researchers. We will also "encrypt" (scramble) your information when we store it, which makes it hard for people to see the information without permission.

What are the risks of taking part in Project Singular?

There is a risk that someone may see your information without permission and a chance your information could be released by accident. This could identify you or your family. We think the chance of this happening is very small, but we can't ensure absolute privacy.

You may learn that you have a genetic risk for a disease other than single ventricle heart disease. Although it's not likely, it is possible, and this could be upsetting to you. Your genetic information is unique to you, but you do share some genes with your parents, siblings, children, and other blood relatives. This means your genetic results could tell you something about your family, which might upset you or your family. Before you join the study, you may want to talk with your family and ask them if and how they want you to share any secondary findings with them.

Do I have to take part in Project Singular?

No. Taking part in Project Singular is by choice. You can choose to take part or not and you can change your mind and quit at any time. Your choice will not affect your health care. There is no penalty or loss of benefits to which you are otherwise entitled for choosing not to take part in the study.

Can I quit Project Singular?

Yes. You can quit Project Singular at any time for any reason. If you quit, we will no longer share your information with researchers for future research studies, but we can't take back any of your information that has already been shared.

To quit the study, you must tell us in writing. Contact the study staff at contact@projectsingular.org. If you choose to quit, it will not affect your health care now or in the future. There is no penalty for quitting, and you will not lose any benefits to which you are otherwise entitled if you quit.

You can quit the study and then choose to rejoin Project Singular in the future. However, you will have to start over with the registration process.

Can my information be removed from this research without my approval?

The lead researcher may decide your information is no longer needed for the research. In this case, we will remove your information, and we will safely destroy any of your information that is not needed.

What if I have questions, concerns, or complaints about Project Singular?

If you have questions, concerns, or complaints, let us know. If you think this research has hurt you or made you sick, contact us right away. You can call us at (650) 561-6750 (24 hour phone line with messages returned within two business days) or you can email us at contact@projectsingular.org.

An Institutional Review Board ("IRB") is overseeing this research. An IRB is a group of people who do independent reviews of research studies. You may reach them at (855) 818-2289 or researchquestions@wcgirb.com. Contact them if:

- You have questions, concerns, or complaints and don't get answers from the research team.
- You can't reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.

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Statement of Consent:

This is what I agree to:

- You may ask my doctor for my medical records. You may also ask hospitals and other places I have received treatment from in the past. You may ask where I am getting treatment now.
- You may do genetic tests on my saliva (spit) sample that I will send you. You may store the sample until the tests are complete, and you may link the results to my health information.
- You may use my de-identified medical records and genetic test results for future research, including for studies not yet designed. These studies may be on diseases other than single ventricle heart disease and may be for commercial uses.
- You may store my de-identified medical records and genetic test results in a system with controlled access.
- You may contact me in the future about this research study. You may contact me to ask me to sign more forms that may be needed to let my hospital(s) share my medical records.

My full name below means:

- I have had enough time to read this form.
- I have thought about the information.
- All my questions were answered.
- I agree to take part in this study.
- I know that I can choose to take part in the study or not.
- I know that if I choose not to join this study, it will not affect my health care.
- I know that I can quit the study at any time, for any reason.
- I know that a copy of the signed consent form will be on the project dashboard webpage at www.projectsingular.org.
- By taking part in this study, I agree that my information may be used for different types of research.

Your signature indicates that you agree to take part in this research.

- Any person not able to provide a signature for consent must still agree to take part in Project Singular if they are able. A legally authorized representative/guardian will explain the study to the person, and then ask if they agree to take part. This is called assent. Some people may not be able to understand. If the legally authorized representative/guardian determines this is the case, the person does not have to assent.
- All people who assent must sign a form if they can. Some people may not be able to sign their name. If the legally authorized representative/guardian determines this is the case, the person does not have to sign.

Your Name (Study Participant):

_____
First Name

_____
Last Name

Your Date of Birth:

_____
MM / DD / YYYY

I understand that when my genes are studied, changes in the genes may be found. These changes may be known to cause some diseases other than single ventricle heart disease. I understand that these results, called secondary findings, are very rare.

If a secondary finding is found in my genes:

☐ I want to know.

☐ I do not want to know.

I understand that if you contact me about a secondary finding, you will connect me with a genetic counselor who will arrange a second genetic test to confirm the result. If it is confirmed, a genetic counselor will tell me what the finding might mean. They will then help me choose what next steps I might want to take.

I understand that these secondary findings are not currently able to be returned to participants who live in Canada because of local and country guidelines. I understand that if guidelines change in the future and make it possible to return results to Canadian participants, these secondary results will be returned.

Your Signature (Study Participant):

_____Date _____
Signature of adult participant capable of consent

For Participants in need of a Legally Authorized Representative to Provide Consent:

_____Date _____
Signature of Legally Authorized Representative

- ❑ I have explained the study to the extent compatible with the participant's capability, and the participant has agreed to be in the study (given assent).

OR

- ❑ The participant is not able to assent because the capability of the participant is so limited that the participant cannot reasonably be consulted.

_____
Signature of legally authorized representative/guardian who has obtained assent from study participant

_____
Date

AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

What information may be used and given to others?
Researchers will be given your information. For example:

- Your past and present medical records.
- Records of you taking part in research.
- Records of phone calls with you about this study.
- Records of visits with you for this study.

Who may use and give out your information?
The study staff may give your information to researchers.

Who else might access your information?
The sponsor of this research may access your information. "Sponsor" is any person or company that is:

- Working for or with the sponsor
- Or owned by the sponsor

Your information <u>may</u> be given to:

- The U.S. Food and Drug Administration (FDA)
- Department of Health and Human Services (DHHS) agencies
- Governmental agencies in other countries
- The institution where the research is being done
- Governmental agencies to whom certain diseases (reportable diseases) must be reported
- An Institutional Review Board (IRB)

Why will your information be used and/or given to others?

- To do the research.
- To study the results.
- To make sure that the research was done right.

The results of this study may be made public. In this case, we will not use information that identifies you.

What if I choose not to give permission to use and give out my information?
Then you will not be able to take part in this research study.

May I review or copy my information?
Yes, but only after the research is over.

May I take away (cancel) my permission?
This permission will be good until December 31, 2070.

You may cancel your permission for us to use and share your information. You may do this at any time. Please send written notice to the study staff. If you take away your permission, you won't be able to remain in this study.

When you cancel your permission, no new information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

Is my information protected after it has been given to others?
There is a risk that your information will be given to others without your permission.

Authorization:
I have been told how my information will be used for this research study. I have been told who my information may be given to. My questions have been answered.

I authorize the use and disclosure of my health information to the parties listed in the authorization section of this consent for the purposes described above.

AUTHORIZATION SIGNATURE:

_____ _____

Signature of Participant or their/Legally Authorized Representative **Date**