



**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  
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**STUDY-RELATED  
PHONE NUMBER(S):** (650) 761-6486 (24 hours)  
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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      **Contact:** [contact@projectsingular.org](mailto:contact@projectsingular.org)

Please carefully read the consent form below. Click “Next” when you are done with this page. This will let you move to the next page. If you have questions about Project Singular or this form, please ask us. You can call us at 650-761-6486. Or you can email us at [contact@projectsingular.org](mailto: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\*\****

## **RESEARCH CONSENT SUMMARY**

In this consent form, “you” always refers to the person participating in the study. If you are a legally authorized representative (such as a guardian), 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 three reasons. You may have a single ventricle heart defect. Or you are a close family member (birth child, sibling, or parent) of someone with a single ventricle heart defect. Or you are a parent or guardian of someone with a single ventricle heart defect.

Taking part in the study is all by choice. You can choose if you want to take part or not. 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. This includes birth parents, siblings, and children.

We will ask you to answer questions about your health. You will need to sign a medical record release form. And we will ask you to send us a sample of your saliva (spit). We will use the spit sample for genetic testing. 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 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 them. We also need to collect this information from their close family. This includes birth parents, siblings, and children.

Project Singular is paid for by Additional Ventures. Additional Ventures is a nonprofit foundation. Its goal is to learn about single ventricle heart disease.

We are asking you to take part in Project Singular for one of three reasons. You may have a single ventricle heart defect. Or you are a close family member (birth parent, sibling, or child) of someone with a single ventricle heart defect. Or you are a parent or guardian 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 take part. It will also tell you 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 650-761-6486. Or you can email us at [contact@projectsingular.org](mailto: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. Our goal is to collect genetic and health information from people with different kinds of single ventricle heart defects. We also need to collect this information from their close family. This will help us learn what may cause the defects. We can also learn what may cause 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. We will also need information from your medical records. And we will send you a survey to fill out. It will ask health questions. We will securely store all this information. The spit samples will be kept in a secure gene bank. The samples will be processed at the Broad Institute of MIT and Harvard. This 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. This makes it hard to link information back to a person.

### **Who is paying for this study?**

Additional Ventures is paying for Project Singular. Additional Ventures is a non-profit foundation. This means 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 650-761-6486. Or you can email us at [contact@projectsingular.org](mailto:contact@projectsingular.org).

### **How long will Project Singular last?**

Project Singular does not have an end date. Researchers will be able to access information from the study. They will be able to access it 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. The person must live in the United States or Canada.

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

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

Any adults with a single ventricle heart defect that are not able to give consent themselves must have consent from a legally authorized representative (such as a guardian) to take part.

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

If you choose to take part, you will need to set up a secure account on [www.projectsingular.org](http://www.projectsingular.org). If you have a single ventricle heart defect, you will need to fill out a survey. It will ask about your age, race, and gender. It will also ask about when you were diagnosed. And it will ask other things about your health.

You will need to send us a sample of your spit. You will collect the sample using a kit we will mail to you and send the sample back to us. You won't need to pay to mail it.

You will need to send us contact information for your doctor. You will also need to sign a medical release form. This will allow your doctor to send us your medical records. The form will ask permission to collect and store your medical records now and in the future. That way we can update your health information. This information 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. You can fax them to us. Or you can upload them through our secure website.

We may call or email you if we need more information. We may contact you if your doctor needs you to sign more forms. We may send you reminders to complete surveys. Or we may need to let you know 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 spit sample?**

When we receive your spit sample, we will do "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." This is a way to read DNA. It 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. They may look at just 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. It gives us a detailed look at all your genes. That 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. We will use a secure online system. We will control access to the system. This means only doctors and researchers can view information in the system. The information will also 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.

### **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. You won’t get to choose if your information is used in these studies. Some of these studies may be on diseases other than single ventricle heart disease. Some researchers may study ways to measure health. They may want to see how health might change with certain treatments or care. Some of these studies may be with for-profit companies for commercial uses. The companies may 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. Researchers that 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. You can’t choose 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. This staff needs 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, call us at 650-761-6486. Or email us at [contact@projectsingular.org](mailto: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. But 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. 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's why we're doing this study. This means 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. 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 we may 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. This is 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. These changes 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. Most people in this study will not have a result like this.

You have a choice. You can tell us now that you would like to know about a result like this. Then, if you have this type of result, we will contact you. We will connect you with a doctor in your state. The doctor can do a second genetic test to confirm the finding. This second test would be free of charge to you. If the finding is confirmed, a genetic counselor will work with you. They will help you understand what the finding means. They will help you understand what the next steps are for you. At the end of this consent form, we will ask if you would want to know about a secondary finding.

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. 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. We will do this before we share your information with researchers. We will also encrypt (scramble) your information when we store it. This 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. There is a chance your information could be released by accident. This could identify you or your family. We think the chance of this 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. This may upset you. You might have to decide what to do. 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. This might upset you or your family. Before you join the study, you may want to talk with your family. You may want to 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. 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. You can quit 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](mailto: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. 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. But 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. 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 650-761-6486 (24 hours). Or you can email us at [contact@projectsingular.org](mailto:contact@projectsingular.org).

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



**Statement of Consent:**

This is what I agree to:

- You may ask my doctor for my medical records. You may ask hospitals and other places I received treatment in the past. You may ask where I am getting treatment now.
- You may do genetic tests on my saliva sample that I will send you. You may store the sample until the tests are complete. You may link the results to my health information.
- You may use my de-identified medical records and genetic test results for future research. It may be for studies not yet designed. It may be for studies on diseases other than single ventricle heart disease. It may be for studies 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. These forms 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 take part, it will not affect my health care.
- I know that I can choose to quit the study at any time.
- I know that a copy of the signed consent form will be on the project dashboard webpage.
- By taking part in this study, I agree that my information may be used for different types of research.

Your signature documents your consent to take part in this research.

- Any person not able to consent must assent (agree) to take part in Project Singular if they are able. Study staff will explain the study to the person. Then the staff will ask if the person agrees to take part. Some people may not be able to understand. If the staff determines this is the case, the person does not have to assent.
- All people who assent must sign an assent form if they can. Some people may not be able to sign their name. If the study staff determines this is the case, the person does not have to sign.

Your Name:

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First Name

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Last Name

Your Date of Birth:

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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 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:

\_\_\_\_\_  
Signature of adult subject capable of consent

\_\_\_\_\_  
Date

Subjects in need of a Legally Authorized Representative:

\_\_\_\_\_  
Signature of Legally Authorized Representative

\_\_\_\_\_  
Date

- ☐ I have explained the study to the extent compatible with the subject's capability, and the subject has agreed to be in the study.
- OR
- ☐ The subject is not able to assent because the capability of the subject is so limited that the subject cannot reasonably be consulted.

\_\_\_\_\_  
Signature of person obtaining consent/assent

\_\_\_\_\_  
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 may 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:**

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**Signature of Subject/Legally Authorized Representative**

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**Date**