



PROJECT  
**SINGULAR**

**RESEARCH SUBJECT CONSENT FORM (FOR CHILD ENROLLMENT BY PARENT/GUARDIAN)**

**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)  
[contact@projectsingular.org](mailto:contact@projectsingular.org)

**PROJECT SINGULAR  
RESEARCH CONSENT FORM**

Parents/Guardians and Other Legally Authorized Representatives of Affected Children and Children 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 each 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.

## **RESEARCH CONSENT SUMMARY**

We are asking your child to take part in a research study. We are asking because your child or a close family member of your child (parent or sibling) has a single ventricle heart defect.

Taking part in the study is all by choice. You can choose if you want your child to take part or not. You can take your child out of 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 and siblings.

We will ask you to answer questions about your child's health. You will need to sign a medical record release form. And we will ask you to send us a sample of your child's 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 child's name and birth date. This makes it hard to identify your child from the information. We will protect your child's privacy the best we can. But there is a small risk someone may see information that identifies your child.

## **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 and siblings.

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 your child to take part in Project Singular. This is because your child or a close family member of your child (parent or sibling) has a single ventricle heart defect. This form will help you choose if you want your child to take part in the study. It will tell you what you will need to do if your child takes 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 have your child 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 your child. Make sure we answer your questions before you choose. Do not sign this form until you are sure you want your child 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 from your child. We will also need your child's 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 at 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 the 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 nonprofit 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. Our goal is for at least 5,000 people with single ventricle heart disease to take part in the study. We would also like many of their family members to take part. Researchers will be able access information from the study. They will be able access it for a long time. We're not sure how long yet.

Your child can quit the study at any time. Please see the section "Can my child 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 my child takes part in Project Singular?**

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

You will also need to send us a sample of your child's spit. You will collect the sample using a kit we will mail to you. You will 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 child's doctor. You will also need to sign a medical release form. This will allow your child's doctor to send us your child's medical records. The form will ask permission to collect and store your child's medical records now and in the future. That way we can update your child's health information. This information will be useful for researchers doing studies.

We can contact your child's doctor to ask for the medical records. Or you can ask the 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 child's 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. We may ask if you want your child to take part in other research studies.

### **What will you do with my child's spit sample?**

When we receive your child's spit sample, we will do "whole genome sequencing." This will give us a detailed look at your child's genes.

Genes are parts of your DNA. Genes have instructions for how cells in your body should work and grow. We will study your child's 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 child's genes. This is called whole genome sequencing. It gives us a detailed look at your child's 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 child's information?**

We will carefully store your child's 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 child's name and birth date. This makes it hard to identify your child from the information.

### **How long will you keep my child's information?**

Research is an ongoing process. We may want to use your child's information for future research. For this reason, we can't set an exact time limit on how long we will store your child's information. When your child reaches the legal adult age, we will ask if your child wants to stay in the study. If your child does, he or she will review and sign a consent form. If your child wants to quit the study, your child can. If we try to contact your child at the time of adulthood and cannot reach him or her, we will continue to use and share any information already collected.

### **Who will have access to my child's information? What will they do with it?**

We may share your child's information with other researchers. But the information will be "de-identified." This means the researchers won't be able to identify your child. This also means they can't ask you if they can use your child's information in future studies. You won't get to choose if your child's 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 want to develop new treatments.

**What choices will I have for sharing my child's information?**

If your child takes part in Project Singular, we will share your child's information with researchers. The information will be de-identified. Researchers that want to access the information will be approved by a science review committee.

We may also need to share your child's information for business and legal reasons. We may share the 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 that we said we would.

If you do not want us to share your child's information in these ways, you may remove your child from 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 my child might be eligible for a clinical trial?**

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

**Will my child benefit from taking part in Project Singular?**

Your child is not likely to benefit directly from taking part in Project Singular. But the information we collect from your child 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 or my child be paid for taking part in Project Singular?**

No. Neither you nor your child will be paid for taking part in Project Singular. Neither you nor your child will be paid if research using your child's information results in new treatments, tests, or commercial products.

**Will I find out the results of the research?**

**You will most likely not get any results** specific to your child. Also, your doctor will not get your child's results. You will not get any data files such as your child's 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 we don't know which parts of your child's DNA may cause your child's single ventricle heart disease. So we cannot give you any information about your child'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 child's 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. That 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 child'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 child's DNA. When we do, we may find changes in your child's 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.

But we could find this result while looking at your child's DNA. You have a choice. You can tell us now that you would like to know about a result like this. Then, if your child has 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 your child. 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 my child be kept private?**

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

### **What are the risks from taking part in Project Singular?**

You may learn your child has 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 child's genetic information is unique to him or her. But your child does share some genes with you. Your child also shares some genes with his or her other parent, brothers, sisters, and other blood relatives. This means your child's genetic results could also tell you something about yourself or 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.

### **Does my child have to take part in Project Singular?**

No. Taking part in Project Singular is by choice. You can choose for your child to take part or not. You can change your mind. You can choose to remove your child from the study at any time. Your choice will not affect your child's health care. There is no penalty for choosing not to take part in the study. Your child will not lose any benefits to which your child is otherwise entitled for not taking part.

### **Can my child quit Project Singular?**

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

To remove your child from the study, you must tell us in writing. Contact the study staff at [contact@projectsingular.org](mailto:contact@projectsingular.org). If you choose to remove your child from the study, it will not affect your child's health care now or in the future. There is no penalty for quitting. Your child will not lose any benefits to which your child is otherwise entitled from quitting the study.

You can quit the study and then choose for your child to rejoin Project Singular in the future. But you will have to start over with the registration process.



### **Can my child's information be removed from this research without my approval?**

The lead researcher may decide your child's information is longer needed for the research. In this case, we will remove your child's information. We will safely destroy any of your child's information that is not needed.

### **What are my child's options when he or she reaches the legal adult age?**

When your child reaches the legal adult age, we will ask if your child's wants to stay in the study. If your child wants to stay, he or she will need to sign a consent form. If you child wants to quit, we will remove his or her information from the study. If we try to contact your child and cannot reach him or her, we will continue to use and share any information already collected.

### **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 your child or made your child 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 child's rights as a research subject.

### **Statement of Consent:**

- All children that are able must assent (agree) to take part in Project Singular. You will explain the study to the child. Then you will ask if your child agrees to take part. Some children may not be able to understand. If you determine this is the case, the child does not have to assent.
- All children who assent must sign an assent form if they can. Some children may not be able to sign their name. If you determine this is the case, the child does not have to sign.

This is what I agree to:

- You may ask my child's doctor for my child's medical records. You may ask hospitals and other places my child received treatment in the past. You may ask places my child is getting treatment now.
- You may do (or work with others to do) genetic tests on my child's saliva sample that I will send you. You may store the sample until the tests are complete. You may link the results to my child's health information.
- You may use my de-identified medical records and results of my child's genetic tests 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 put my child's de-identified medical records and 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 child's hospital(s) share my child's medical records.

- You may collect my child's medical records until my child reaches the legal adult age. (The legal adult age is between 18 and 21 years old, depending on where you live.) At that time, my child can choose to consent or not. Medical records may be collected after my child reaches the legal adult age. But these records will only be from the time when my child was a minor.
- If my child stays in the study until he or she reaches the legal adult age, you may contact my child to see if my child wants to stay in the study. You may contact me to get my child's contact information.

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 have my child take part in this study.
- I know that I can choose for my child to take part in the study or not.
- I know that if I choose for my child not to take part, it will not affect my child's health care.
- I know that I can choose to remove my child from 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 child's information may be used for different types of research.

Your signature documents your permission for the individual named below to take part in this research.

Your Child's Name:

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First Name

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Last Name

Your Child's Date of Birth:

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MM / DD / YYYY

☐ I have explained the study to the extent compatible with my child's capability, and my child has agreed to be in the study.

I understand that when my child's genes are studied, changes in the genes may be found. These changes may be known to cause some disease 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 child's 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 to arrange a second genetic test to confirm the result. If it is confirmed, the 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.

Parent/Guardian Signature:

\_\_\_\_\_  
Signature: \_\_\_\_\_ Date \_\_\_\_\_

\_\_\_\_\_  
First Name

\_\_\_\_\_  
Last Name

Relationship to subject:

\_\_\_\_ Parent

\_\_\_\_ Guardian

Person Providing Consent:

\_\_\_\_\_  
Signature: \_\_\_\_\_ Date \_\_\_\_\_

**Signature of person obtaining consent**

## **AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES**

### **What information may be used and given to others?**

Researchers will be given your child's information. This may include:

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

### **Who may use and give out your child's information?**

The study staff may give your child's information to researchers.

### **Who else might access your child's information?**

The sponsor of this research may access your child's information. "Sponsor" is any person or company that is:

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

### **Your child's 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 child's information be used and/or given to others?**

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

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

**What if I choose not to give permission to use and give out my child's information?**

Then your child will not be able to take part in this research study.

**May I review or copy my child's 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 give out your child's information. You may do this at any time. Just send written notice to the study staff. If you cancel your permission, your child won't be able to stay in this study.

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

**Is my child's information protected after it has been given to others?**

There is a risk your child's information will be given to others without your permission.

**Authorization:**

I have been told how my child's information will be used for this study. I have been told who my child's information may be given to. My questions have been answered.

I authorize the use and disclosure of mychild's 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 Parent/Guardian**

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**Date**