

**INFORMATION AND CONSENT FORM**  
For Adult Participants/Parents/Guardians

**Project Title:** The Chordoma Foundation Biobank: A Collection of Biospecimens and Clinical Data to Facilitate Research

**Project #:** 001

**Sponsor:** Chordoma Foundation

**Principal Investigator:** Patricia Cogswell  
Chordoma Foundation  
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**Telephone Number:** (919) 809-6779

The Chordoma Foundation is a 501(c)(3) nonprofit organization dedicated to developing treatments and ultimately a cure for chordoma, and improving the diagnosis, treatment, and quality of life for chordoma patients. The Chordoma Foundation wants to know if you would like to provide samples and information that may help researchers. This form describes the project in order to help you decide if you want to participate. This form will tell you what you will have to do and the risks and benefits of participating.

If you have any questions about or do not understand something in this form, you should ask the consent staff. You should discuss your participation with anyone you choose in order to better understand this project and your options. Do not sign this form unless the staff has answered your questions and you decide that you want to be part of this project.

Participating in research is not the same as getting regular medical care. The purpose of regular medical care is to improve your health. The purpose of medical research is to advance the understanding and treatment of disease. Participating in this project does not replace your regular medical care.

When reading this form, please note that the words “you” and “your” refer to the person in the project rather than to a parent or guardian who might sign this form on behalf of the person in the project.

**WHAT IS THIS PROJECT ABOUT?**

By participating in this biobank project, you will be asked to provide tissue, blood, saliva/cheek swabs, other fluids left over from past medical tests, and/or medical information to be used for research. When samples and medical information are collected from multiple people and made available for various types of research, this is called a “**biobank**”. The Chordoma Foundation is creating this biobank to support research. Some samples may be used immediately while others will be stored for future use by researchers from universities, the government, health-related

companies, and other research institutes. Some researchers will be from the United States and some may be from other countries around the world.

We (the Chordoma Foundation) would like your permission to use your medical information along with your specimens to do a variety of kinds of research that could improve future health care for people with chordoma and/or other diseases. Because technology is changing all the time it is not possible to know all of the techniques that researchers may use now or in the future.

Some of the research might involve creating cell lines from your tissue so that your cells can grow indefinitely to be used in various projects. Cell lines may be useful because of the characteristics of the cells and/or the products they may produce.

Some of the research might involve studying DNA contained in your samples. DNA is the material that makes up genes. Genes determine things like hair color and eye color, and also influence diseases, such as cancer. Some researchers will analyze your DNA by a technique called "genome sequencing" to look for changes in some or all of your genes. **You do not have to agree to genetic testing if you do not want to. However, you cannot be in the biobank project if you do not want genetic testing performed on your samples.**

#### **WHAT WILL HAPPEN IF I DECIDE TO PARTICIPATE IN THE BIOBANK PROJECT?**

With your consent, project staff will collect medical information by asking you questions about your health, the doctors you have seen and your medical and family history and/or by having hospital staff review your medical records to collect such information. The medical information collected about you may include any information in your medical records such as your patient history, response to treatment, pathology (disease) reports, radiographic (imaging) reports, etc.

The types of samples the Chordoma Foundation wants to collect include:

- leftover tissue (such as tumor) or fluids that have been taken, are scheduled to be taken, or that may be taken in the future, as part of your regular medical care;
- blood;
- saliva/cheek swabs.

Each type of sample collection is optional. You can decide to participate in each type of sample collection separately, which means you can agree to some, all, or none of the different types of samples.

If you have had surgery in the past and you provide consent, project staff will contact the hospital(s) where you had surgery to get leftover tissue or fluids that may be stored there. If you are scheduled for a medical procedure or surgery, medical staff will obtain the types of samples you have agreed to provide. No additional tissue will be taken during surgery beyond what is needed for your care. Only material that is not needed for your diagnosis will be sent to the biobank.

If you consent to have blood drawn for the biobank, it may be collected at the same time as other blood tests or during your surgery. If it is not possible to collect blood during a scheduled procedure, the biobank may send you a blood collection kit with tubes and instruction that you

can take to your doctor or local laboratory so they can obtain a blood sample. The amount of blood collected will be about 3-5 teaspoons.

If you agree to provide a saliva sample or cells from inside your cheek, you will receive a kit with instructions describing how to spit into the special container or how to use a swab to gently rub the inside of your cheek.

If you give your consent to be re-contacted, biobank staff may contact you about once a year to update your medical information. You may also choose if you would like the Chordoma Foundation to notify you about other research studies in the future.

You may also choose to be re-contacted about the possibility of return of research results. Currently, the Chordoma Foundation does not plan to provide you information on research performed with your specimens or the results of that research. You may give your consent to be re-contacted if this changes in the future. In the event of such a change, the Chordoma Foundation would contact you to explain the risks and benefits of obtaining research results and to obtain separate consent to provide such results to you or to your physician. At this time, the Chordoma Foundation is only asking if you would like to be contacted to obtain your consent if such a change occurs. Even if you are re-contacted for this consent, it does not mean that research results will be available.

People who work with the sponsor will store your samples in a secure laboratory at Ohio State University, or other laboratory. Your samples will be stored as long as the sponsor decides to keep them.

#### **WHAT IS MY ALTERNATIVE TO BEING IN THE BIOBANK PROJECT?**

Your participation in the biobank project is voluntary. Your alternative is not to participate. The biobank project does not involve treatment for any condition, so your decision to participate or not to participate will not affect your medical care. Your decision not to participate or to stop participating at any time will not involve any penalty to you and will not involve any loss of benefits to which you might otherwise be entitled.

#### **WHO IS PAYING FOR THIS BIOBANK PROJECT?**

The Biobank is funded by the Chordoma Foundation through donations, grants and researcher user fees.

The study doctor is an employee or executive of the sponsor. If you have concerns about this employment, ask the study doctor for more information.

#### **WILL IT COST ANYTHING TO BE IN THIS BIOBANK PROJECT?**

Participating in the biobank project will not cost you anything.

## **HOW LONG WILL I BE IN THE BIOBANK PROJECT?**

Your direct involvement will be limited initially to the time it takes to obtain your consent and to collect samples and medical information. Because this project involves a biobank, your samples may be used immediately or may be stored indefinitely for future use. If you agree, we may also re-contact you to get updates about your health and medical care or to tell you about other studies.

If a participant is a minor when his/her samples are first placed in the biobank, and he/she later becomes an adult, the project staff will contact the participant to seek his/her consent to continue to use the samples in the biobank. At that time, the participant can decide to continue in this biobank project, or ask that the samples be destroyed. If such a participant cannot be contacted, the sponsor will continue to use any samples already collected.

If you want to stop being in the biobank project, tell the Principal Investigator or project staff. If you decide to withdraw from the project early, the Principal Investigator or project staff may ask you some questions about being in the project. The Principal Investigator or the sponsor can remove you from the project at any time, even if you want to stay in the project.

*For adults considering whether to be in the biobank project:*

What if I work for the sponsor or site? What if I am a family member of someone who works for the sponsor or site?

Sponsor/site employees and their family members do not have to be in this biobank project. No one should influence or pressure you to be in this biobank project. An employee's or his/her family member's decision to be in the biobank project, or to leave the biobank project early, will not affect the employee's job or job benefits.

*For parents/guardians who are considering whether to allow their child to be in the biobank project:*

What if I work for the sponsor or site? What if I am a family member of someone who works for the sponsor or site?

Sponsor/site employees and their family members do not have to let their children be in this biobank project. No one should influence or pressure you to let your child be in this biobank project. An employee's or his/her family member's decision to allow a child to be in this biobank project, or to have the child leave the biobank project early, will not affect the employee's job or job benefits.

## **HOW WILL YOU KEEP MY INFORMATION PRIVATE?**

Access to information with your name, such as the consent form, will be restricted to healthcare staff, the Principal Investigator, designated Chordoma Foundation staff, and approved Chordoma Foundation contractors. Documents will be kept in a locked cabinet and information in computers will be protected by passwords. In order to protect your private information, only a

unique code number, not your name or medical record number, will appear on your samples or on information sent to researchers outside the Chordoma Foundation. Some people who work for the biobank will be able to find your name from the code so they can possibly have your sample(s) destroyed if you change your mind later. Except when required by law, your personally identifying information will not be disclosed outside of the Chordoma Foundation.

The Chordoma Foundation also plans to apply to the federal government to receive a Certificate of Confidentiality. A Certificate of Confidentiality helps researchers protect the privacy of participants in studies involving sensitive information. It allows the project staff to refuse to release your name or other identifying information to anyone who is not involved in the project. However, even with a Certificate of Confidentiality, the project staff may release your name or other identifying information if:

- There is a federal audit of the project. In this situation, certain government workers will be able to see your information
- You chose to release your information to other people not involved in the project.
- You request in writing to the release of your information to insurers, employers, or other people.
- The project staff suspects things they must report under federal, state, or local law. This might include child or elder abuse, certain communicable diseases, or a possible threat to yourself or others. There may be other things that must be reported by law.

Ask the project staff if you have any questions about Certificates of Confidentiality.

#### **WHAT HAPPENS IF I CHOOSE TO STOP TAKING PART IN THIS BIOBANK PROJECT?**

If you change your mind about your participation, you must notify the Principal Investigator at the address on the first page of this form. You will need to tell the Principal Investigator in writing, with your signature, what you want to do. There are three ways you can choose to stop participating in the Biobank:

1. You may choose to leave your data and unused samples in the Biobank while requesting not to be re-contacted in the future.
2. You may request that your personally identifying information be destroyed, but allow some or all of your samples to continue being used anonymously for future research.
3. You can choose to end all participation, in which case all of the unused samples in the Biobank will be destroyed and your medical information will be deleted.

If samples and information have already been sent to researchers, the Chordoma Foundation will notify the researchers that the samples and information with your code number should be destroyed. However, we cannot guarantee that samples already sent to researchers can be retrieved or destroyed.

#### **WILL PARTICIPATING IN THIS BIOBANK PROJECT BENEFIT ME?**

Research conducted with your information and specimens may not help you directly, but it may help people in the future. Research performed with your information and specimens could result in the discovery and development of new drugs, tests or commercial products. Currently

the Chordoma Foundation is not able to provide information about research performed with your specimens or any associated research results.

### **WHAT ARE MY RISKS IF I TAKE PART IN THIS BIOBANK PROJECT?**

Your regular medical care will not change if you participate in this biobank project. The collection of medical information, tissue samples already taken as part of your regular medical care, saliva, or cheek swabs should not involve any physical risk to you. If you agree to give blood, the medical staff will take your blood by sticking a needle in your arm to remove about 3-5 teaspoons of blood, or they may collect the blood during surgery. Some problems you might have from this are:

- It may hurt.
- You may get a bruise.
- You may feel dizzy.
- You may get an infection.

There are some risks related to the use of your medical information and specimens. There could be an accidental release of your medical information to people who are not involved in your medical care. Your specimens and medical information may be used to study your genes. An accidental release of your genetic information could be used to identify you and your family members. This risk is very small.

The federal government has passed the Genetic Information Nondiscrimination Act (GINA) which protects people from employment or health insurance discrimination based on genetic findings. This law will generally protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information from this research.
- If health insurance companies and group health plans do somehow receive your genetic information from this research, they may not use it to make decisions about your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

All health insurance companies and group health plans must have started following this law by May 21, 2010. All employers with 15 or more employees must have started following this law by November 21, 2009.

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

### **WHAT IF I GET HURT WHILE I AM IN THE BIOBANK PROJECT?**

If injury (i.e. physical, psychological, social, financial, or otherwise) occurs as a result of participation in this project, there are no plans for providing compensation to you or your family.

You do not give up any of your legal rights by signing this form.

### **WILL I BE PAID FOR PARTICIPATING IN THE BIOBANK PROJECT?**

You will not get payment for being in this biobank project. The sponsor does not plan to give you any money or payment resulting from any discoveries or products made from this research project.

### **WHO CAN I TALK TO ABOUT THIS PROJECT?**

You can ask the consent staff any questions you may have about this project. You may also contact the Principal Investigator listed on page one of this form if you have any concerns or complaints. You can learn more about the Chordoma Foundation by visiting our website at [www.chordoma.org](http://www.chordoma.org).

Quorum Review reviewed this project. Quorum Review is a group of people who review research studies to protect the rights and welfare of research participants. Review by Quorum Review does not mean that the project is without risks. If you have questions about your rights as a research participant, if you are not able to resolve your concerns with the Principal Investigator, if you have a complaint, or if you have general questions about what it means to be in a research project, you can call Quorum Review or visit the Quorum Review website at [www.quorumreview.com](http://www.quorumreview.com).

Quorum Review is located in Seattle, Washington.  
Office hours are 8:00 AM to 5:00 PM Pacific Time, Monday through Friday.  
Ask to speak with a Research Participant Liaison at 888-776-9115 (toll free).

### **WHO WILL USE AND SHARE INFORMATION COLLECTED ABOUT ME?**

With your consent, biobank staff will obtain information about you either directly from you or by having healthcare staff review your medical records. They may share your consent information with healthcare providers or Quorum Review as needed. This information, along with your identifying information (such as name and address) and signed consent(s), will be part of the biobank project records. You should know that:

- Your samples and information will be coded so that researchers will not know your name or other identifying information.
- The Chordoma Foundation and/or researchers may use facts related to your specimens in books, magazines, journals, and scientific meetings. If this happens, no one will use your name or other information that could be used to identify you.
- The Chordoma Foundation may require researchers to share their research results so that it can be compared or provided to help other researchers.
- Please note that biobank project staff may share personal information about you if required by law or to comply with the requirements of the Food and Drug Administration (FDA) or any other governmental agency in the United States and other countries; however, this is not a common occurrence for a biobank project.
- Some research information based on your samples might be made available in public scientific databases that other researchers can use. This information will be anonymous;

however, it is possible that someone with a very high level of expertise could link anonymous data stored in such a database with an individual person.

**All information authorized to be released during this study may include records that indicate the presence of a communicable or noncommunicable disease.**

**DO YOU WANT TO BE IN THIS BIOBANK PROJECT?**

I have read this form, and I have been able to ask questions about this biobank project. The consent staff has talked with me about this project. They have answered all my questions. I voluntarily agree to participate. I agree to allow the use and sharing of my data as described above.

By signing this form, I have not given up any of my legal rights as a research participant. I will get a signed copy of this consent form for my records.

I have been asked for my permission to collect my specimens and medical information for use in research. I have been asked for my permission to be re-contacted to obtain updated medical information, to be notified of additional research studies, and/or to be asked for my consent to return research results. **I agree to the following parts of this project by circling my choice for each item below.**

I am willing to provide my **past specimens** (tissue, fluid and/or blood) for the biobank. **YES or NO**

I am willing to provide the biobank with specimens (tissue, fluid and/ or blood) from my **currently scheduled medical procedure(s)**. **YES or NO**

I am willing to provide my **future** specimens to the biobank. **YES or NO**

I am willing to have **blood** drawn for the biobank. **YES or NO**

I am willing to provide a **cheek swab** and/or **saliva** for the biobank. **YES or NO**

I am willing to be **re-contacted** to update my **medical information**. **YES or NO**

I am willing to be **re-contacted** to get my consent for the possible **return of research results**. **YES or NO**



You may re-contact me to notify me about **additional research opportunities**

**YES or NO**

\_\_\_\_\_  
Name of Participant (Print)

\_\_\_\_\_  
Date of Birth

\_\_\_\_\_  
Signature of Participant (If an Adult)

\_\_\_\_\_  
Date

*If participant does not have the legal capacity to consent to their participation:*

I certify that under state law I am the parent/guardian of the participant named above and that I am authorized to sign this consent to his/her participation in the biobank project described above. I am also authorized to allow the use and sharing of the participant's data as described above.

\_\_\_\_\_  
Name of Parent/Guardian  
(Print)

\_\_\_\_\_  
Relationship to Participant

\_\_\_\_\_  
Signature of Parent/Guardian

\_\_\_\_\_  
Date

I attest that the participant and/or parent/guardian named above had enough time to consider this information, had an opportunity to ask questions, and voluntarily agreed to be in this biobank project or allow his/her child to be in this biobank project.

\_\_\_\_\_  
Name of Person Explaining Consent (Print)

\_\_\_\_\_  
Signature of Person Explaining Consent

\_\_\_\_\_  
Date

**WITNESS STATEMENT** (to be used if participant is unable to read)

As an impartial third party, I witnessed the entire consent discussion and the signature of the participant (or, if applicable, the participant's legally authorized representative) on this form.

\_\_\_\_\_  
Name of Witness (Print)

\_\_\_\_\_  
Signature of Witness

\_\_\_\_\_  
Date