PARENTAL PERMISSION FORM
CONSENT FORM: Ages 18 and up
ASSENT FORM: Ages 13-17

Study Title: CHronic nonbacterial Osteomyelitis International Registry (CHOIR)

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The Study team:

Name/Degree	**Phone Number**	**E-mail**
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If you have questions about your rights as a registry participant, you can call the Institutional Review Board at (206) 987-7804.

1. Researchers' Statement:

You have the option to take part in this registry. The goals of this form are to give you information about what would happen if you choose to take part and to help you decide if you want to be in the registry.

Feel free to take notes, write questions or highlight any part of this form.

Potential Participants 18 years and older: This is a consent form. It provides a summary of the information the study team will discuss with you. If you decide that you would like to take part in this registry, you would sign this form to confirm your decision. If you sign this form, you will receive a signed copy of this form for your records

Potential Teen Participants: This form serves as an assent form. That means that if you choose to take part in this registry, you would sign this form to confirm your choice. Your parent or legally authorized representative would also need to give their permission and sign this form for you to join the registry.

Parents/Legally authorized representatives: You have the option of having your child or teen join a registry. This is a parental permission form. It provides a summary of the information the study team will discuss with you. If you decide that your child can take part in this registry, you would sign this form to confirm your decision. If you sign this form, you will receive a signed copy for your records.

The word **"you"** in this form refers to your child/teen.

2. What you should know about this registry:

- This form explains what would happen if you join this registry.

- Please read it carefully. Take as much time as you need.
- Please ask the study team questions about anything that is not clear.
- You can ask questions about the registry any time.
- If you choose not to be in the registry, it will not affect your care at Seattle Children's.
- If you say 'Yes' now, you can still change your mind later.
- You can quit the registry at anytime.
- You would not lose benefits or be penalized if you decide not to take part in the registry or to quit the registry later.

3. What is the goal of this registry?

The goal of this registry is to investigate the history of chronic recurrent multifocal osteomyelitis (CRMO)/chronic nonbacterial osteomyelitis (CNO) and the patient responses to different clinical treatments that are part of standard of care.

4. Why do I have the option of joining the registry?

You have the option to take part in this registry because you have chronic recurrent multifocal osteomyelitis (CRMO)/chronic nonbacterial osteomyelitis (CNO).

5. How many people will take part in this registry?

We think that at least 200 people will take part in this registry at Seattle Children's Hospital. More than 1,000 people will take part at hospitals and clinics around the world.

6. If I agree to join this registry, what would I need to do?

If you join the registry, the study team would collect information from you and your medical record every time you come to Seattle Children's Hospital for an appointment related to CRMO/CNO.

The tasks related to this registry are:

- Completion of study related questionnaires during your regularly scheduled clinic visits.
- Chart Review: Most of the information we collect will come from your medical record. This will require no extra steps from you at all. We will read your record and write down how you are doing. We will collect information such as:
    - Demographic information
    - Medications
    - Medical history
    - Imaging and laboratory results
    - Answers to questionnaires

Banking Information

Storing information so researchers can use it in the future is called "banking." Researchers also bank information so they can share it with other researchers.

If you decide to take part in this study:

- We would store your information in the study team's office in a locked cabinet indefinitely. Your information will be de-identified and the code linking your name to your study ID will be kept separately.
- We may share your de-identified information with other researchers studying CRMO/CNO.
- Your information would be used in future research on CNO/CRMO.
- We would not be able to give you the results from research that is done using your information.
- Your information could be used to make new products, tests or findings. These may have value and may be developed and owned by the research team and/or others. If this happens, there are no plans to pay you.

What if I changed my mind about banking my information/samples?

You could always tell us to stop storing your information/samples. We would destroy your information/samples and any information that identifies you. However, we would not be able to destroy or get data if the information has already been made anonymous.

7. How long would I be in the study?

If you choose to take part in this registry, you would have data collected for up to 20 years.

If you join the registry, you can decide to stop **at anytime for any reason**. If you decide to leave the registry, nothing about your care would change. Please call or email Dr. Zhao (information listed on first page), if you want to leave the registry. If you decide to leave the registry, we will stop collecting more information. If you want us also to remove the information we have already collected, please call Dr. Zhao to request that we do so. Otherwise, we will keep the information we have already collected.

Dr. Zhao and his study team could also decide to take you out of this registry. For example, if you become incarcerated or enter the foster system, we would need to take you out of the registry. If we ask you to leave the study, we would always explain why

8. What are the potential harms or risks if I join this study?

Potential Harms and Discomforts:

It is possible that you may become emotionally upset when completing the questionnaires. It is okay to skip any questions that you do not want to answer.

There is a risk that your confidentiality or privacy could be breached. This would mean that someone other the study team or our collaborators may find out that you were in the registry or see your answers or medical information. However, we will take every precaution to make sure that this does not happen.

9. What are the potential benefits if I join this registry?

Potential Benefits for You:

We do not expect this study to benefit you.

Potential Benefits for Others:

We hope to use information collected as part of the registry to benefit others who have CRMO/CNO.

10. What other options do I have?

If you choose not to be in this registry, you can receive your usual clinical care. Whether or not you participate in this registry, your access to care is not affected. Please talk to your doctor or the study team about your options.

11. What about confidentiality and privacy?

If you join the study, we will keep your information confidential as provided by law.

You have certain privacy rights with regards to your health information, and only with your permission may we collect, use, or share your health information for this study. The following describes the type of information the study will create, use or share, who may use it or share it, and the purposes for which it may be used or shared.

This information may include things like:

- Past or future medical records,
- Research records, such as surveys, questionnaires, interviews, or self-reports about medical history
- Medical or laboratory records related to this study, and
- Information specific to you like your name, address, or birthday

This information may be used by or shared with:

- Researchers (such as doctors and their staff) taking part in this study here and at other centers,
- Research sponsors – this includes any persons or companies working for, with, or owned by the sponsor,
- Review boards (such as Seattle Children's Institutional Review Board), data and safety monitoring boards, and others responsible for watching the conduct of research (such as monitors),
- Governmental agencies like the U.S. Food and Drug Administration (FDA) and the

  Department of Health and Human Services (DHHS), including similar agencies in other countries, and
- Public health authorities to whom we are required by law to report information for the prevention or control of disease, injury, abuse, or disability.
- If the sponsor pays any of your medical expenses, we may be required to give the sponsor your name, date of birth, and Medicare ID or social security number.

This information may be used or shared to:

- Complete and publish the results of the study described in this form,
- Study the results of this research,
- Check if this study was done correctly, and
- Comply with non-research obligations (if we think you or someone else could be harmed).

You may look at or copy the information that may be used or disclosed. However, for certain types of research studies, some of the research information may not be available to you during the study. This does not affect your right to see what is in your medical (hospital) records.

There is no time limit for the use or sharing of your information. Researchers continue to analyze data for many years, and it is not always possible to know when they will be done. If your information will be banked as part of this study, it may be used in the future for other research. We would not ask for your permission prior to this future research.

Your permission for the use or sharing of your information will not expire, but you may cancel it at any time. You can do this by notifying the study team in writing. If you cancel your permission, no new information will be collected about you, but information that has already been collected may still be used and shared with others.

The use or sharing of your information will follow privacy laws, but these laws only apply to doctors, hospitals, and other health care providers. Some people who receive your health information as part of this study may share it with others without your permission if doing so is permitted by the laws they must follow.

If the results of the study are published, information that identifies you would not be used.

Your permission is documented by signing this form below. If you decide that we cannot use or share your information, you cannot participate in this study.

12. Would it cost me money to be in the registry?

If you take part in this study, there would be no cost to you and no cost to your insurance company.

13. What if I were injured because I joined the registry?

If you think you have been harmed from this registry, please call Dr. Zhao at 206-987-2057.

14. Would I be paid if I join this registry?

You will not be paid to take part in this registry.

15. Who do I contact if I have problems, questions or want more information?

If I have questions or would like to know about …	You can call …	At …

If I have questions or would like to know about …	**You can call …**	**At …**
Emergencies **General study questions** **Research-related injuries** **Any research concerns or complaints**	**Dr. Zhao**	**Phone: 206-987-2057**
Your rights as a research participant **Study questions, concerns or complaints.** **Contacting someone outside of study team**	**Institutional Review Board** **This is a group of scientists and community members who make sure research meet legal and ethical standards.**	**Phone: 206-987-7804**

16. If I join the registry, can I stop?

Yes. Taking part in research is always a choice. If you decide to be in the registry, you can change your mind at any time. We ask that you tell Dr. Zhao. You can contact this person by phone at 206-987-2682.

If you choose to leave the registry, it will not affect your care at Seattle Children's. You will not lose any benefits or be penalized if you choose to leave the registry.

17. What would my signature on this form mean?

Your signature on this form would mean:

- The registry was explained to you.
- You had a chance to ask all the questions you have at this time. All your questions have been answered in a way that is clear.
- You understand that the persons listed on this form will answer any other questions you may have about the registry or your rights as a registry participant.
- **You have rights as a research participant. We will tell you about new information or changes to the study that may affect your health or your willingness to stay in the registry.**
- By signing this consent form, you do not give up any of your legal rights. The researcher(s) or sponsor(s) are not relieved of any liability they may have.
    - You agree to take part in the registry.
    - If the person reading this form is a parent/ legally authorized representative, you agree to have your child take part in this registry.
    - You permit the creation, use, and sharing of your health information for the purposes of this registry as described in Section 11 above.

Please Note: If the person taking part in this registry is a foster child or a ward of the state, then please tell the researcher or their staff.

If using electronic documentation *(this means using something like a computer or phone instead of paper)*: *You agree this form and any later updates to this form and notices provided in connection with this study may be* ***provided*** *to you in an electronic version. You agree that you are able to* ***electronically receive, review, and save*** *a printed or electronic copy of this form containing your signature. We and you agree to* ***electronically sign*** *this form. We and you agree that* ***our actions*** *to electronically sign this form document your assent. We and you agree that our electronic signatures* ***have the same meaning and effect as handwritten signatures****. You understand that you can request a paper form if you would prefer to use a paper assent form.*

____

Printed Name of Research Participant

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Signature of Research Participant (required if 13 years or older)

____________ __________

Date *Time*

If using electronic documentation: *You agree this form and any later updates to this form and notices provided in connection with this study may be* ***provided*** *to you in an electronic version. You agree that you are able to* ***electronically receive, review, and save*** *a printed or electronic copy of this form containing your signature. We and you agree to* ***electronically sign*** *this form. We and you agree that* ***our actions*** *to electronically sign this form document your informed consent. We and you agree that our electronic signatures* ***have the same meaning and effect as handwritten signatures****. You understand that you can request a paper form if you would prefer to use a paper consent form.*

____

Printed Name of Parent or Legally Authorized Representative

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Signature of Parent or Legally Authorized Representative

____________ __________

Date *Time*

For study team use only:

If signature of second parent not obtained, indicate why: (select one)

- ☐ The IRB determined that the permission of one parent is sufficient.
- ☐ Second parent is deceased, unknown, incompetent or not reasonably available
- ☐ Only one parent has legal responsibility for the care and custody of the child

For study team use only (fill out for any enrolled minors and any enrolled adult participants incapable of providing consent):

Assent

- ☐ Obtained
- ☐ Not obtained because the capability of the subject is so limited that the subject cannot reasonably be consulted.

18. Researcher's Signature

I have fully explained the registry described by this form. I have answered the participant and/or parent/ legally authorized representatives questions and will answer any future questions to the best of my ability. I will tell the family and/or the person taking part in this research of any changes in the procedures or in the possible harms/possible benefits of the study that may affect their health or their willingness to stay in the study.

____
Printed Name of Researcher Obtaining Parental Permission or Consent

____
Signature of Researcher Obtaining Parental Permission or Consent

____
Date

____
Time

Original form to: Research Team File

Copies to: Participant, Parent(s)