

**PARENTAL PERMISSION FORM (INSPPIRE2)**  
**CONSENT FORM: Ages 18 and up**  
**ASSENT FORM: Ages 13-17**

**Study Title: WebMAP Chronic Pancreatitis**

**Principal Researcher: Dr. Tonya Palermo**

**The Research Team:**

Name/Degree	Phone Number	E-mail
Tonya Palermo, PhD	206-884-4208	<a href="mailto:tonya.palermo@seattlechildrens.org">tonya.palermo@seattlechildrens.org</a>
Tricia Jessen-Fiddick, BS	206-884-1308	<a href="mailto:tricia.fiddick@seattlechildrens.org">tricia.fiddick@seattlechildrens.org</a>
Homer Aalfs, BS	206-884-1845	<a href="mailto:homer.aalfs@seattlechildrens.org">homer.aalfs@seattlechildrens.org</a>

If you have questions about your rights as a research study participant, you can call the Institutional Review Board at (206) 987-7804.

**1. Researchers' Statement:**

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

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 research team will discuss with you. If you decide that you would like to take part in this research study, 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.

**Teen Participants:** This form also serves as an assent form. That means that if you choose to take part in this research study, 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 study.

**Parents/Legally authorized representatives:** You have the option of having your child or teen join a research study. This is a parental permission form. It provides a summary of the information the research team will discuss with you. If you decide that your child can take part

in this study, 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 you or your child/teen.

## **2. What you should know about this study:**

- This form explains what would happen if you join this research study.
- Please read it carefully. Take as much time as you need.
- Please ask the research team questions about anything that is not clear.
- You can ask questions about the study any time.
- If you choose not to be in the study, 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 study at anytime.
- You would not lose benefits or be penalized if you decide not to take part in the study or to quit the study later.

## **3. What is the goal of this study?**

The goal of any research study is to answer questions. We (the research team listed on the front of this form and our staff) are doing this research study

- To help children who have chronic or acute recurring pancreatitis
- To learn more about pain management approaches for children with chronic or acute recurring pancreatitis

## **4. Why do I have the option of joining the study?**

You have the option to take part in this research study because you have chronic or acute recurring pancreatitis and are part of the INSPPIRE network.

## **5. How many people will take part in the study?**

We think that about 260 youth and their parents will take part in this research study, about 30 will be from Seattle Children's.

## **6. If I agree to join this study, what would I need to do?**

## Surveys & Diaries

If you join the study, all participants will complete questionnaires at 3 different times:

- Timepoint 1: At the time of enrolling in the study
- Timepoint 2: Immediately following completion of the online pain management program
- Timepoint 3: 6 months following completion of the online pain management program

The surveys will take 20-30 minutes to complete each time. Children will also fill out a diary for 7 days during each time point, this will take 1-2 minutes per day. The surveys will ask about your health and well-being.

## Pain Management program:

If you join this study, we would randomly assign you to one of two study groups-**Group A** or **Group B**. Randomization means that you will be put into a group by chance. This means whichever group you are in would be decided by chance, like flipping a coin. Neither you nor the researcher will know in advance which group you will be in. People in **Group A** and **Group B** would have access to different versions of the study website that focus on education or skills training. Both groups will continue with standard medical care prescribed by their treating specialist during their participation in the study.

### Group A:

If you were randomized into Group A, you would complete study assessments at Time 1, 2 and 3. In addition, both adolescents and their parents would have access the internet program focused on skills training. Both adolescents and parents would be asked to complete weekly readings and assignments on the Internet using their own, separate versions of the Internet program. Weekly readings and assignments would take 20 to 30 minutes to complete. You would be using this website regularly for 8 to 12 weeks.

During your participation, a member of the study team would call you to check in with you, and to see if there are any problems using the program.

### Group B:

If you are randomized into Group B, in addition to completing study assessments at Time 1, 2, and 3, both adolescents and their parents would have access to the internet program focused on education about managing chronic pain in youth. Both adolescents and parents would be asked to complete weekly readings on the Internet using their own, separate versions of the Internet program. Weekly readings would take 20 to 30 minutes to complete. You would be using this website regularly for 8 to 12 weeks.

## INSPPIRE 2 Data

Your INSPPIRE 2 subject ID will be used in this study by Seattle Children's to access previously collected data and blood sample. The blood sample will be used to look at genetic co-variants associated with pancreatitis.

### 7. How long would I be in the study?

If you choose to take part in all of the study assessments, you would be in the study for about 9 months.

If you join the study, you can decide to stop **at any time for any reason**. If you decided to stop, you would need to talk with Dr. Palermo or a member of the study team, so you leave the study in a safe way.

The research team could also decide to take you out of the study. This might happen if we find out it is not safe for you to stay in the study or if you do not follow the study instructions.

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

There are potential harms or risks if you take part in this study. Some of the questions you and your parent would be asked may seem personal. You may refuse to answer 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 than the research team or our collaborators may find out that you were in the research 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 study?

**Potential Benefits for You:** You may or may not benefit personally from participating in this study. You may find that the Internet program helps you manage pain better.

**Potential Benefits for Others:** We hope to use information we get from this study to benefit others who have pancreatitis in the future.

## 10. What other options do I have?

You participation will not affect your health care. You do not have to participate in this study. If you choose to participate in this study, you can withdraw from the study at any time. You would tell the research staff if you would like to withdraw.

## 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.

The following section in *italics* will be completed by different individuals depending on the age of the minor participants. Because adolescents may agree to the use or sharing of certain kinds of information on their own, adolescents fitting the criteria below will complete this section for themselves. For all other minor participants, the parent/legally authorized representative providing permission will complete this section on behalf of the child.

*Please consider whether we may use or share the information listed below for this research. If you agree, please mark your permission with your initials.*

\_\_\_\_\_ *Behavioral or mental health/illness (13 and above)*

## Certificate of Confidentiality

We have a Certificate of Confidentiality from the federal government. It means we can't be forced to give out information about you if you take part in this study. This is true even if we are asked to by a court of law. It's not likely that someone would ask us to give out your personal information but this Certificate helps protect it. However, there are times when we would still need to share information about you.

Even with the Certificate, your information could still be given out under these situations:

- Federal agencies, like the FDA, may review study records
- Seattle Children's or the funding agency may look at study records to make sure the study is being done well
- You or a family member could share information about you or your part in this research study
- You give written permission to an insurer, employer or other person to receive information about you
- We must report child abuse or if you intend to hurt yourself or others

## **12. Would it cost me money to be in the study?**

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 study?**

If you think you have been harmed from this study, please call Principal Investigator Dr. Tonya Palermo at 206-884-4208.

## **14. Would I be paid if I join this study?**

You and your parent will each receive a \$50 gift card after completing an assessment time point. This would be a total of \$300 per family if you both complete all assessment time points.

The IRS has certain rules about paying people who take part in research studies. If you took part in this study, we would ask you to provide your name and mailing address so we could pay you.

You can be in this study even if you do not give us this information. If you decide not to give us this information, you would receive no payment.

The payments you would receive for being in this study might be taxable. Seattle Children's is required to report to the IRS study payments of \$600 or more made to anyone in any year.





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

<b>? If I have questions or would like to know about ...</b>	<b>👤 You can call ...</b>	<b>📞 At ...</b>
<ul style="list-style-type: none"> <li>• Emergencies</li> <li>• General study questions</li> <li>• Research-related injuries</li> <li>• Any research concerns or complaints</li> </ul>	Dr. Tonya Palermo	Phone: 206-884-4208
<ul style="list-style-type: none"> <li>• Emergencies</li> <li>• General study questions</li> <li>• Research-related injuries</li> <li>• Any research concerns or complaints</li> </ul>	Tricia Jessen-Fiddick	Phone: 206-884-1308
<ul style="list-style-type: none"> <li>• Your rights as a research participant</li> <li>• Study questions, concerns or complaints.</li> <li>• Contacting someone outside of study team</li> </ul>	<b>Institutional Review Board</b> 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 study, can I stop?**

Yes. Taking part in research is always a choice. If you decide to be in the study, you can change your mind at any time. We ask that you tell Homer Aalfs. You can contact this person by calling 206-884-1845.

If you choose to leave the study, 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 study.

**17. What would my signature on this form mean?**

Your permission would mean:

- The research study 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 study or your rights as a research study 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 study.**
- By typing your name below, 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 research study.
  - If the person reading this form is a parent/ legally authorized representative, you agree to have your child take part in this research study.
  - You permit the creation, use, and sharing of your or your child's health information for the purposes of this research study as described in Section 11 above.

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## PARENT PARTICIPANT ADDENDUM

### 18 Parent Participants

#### Why do parents have the option of taking part?

As a part of this research study, we would like to have you fill out some questionnaires. We plan to use this information to further assist in our investigation of the research question.

If you join the study, you would complete online survey questionnaires at 3 time points.

- Timepoint 1: At the time of enrolling in the study
- Timepoint 2: Immediately following completion of the online pain management program
- Timepoint 3: 6 months following completion of the online pain management program

The surveys will take 20-30 minutes to complete each time.

You will also be randomized to the same group (Group A or Group B) as your child and participant in the weekly readings on the online program.

#### Do parents have to take part?

Taking part in research is optional. If you decide not to join you will not be penalized nor lose any benefits that you are otherwise entitled to.

#### What are the possible risks?

The main risk of participating as a parent in this study would be breach of confidentiality.

#### What are the possible benefits?

You may find that the internet program helps your teen manage pain better.

#### How will you protect my information and privacy?

The same general rules and procedures as discussed above about your child's information will apply to the use and sharing of your information. The information will relate to you and your health, it may be used by or shared with others involved in these research or in future research studies, and its use or sharing will be consistent with the purpose for which it was collected.

You can find the rules and procedures in the form under section 11 - "What about confidentiality and privacy?"

#### Can I change my mind?

You can decide to take part and change your mind at any time. Research is always voluntary. If you change your mind, your relationship with Seattle Children's and your medical provider will

not be impacted in any way. Any information that you have provided will have all identifying information removed thus protecting your identity.

If you have questions about the study, your rights, or feel you have been harmed by the study, please contact the study team members listed on the front of this form.

**What would my consent mean?**

- You agree to take part in the research study.
- You keep all your legal rights. The researcher(s) or sponsor(s) are not relieved of any liability they may have.
- You permit the creation, use, and sharing of your health information for the purposes of this research study.