

**Developing a Tool to Support Shared Decision-Making Post-Concussion  
Between Adolescents, Parents and Clinicians**

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## AIM 4B: INFORMATION SHEET

**Study Title: Family shared decision making: Piloting a decision aid for adolescent sport**

**Principal Researcher: Dr. Emily Kroshus**

**Address: 2001 8th Ave Seattle, WA 9812**

**The Research Team:**

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

**Key Information:** You have the option to take part in a research study. This is a consent, assent, and parental permission form. The goal of this form is to give potential participants the information they need to decide whether to participate in the research. The first portion of this form includes a summary of the key information about the research study. Participation in the study is voluntary.

**Potential Teen Participants:** This information sheet also serves as an assent form. That means that if you choose to take part in this research study, you would confirm your choice. Your parent or legally authorized representative would also need to give their permission and agree 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 verbally or electronically confirm your decision.

**Joining the study as a parent (and/or Legally Authorized Representative):** Parents also have the option to take part in this research study. This form also serves as a consent form for parent participation. The word “you” in this form may refer to you and/or your child.

If you are interested in participating after reviewing the key information below, continue through the portion of the form containing the “Detailed Information” about the study. Feel free to take notes, write questions or highlight any part of this form.

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## What should I 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 any time.
- You would not lose benefits or be penalized if you decide not to take part in the study or to quit the study later.

## What is the purpose 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 answer the following question:

- How do families and their medical provider discuss decisions to resume or stop sport participation after recovery from a sport-related concussion?
- How useful are tools in helping families make these decisions?

## How long would I be in the study and what will I need to do?

If you choose to take part in all the study visits, you would be in the study until all data has been collected, or up until 6 months from your first participation. You will be asked to complete a minimum of 3 surveys at the following timepoints: before your first visit, after your visit and after each subsequent visit, and 3 months after your initial visit.

More detailed information about the study procedures can be found under **"If I agree to join this study, what would I need to do?"**

## What are the risks or discomforts if I join this study?

You might feel uncomfortable answering some questions. You could skip any questions you did 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.

## Will being in this study benefit me in any way?

There are no benefits to you from your taking part in this research. We cannot promise any benefits to others from your taking part in this research. We cannot promise any benefits to others from your taking part in this research.

## What are the alternatives if I choose not to participate?

Participation in research is completely voluntary. You can decide to participate or not to participate.

**Detailed Information:** The following is more detailed information about this study in addition to the information listed above.

## Why do I have the option of joining the study?

You have the option to take part in this research study because you have been identified as one or more of the following:

- A teen between the ages of 11-17 years
- A teen who has sustained a concussion during the study period
- A parent of a teen who has any of the above

## How many people will take part in the study?

We think that about 80 people will take part in this research study at Seattle Children's. We anticipate that 700 participants will take part in this study overall at Seattle Children's.

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

If you join the study, you would complete a minimum of three surveys. You will also be asked to complete a tool that will be shared with your clinician (via a link in the patient's chart) prior to your first appointment. The first survey would be before your first clinic visit. The follow-up survey(s) would be after each subsequent clinic visit (up to and including your final clinic visit). The third survey would be 3 months after your initial clinic visit. We think that each survey will take about 10 minutes to complete. The surveys will ask about demographic information, your experiences during your clinic visit, and the return to sport decision making process. We will also ask about your/your child's recovery.

All surveys (and tools) will be completed remotely. We will reach out to you by telephone, email, or text message and you may choose to complete it over the phone, or request the link to the

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online survey via email or text message. For surveys following the clinic visit, you will have the option to take the surveys immediately following your visit.

Identifiers will be removed from the identifiable private information and after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative

**What are my responsibilities if I take part in the study?**

If you take part in this research, you will be responsible to: complete a minimum of three surveys and complete a tool about the return to sport decision.

**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 regarding your Protected Health Information (PHI). Only with your permission may we create, use, or share your PHI for this study. The following describes the types of PHI 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.

PHI 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, or
- Information specific to you like your name, address, birthday, ethnic origin, or identifying numbers like your social security number.

PHI may be created by, 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,
- Other people or organizations involved with your health care
- Review boards (such as Seattle Children's Institutional Review Board), data and safety monitoring boards, and others responsible for overseeing the conduct of research (such as monitors),
- Governmental agencies like the U.S. Food and Drug Administration (FDA), the Department of Health and Human Services (DHHS) and similar agencies in other countries, or
- Public health authorities to whom we are required by law to report information for the prevention or control of disease, injury, or disability.

PHI may be created, used, or shared to:

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

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

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. However, information that has already been collected may still be used and shared with others.

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 will not ask for your permission prior to this future research.

We will follow privacy laws when creating, using, or sharing your information, 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 will not be used.

Your permission is documented by verbally agreeing to participate in the study. If you decide that we cannot create, use or share your information, you cannot participate in this study.

*The creation, use or sharing of specific kinds of information requires that certain minors provide separate permission. Adolescents who are within the age ranges below will complete this section. For all other minor participants, the parent/legally authorized representative providing permission will complete this section on behalf of the child. You will need to provide your verbal or electronic permission to use or share each kind of information.*

- *Behavioral or mental health/illness (age 13 and older)*

*Your agreement to participate will indicate your authorization to use this information.*

### **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

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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

### **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 for the research procedures.

### **What if I were injured because I joined the study?**

If you think you have been harmed from this study, please call 206-987-1520.

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

To thank you for taking part in the study we would give you \$25 after the first survey is complete, \$25 after the follow-up surveys are complete, and \$50 after the 3-month follow-up survey is complete. You would receive the payment on a reloadable debit/gift card called a ClinCard. The study staff will provide you with additional information about how the ClinCard works. It is important that you do not lose the ClinCard. Costs for replacing a lost or stolen ClinCard will be your responsibility. The cost to replace the ClinCard is \$7.

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, mailing address, and social security number 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 totaling \$600 or more made to anyone in any year.

### **If I join the study, can I stop, or can I be removed?**






If you join the study, you can decide to stop **at any time for any reason**. If you decided to stop, we ask that you talk with Dr. Emily Kroshus. You can contact this person by calling 206-884-5326.

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.

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

This study has been reviewed and approved by an Institutional Review Board (IRB). You may contact the IRB, see the information below.

 If I have questions or would like to know about ...	 You can call ...	 At ...
<ul style="list-style-type: none"> <li>• <b>Emergencies</b></li> <li>• <b>General study questions</b></li> <li>• <b>Research-related injuries</b></li> <li>• <b>Any research concerns or complaints</b></li> </ul>	<b>Dr. Emily Kroshus</b>	<b>Phone: 206-884-5326</b>
<ul style="list-style-type: none"> <li>• <b>Your rights as a research participant</b></li> <li>• <b>Study questions, concerns or complaints.</b></li> <li>• <b>Contacting someone outside of study team</b></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.	<b>Phone: (206) 987-7804</b>

### More Information:

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

## What would my agreement to be in the study mean?

Your agreement means:

- 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.

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- 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 agreeing to be in the study, 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 and/or your child's health information for the purposes of this research study as described in the "**What about confidentiality and privacy?**" section above.

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

<b>For study team use only (fill out for any enrolled minors):</b>
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Assent

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

**Original form to:**

Research Team File

**Copies to:**

Participant