

Information and Consent



Research Title: Cancer Pain Assessment and Management in Children: Using Social Media to Bridge the Gap; **Pain Squad App Study**

Researchers:

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Introduction

Your child/teen is being invited to take part in the research study named above. The main researcher on this study is Dr. Christine Chambers, a Professor and Researcher at Dalhousie University and the IWK Health Centre. This form provides information about the study. It is important that you and your child/teen understands the purpose of the study, how it may affect you and your child/teen, the risks and benefits associated with the study and what you and your child will be asked to do before you decide if you will participate. The purpose of this Information Form is to help you decide if it is in your and your child's best interest to take part in this study. You and your child/teen do not have to take part in this study. Taking part is entirely voluntary (up to you). Informed consent starts with the initial contact about the study and continues until the end of the study. You and your child/teen may decide not to take part or you

may withdraw from the study at any time. If you have any questions that this form does not answer, a member of the IWK Health Centre research team will be happy to give you further information.

Why are the researchers doing the study?

The overall goal of this study is to gain information on pain experienced by children and teens with cancer using an iPhone cancer pain application called “Pain Squad”.

How will the researchers do the study?

Participants will be children and teens of parents who have completed the “Making Cancer Less Painful for Kids” online research survey. Parents who opt-in to learn about future research in this survey will be contacted and their children/teens invited to participate in this study, the **Pain Squad App study**. Your child’s responses on the Pain Squad app will be used to learn more about pain experienced by children and teens with cancer, and whether this changes after the “Making Cancer Less Painful for Kids” campaign (#kidscancerpain). The study is being led by Dr. Christine Chambers, a Professor of Pediatrics and Psychology at Dalhousie University and conducted by Cancer Knowledge Network (CKN).

What does the study entail?

Your child/teen will be asked to download the free Pain Squad app from the iTunes App Store onto their Apple device (e.g., iPhone, iTouch, iPad) and complete a pain assessment twice daily for one week. Pain Squad will tell your child/teen when it is time to fill it out by a notification and making a beeping noise. The application will notify you/beep two times a day: when they wake up and just before bed. Each time they fill out Pain Squad, they will be asked to rate how much pain they have, show where they hurt on a body diagram, choose words that describe their pain, and rate how the pain affects the things they do, through surveys. Your child/teen will also be asked to record pain medicines that they use and any other things they do to reduce their pain. The surveys will take them about 5-10 minutes each day to do. At the end of the one-week period your child/teen will be asked to download the pain assessment report generated from Pain Squad app and email it to the research team at CPPRWest@iwk.nshealth.ca. You and your child/teen may be contacted again in 12 months’ time to complete an additional one-week Pain Squad App pain assessment. You and your child/teen will be able to call a member of the research team from Monday to Friday between 9am – 5pm (AST) if you have questions about the Pain Squad application (902-470-6906).

Potential harms and burdens

There are no expected harms for taking part in this study. Children/Teens may experience emotional upset while filling out the surveys on the Pain Squad app. If so, you are encouraged to contact their health care provider. Although taking part may not benefit you or your child/teen directly, the results may benefit other families by helping researchers to understand more about pain experienced by children and teens with cancer and the impact of the “Making Cancer Less Painful for Kids” campaign.

What alternatives to participation do I have?

Before deciding to enroll in this study, you should know that you and your child/teen do not have to take part.

Can I withdraw from the study?

Taking part in this study is entirely voluntary (your choice). You and your child/teen can stop at any time. You and your child/teen may decide at the end of the one-week period if you wish to email the Pain Squad app report to the researchers. If you or your child/teen chooses to withdraw from this sub-study, it will not impact your involvement with the survey you participated in on CKN (the data from the Pain Squad and the survey cannot be linked).

Costs and reimbursements

There are no costs associated with participating. After the completion of the first one-week Pain Squad app assessment your child/teen will receive a \$25 e-gift card. Those who complete the first Pain Squad app assessment and choose to complete the 2nd Pain Squad app assessment in 12 months' time will receive an additional \$40 e-gift card. Please note your contact information will not be linked to the Pain Squad app responses.

Are there any conflicts of interest?

None.

What about possible profit from commercialization of the study results?

None.

How will my privacy be protected? What are my research rights?

The study has been designed so that your responses are kept completely confidential. The Pain Squad app does not have any network or server connectivity. All data collected on the device is stored directly on the device and cannot be accessed by anyone other than the user. As with any email that you send, there is a small risk of loss of privacy and by participating in this study and sending us the report by email you and your child/teen accept this risk. The email address that you are sending the report to is an IWK Health Centre email address and only the research team has access to it. All electronic Pain Squad app records emailed to the researchers will be anonymized upon receipt (your child's name and email address removed) and will be kept secure at the IWK Health Centre in Halifax, NS, Canada for a minimum of 5 years following publication. Only research staff and the IWK Health Centre's Research Ethics Board will be able to access study information.

Your child's/teen's completion of the Pain Squad app pain assessment will serve as your consent for them to participate. In no way does this waive your legal rights nor release the investigators, sponsors, or involved institutions from their legal and professional responsibilities. If you have any questions at any time during or after the study about the research in general you may contact the IWK Health Centre's Research Office at (902) 470-8765, Monday-Friday, 9am-5pm (AST).

How will I be informed of study results?

A summary of the results will be posted on our website (www.pediatric-pain.ca) and on social media (Facebook '[Centre for Pediatric Pain Research](#)' & Twitter: [@DrCChambers](#)) upon study completion (expected Spring 2018).

What if I have questions or problems?

Comments, questions, or concerns can be directed to Dr. Christine Chambers at Christine.Chambers@dal.ca