BROWN UNIVERSITY
PARENT PERMISSION FOR RESEARCH PARTICIPATION OF MINOR

Improving Pain Management after Wisdom Tooth Extraction Surgery: iPAWS
Version #2, October 14, 2025

KEY INFORMATION:
Dr. Melissa Pielech and her associates at Brown University are conducting a research study. Your child was selected as possible participant after expressing interest. **Your child's participation in this research study is voluntary.**

- PURPOSE: This research study is about learning whether iPAWS, an online education program, helps young people cope with pain after wisdom tooth extraction surgery.
- PROCEDURES: If your child takes part in this study, your child will be asked to participate in up to four study sessions—two before and two after their surgery. During each session, they will answer questions about their health, pain, mood, sleep, and substance use habits. In the week of their surgery, they will receive either educational materials or those materials plus iPAWS. They'll also use a smartphone app to answer daily questions for up to 6 weeks. Three weeks after surgery, they will have a conversation—called an "exit interview"—with a research staff member. This is their chance to give feedback about the educational program and the study. The conversation will be audio recorded for research purposes. The last study session will take place 3 months after surgery.
- TIME INVOLVED: Study sessions will take a total of about 6-7 hours of their time. Using the smartphone app will take about 5-10 minutes per day for 6 weeks. The entire study is approximately 6 weeks, plus a final study session 3 months later.
- COMPENSATION: Your child will receive up to $360 for their time if they complete the study.
- RISKS: Possible risks are emotional discomfort, breaches of confidentiality, and coercion (meaning feeling pressured to participate).
- BENEFITS: Your child may not directly benefit from being in this research study.
- ALTERNATIVES TO PARTICIPATION: We do not offer alternatives to this study.

1. **Researcher:**

Melissa Pielech, PhD is the principal investigator. Dr. Pielech can be reached at 401-863-6583 or melissa_pielech@brown.edu.

Study sponsor: The National Institutes of Health is funding this study.

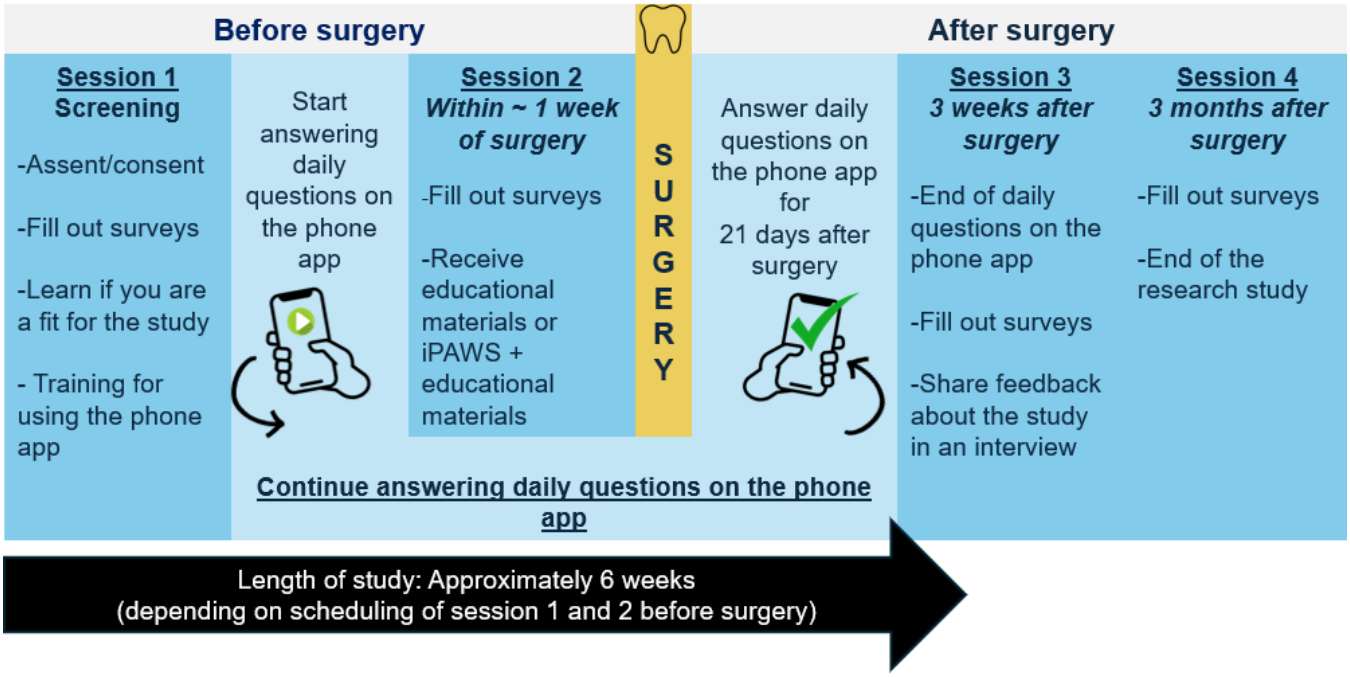
2. **What is this study about?**

This study wants to find out if an online program called iPAWS can help young people deal with pain and make healthy choices, like staying away from marijuana and other drugs, after having their wisdom teeth removed. The program is just one session that lasts about 45 minutes. The program includes activities to help your child learn and use new skills for after surgery and in your everyday life. We also want to understand how iPAWS works. We plan to enroll up to 150 young people and their parents.

Your child is being asked to join this study because they are between 15 and 20 years old and are about to have wisdom tooth surgery for the first time.

As their parent/ guardian, you are also invited to join the study to see if iPAWS can help you support your child after surgery. Your child can still take part in the study even if you choose not to.

3. **What will my child be asked to do?** Here's a picture summarizing the study:



Randomization: This study will have 2 different groups of research participants:

- Participants in group 1 will only receive educational materials at Session 2
- Participants in group 2 will receive education materials and iPAWS at Session 2

To decide which group your child will be in, we will use a method of chance. This method is like flipping a coin.

- **Session 1:** In the month before your child's surgery, your child will attend a screening session, either in person or on zoom (based on your family's preference) that will take about 1 hour. In this session:
    - Study staff will fully explain the purpose and procedures of the study and answer any questions you and your child have.
    - Your child will answer some survey questions about their health history, pain, mood, and health behaviors, including substance use, to confirm if they are eligible to participate in the study.
    - If still eligible, your child will be trained to use a phone app (called "EMA") that asks you questions and collects information about their daily life and activities.
    - This app does not require WIFI or internet connection to work. We recommend that your child respond to the app at a time and place that allows for privacy. Your child can skip or delay responding when necessary

- After session 1 your child will begin using the EMA app every day. We will check in with your child after 3 or 4 days to see if they have any questions or issues with the app.
- Throughout the study we will check in weekly (5–10-minute phone call) to see how your child is doing with the app and answer any questions they have.

- **Session 2:** Session 2 will occur on zoom or in person (based on your families' preference) within approximately 7 days of their surgery date and will take about 2 hours. In this session they will:
    - Complete surveys about pain, mood, and health behaviors
    - Next, they will either receive educational materials about post -surgical care or participate in iPAWS (the brief, online skills and education program about pain management and healthy behaviors after surgery) and receive educational materials about post-surgical care.
- After session 2, they will continue to use the EMA app every day before surgery and for three weeks after surgery to answer questions about their pain, recovery from surgery, and other health behaviors. We'll continue to check in weekly (via 5-10 minute phone calls) to see how they're doing and answer any questions about the app.

- **Session 3:** At 3 weeks after your surgery, your child will complete follow up surveys about pain, mood, and health behaviors and an exit interview to provide feedback about the study procedures and educational program. The exit interview will be audio recorded for research purposes. Audio recordings will be stored securely on password-protected Brown servers and destroyed after they are transcribed or the study ends, whichever comes first. Video will not be recorded. The recording can be stopped at any time if they no longer feel comfortable. This session will take about 1.5 hours and will occur on Zoom or in person, depending on what you and your child choose.

- **Session 4:** At 3 months after surgery, your child will again complete follow up surveys about pain, mood, and health behaviors. This session lasts approximately 1 hour and will occur on zoom or in person, depending on your preference.

Your child may refuse to answer or skip any questions at any time during the study

4. **<u>Will my child be paid?</u>**

If your child participates, they will receive up to $360, via Amazon gift cards or a Clincard, for their time.

Session	Payment
Session 1	$15
Session 2	$40
**Up to 3 weeks of daily EMA before surgery ($5 per day + $5 for up to three weekly check ins)	~$120
3 weeks of daily EMA after surgery ($5 per day + $5 for up to three weekly check ins)	$120
Session 3 (3-week post-surgery)	$30
Session 4 (3 -month post-surgery)	$35
Total:	**~$360**

**depending on the scheduling of study sessions before surgery

Payment schedule: Your child will be compensated throughout the study at up to 9 time points: Session 1, Session 2, weekly throughout the pre-surgery EMA period (up to 3 weeks), weekly throughout the three-week post-surgery EMA period, Session 3, and Session 4.

Payment format: Your child will choose to receive compensation in the form of Amazon gift cards or a Clincard. ClinCard is a pre-paid Mastercard that works like a debit card. If they choose ClinCard, they will be given one card for the entire time of their participation and this card may be used to pay them in any future Brown University studies that use ClinCard. They will also get information about how to use this card and whom to call if they have any questions. Be sure to read this information, including the cardholder agreement from Greenphire.

Money will be added to their card based on the study's payment schedule (see above). Your child can use this card online or at any store that accepts Mastercard. Please read the FAQ information sheet from the study team for details about the ways you can use the card, some of which may involve fees that will reduce the amount of money on the card.

This card is administered by an outside company called Greenphire. Greenphire will be given your child's name, address, and date of birth. They will use this information only as part of the payment system, and it will not be given or sold to any other company. Greenphire will not receive any information about their health status or the study in which they are participating. If their card is lost or stolen, please call the study team for a free replacement card. If they request a replacement card from Greenphire directly, they may be charged a fee.

If your child earns $600 or more from Brown University in a single calendar year (either in a one study or across multiple studies), Brown will request their social security number to correctly identify them in the payment system and issue them an IRS 1099 Form. You may also be asked to complete a Form W9 for your child. This may affect their taxes. Only payments for being in research studies will be used to decide if you should receive the IRS form. Money for study-related parking, food, and other expenses are not included in this IRS disclosure.

5. **What are the risks?**

The risks of participating in the study are minimal, and include:

- **Emotional discomfort:** Some questions we ask may be upsetting or your child may feel uncomfortable answering them. If they do not wish to answer a question, they can skip it and go to the next or stop doing the study at any time. We will make every effort to minimize any discomfort your child may feel during this process.
- **Loss of confidentiality:** As this study involves the use of your child's identifiable, personal information, there is a chance that a loss of confidentiality or privacy will occur. We have procedures in place (detailed below) to reduce the chances of this happening. Your child's answers will be confidential and will not be shared with you.
- **Undue influence:** Undue influence can happen when the payment a child receives to participate in a research study is large. Such pressure is unlikely in this study because payments are fair for the time and effort required and payment is similar to other studies like this one.

6. **What are the benefits?**

Your child may not directly benefit from being in this research study. However, receipt of the pre-surgical program may improve your child's ability to effectively manage pain after surgery.

This project will add to our knowledge about how to help teens cope with and manage pain before and after an acutely painful procedure. This includes how to safely use and dispose of prescription pain medications if received. Our intention is that this knowledge will indirectly benefit the entire community, including study participants like your child.

7. **How will my child's information be protected?**

CONFIDENTIALITY: To protect your child's information, we will assign all of your child's data a code number. All of your child's information and responses will be identified only by this code number, not their name. Any information that identifies your child will be stored separately. It will be carefully protected on a secure, password-protected computer server that is available only to the research staff on this project. Information collected throughout the study is treated as confidential, will not be shared, and will be protected according to the rules of Brown University. Audio from the programs will be digitally recorded and stored on secure, password protected computer servers. Only members of the study team will have access to digital recordings of your child's voice. After the recording has been transcribed, the recording will be deleted. Your child's responses will not be linked to their identity, and their responses, participation in this study, and identifiable information will not be shared with anyone.

Your permission to participate form, your child's assent form, and all other identifying information will be stored in a locked filing cabinet separate from questionnaire responses and any other written or computer stored data (or a password protected database, if the permission/ assent forms are signed electronically). Your child will not be personally identified

in any reports or publications that may result from this study. Brown University staff sometimes review studies like this one to make sure they are being done safely and correctly. If a review of this study takes place, your child's records may be examined. The reviewers will protect your child's confidentiality

There are times when the law might require us to release your child's information without your permission. To give you some examples, your child reports any information that makes us suspect that they have been the victim of abuse or neglect, State Law requires that we report that information to the Department of Children, Youth, and Families (DCYF).

Certification of Confidentiality: To help us protect your child's privacy, we have a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify your child, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States federal or state government agency sponsoring the project and that will be used for auditing or program evaluation of agency funded projects. You should understand that a Certificate of Confidentiality does not prevent your child or a member of your family from voluntarily releasing information about their involvement in this research. The Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities of such as reports of child abuse and neglect, or harm to self or others.

8. **Are there any alternatives to this study?**

We do not offer any alternatives to participation.

9. **What if I want my child to stop participating or they want to stop?**

You do not have to give permission for your child to be in this study if you do not want them to be. Even if you decide for your child to be in this study, you can change your mind and they stop at any time. If you decide to stop participating in this research study, already collected data may not be removed from the study database
If you refuse to give your child permission to participate or they leave the study, you and their current or future relationship with Brown University, Dr. Pielech, Principal Investigator, or their treatment at the oral surgery clinic should not be impacted.

10. **Who can my child or I talk to if I have questions about this study?**

If you have any questions about your child's participation in this study, you can call Dr. Melissa Pielech at (401) 863-6583 or email melissa_pielech@brown.edu

11. **Who can I talk to if I have questions about my child's rights as a participant?**

If you have questions about your rights as a research participant, you can contact Brown University's Human Research Protection Program at 401-863-3050 or email them at IRB@Brown.edu.

You can also submit any concerns or complaints related to your child's participation in a human subjects research study using this link: https://brown.co1.qualtrics.com/jfe/form/SV_5p3gWaxVwu0S2d8

Your report can be submitted anonymously, and all responses will be kept confidential.

12. **Where can you find public information about this study?**
    A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by US 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.

13. **Permission to Participate**

Your signature below shows that you have read and understood the information in this document, you are the child's parent or legal guardian, and that you give permission for your child to volunteer as a research participant for this research study.

You acknowledge that even if you have granted permission for your child to enroll in this research study, if your child declines enrollment, resists participation, or chooses to withdraw, their decision prevails.

You will be offered a copy of this form.

_____

Parent/Legal Guardian's Signature and Date / PRINTED NAME

_____

Child's Name

Indicate Yes or No [any blank responses must be interpreted as permission NOT given]:

I give permission for my child to be audio recorded during this study: ☐ Yes ☐ No

- CONTACT FOR FUTURE STUDIES

Did parent/guardian verbally affirm their permission directly with the research team for their child to participate? ____Yes ____ No

Brown University IRB Approval Oct 16 2025