BROWN UNIVERSITY
CONSENT FOR RESEARCH PARTICIPATION

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

KEY INFORMATION:

You are invited to take part in a Brown University research study. Your participation 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: You will participate in up to four study sessions—two before and two after your surgery. During each session, you will answer questions about your health, pain, mood, sleep, and substance use habits. In the week of your surgery, you will receive either educational materials or those materials plus iPAWS. You'll also use a smartphone app to answer daily questions for up to 6 weeks. Three weeks after surgery, you will have a conversation—called an "exit interview"—with a research staff member. This is your 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 your 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: You will receive up to $360 for your time if you complete the study.
- RISKS: Possible risks are emotional discomfort, breaches of confidentiality, and coercion (meaning feeling pressured to participate).
- BENEFITS: You 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.

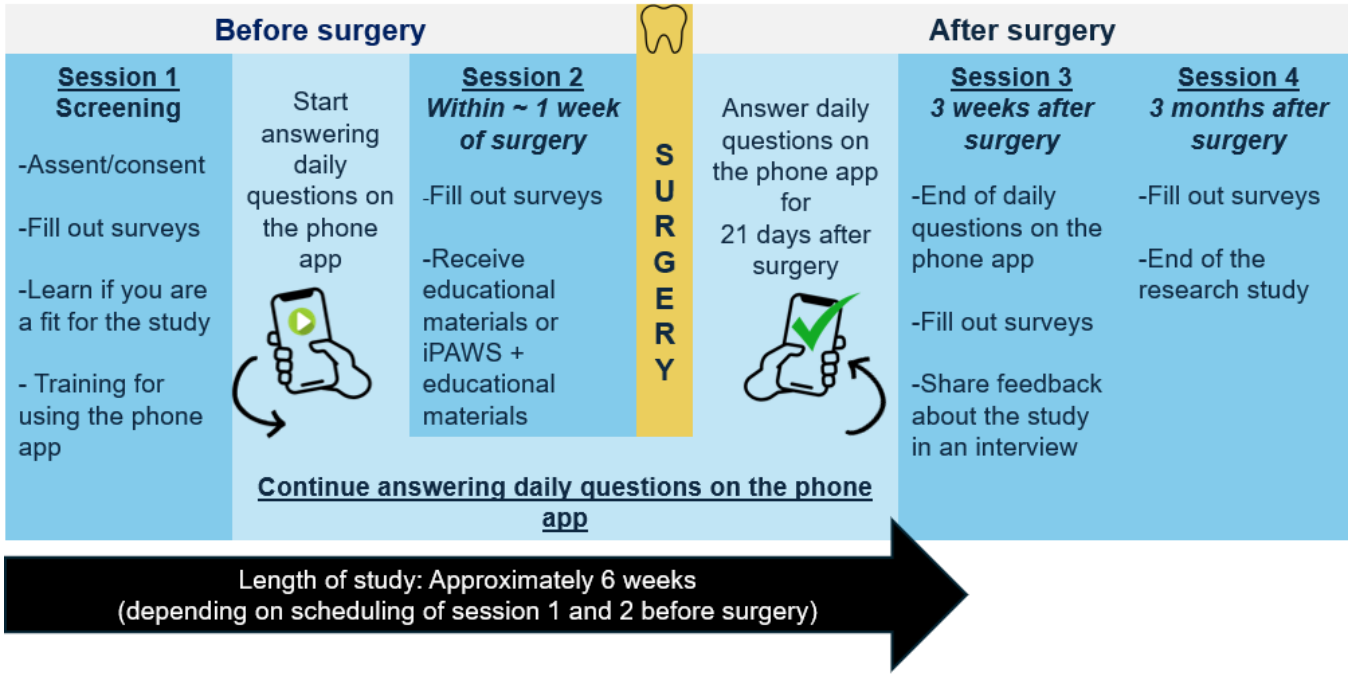
2. **What is this study about?**

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 you 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.

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

One of your parents or guardians will also be invited to join the study to see if iPAWS can help them support you after your surgery. You can still take part in the study even if your parent or guardian chooses not to.

3. **What will I be asked to do?** Here's a picture summarizing the parts of this 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 you will be in, we will use a method of chance. This method is like flipping a coin.

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

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

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

- **Session 3:** At 3 weeks after your surgery, you 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 you no longer feel comfortable. This session will take about 1.5 hours and will occur on Zoom or in person, depending on what you choose.

- **Session 4:** At 3 months after surgery, you 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.

You may refuse to answer or skip any questions at any time during the study.

4. <u>Will I be paid?</u>

You will receive up to $360.00 for your participation. You will be paid for all parts of the study you complete even if you stop the study early for any reason. You will be paid $15 for the Session 1 even if you are found to be ineligible. Here is the payment schedule:

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: You 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: You 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 you choose ClinCard, you will be given one card for the entire time of your participation and this card may be used to pay you in any future Brown University studies that use ClinCard. You will also get information about how to use this card and whom to call if you have any questions. Be sure to read this information, including the cardholder agreement from Greenphire.

Money will be added to your card based on the study's payment schedule (see above). You 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 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 your health status or the study in which you are participating. If your card is lost or stolen, please call the study team for a free replacement card. If you request a replacement card from Greenphire directly, you may be charged a fee.

If you earn $600 or more from Brown University in a single calendar year (either in a one study or across multiple studies), Brown will request your social security number to correctly identify you in the payment system and issue you an IRS 1099 Form. You may also be asked to complete a Form W9. This may affect your 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:

Risk	Description	Protection Against Risk
Emotional discomfort	Some questions we ask may be upsetting or you may feel uncomfortable answering them.	If you do not wish to answer a question, you 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 you may feel during this process.

Breach of confidentiality:	As this study involves the use of your 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 answers will be confidential and your participation in the study will in no way impact your dental care. It is also important for you to know that if your parent/ guardian participates in the study the researchers will not share what you say or do during any study procedures with your parent/guardian, except for if you disclose suspected harm or abuse towards yourself or someone else.
Coercion/ Undue influence:	Undue influence can happen when you receive payment to participate in a research study.	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?

You may not directly benefit from being in this research study. However, receiving the pre-surgical program may improve your ability to effectively manage pain and make healthy decisions after surgery as well as potentially improve your post-surgical recovery experience.

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 yourself.

7. How will my information be protected?

To protect your information, we will assign all of your data a code number. All of your information and responses will be identified only by this code number, not your name. Any

information that identifies you 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 during the interviews is treated as confidential, will not be shared, and will be protected according to the rules of Brown University. Audio from the exit interview 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 voice and responses. After the recording has been transcribed, the recording will be deleted. Your responses will not be linked to your identity, and your responses, participation in this study, and identifiable information will not be shared with anyone.

Your consent 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 your consent form is signed electronically). You 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 records may be examined. The reviewers will protect your confidentiality

There are times when the law might require us to release your information without your permission. For example, if you disclose information that makes us suspect 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 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 you, 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 you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. The Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities of 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 to stop?**

You do not have to be in this study if you do not want to be. Even if you decide to be in this study, you can change your mind and 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 participate in or leave the study, your current or future relationship with Brown University, Dr. Pielech, Principal Investigator, or your treatment at the oral surgery clinic should not be impacted.

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

If you have any questions about your 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 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 report any concerns or complaints related to a human subjects research study and/or research personnel, Institutional Review Board (IRB), and/or the Human Research Protection Program using this form. Your report can be submitted anonymously, and all responses will be kept confidential.
https://brown.co1.qualtrics.com/jfe/form/SV_5p3gWaxVwu0S2d8

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. **Consent to Participate**

This form contains important information to help you decide if you want to join this study. If you have any questions that are not answered in this form, ask the principal investigator or another study team member.

Before you say yes or no to being in this study, we want to make sure you fully understand what this study is about and what you would be asked to do if you decide to enroll. Before signing this consent form, please answer the following six questions.

1. Can you tell me what this study is about?

2. What is something that you will be asked to do in the study?
3. Can you tell me one of the risks of the study?
4. Will this study help you?
5. Will the researchers ever tell someone you were in this study?
6. Do you have to be in this study?

Your signature below shows that you have read and understood the information in this document, and that you agree to volunteer as a research participant for this study.

You will be offered a copy of this form.

_____

Participant's Signature and Date / PRINTED NAME

_____

Research Staff Signature and Date / PRINTED NAME

- CONTACT FOR FUTURE STUDIES

Do you agree to be re-contacted for future studies? ____Yes ____ No