Participant Research Consent Form

Study Title: Harnessing mobile technology to deliver tailored, brief pain-CBT for advanced cancer patients on opioids for pain

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Protocol Title:

Harnessing mobile technology to deliver tailored, brief pain-CBT for advanced cancer patients on opioids for pain

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INTRODUCTION AND KEY INFORMATION

All research is voluntary. It is your choice whether you take part in this research or not. If you decide to participate, please sign and date at the end of this form. We will give you a copy and you can refer to this consent form at any time.

The following is a short summary of this research study to help you decide whether you would like to be a part of this study. More detailed information is provided later in this form.

For purposes of this research, you will be referred to as a "participant."

1. Why am I being invited to take part in a research study?

You are invited to take part in in this research study, because you have a history of cancer pain.

2. Why is this research being done?

The purpose of this study is to test whether this mobile application, that is meant to help you learn to manage your cancer pain, is useful and helpful to patients with cancer, and to get your feedback about how it felt to use the app for four weeks.

3. Who is supporting this research?

An institution that is supporting a research study either by giving money or supplying something that is important for the research is called the "sponsor." The sponsor of this protocol is the National Palliative Care Research Center (NPCRC) and the NPCRC is providing the funding for the research study.

4. What does this research study involve and how long will it last?

This research study involves the use of a smartphone app at home in addition to surveys and potentially an interview at the end of the study.
The research study procedures include screening for eligibility, study interventions include surveys at the beginning of the study, after 4 weeks, and after 6 weeks and use of the smartphone app.

You will be in this research study for up to 6 weeks.

It is expected that about 15 people will take part in this research study.

Information about you and your health is personal and private. Generally, it cannot be obtained without your written permission. By signing this form, you are providing that permission and your information may be obtained and used in accordance with this informed consent and as required or allowed by law. This means that researchers may obtain information regarding your past medical history, as well as specimens and samples from previous health care providers such as hospitals and labs.

5. What are the risks to participating in this study?

There are risks to taking part in any research study. We want to make sure you know about a few key risks right now. More detailed information is provided in the "What are the risks or discomforts of the research study?" section

Major known risks to participating in this research study include:

- Disclosure of sensitive personal information may result in a loss of privacy
- Possible emotional distress due to personal questions
- Amount of time required to complete questionnaires (online and/or in person) or study visits

6. Will being in this study benefit me in any way?

We do not know if taking part in this study will benefit you; however, you may find that your pain is better managed and you might be able to cope with your pain better. This study may help researchers learn information that could help people in the future.

7. What are my options?

Instead of being in this research study, you have other options which may include the following:

- Decide not to participate in this research study
- Participate in another research study.

If you choose not to participate, are not eligible to participate, or withdraw from this research study, this will not affect your present or future care and will not cause any penalty or loss of benefits to which you are otherwise entitled.

We encourage you to take some time to think this over, to discuss it with other people and your primary doctor, and to ask questions at any time.

A. WHY IS THIS RESEARCH STUDY BEING DONE?

This research study is a Feasibility Study, which is the first-time investigators are examining this mobile application that is meant to help you learn behavioral techniques to manage your cancer pain. The purpose is to make sure the app is usable and helpful for patients with cancer, and to get feedback about patient experiences after using the app for four weeks.

- The intervention being studied is the use of a mobile application to deliver pain-Cognitive Behavioral Therapy or behavioral coping skills to help cancer patients better manage their pain.
- This intervention was created by a team of pain psychologists, oncologists, palliative care specialists, clinicians, researchers, and other patients with cancer pain and then translated to a mobile app with app developers.
- We expect this intervention to work by providing education, self-monitoring, and behavioral techniques to help participants better manage their cancer pain.
- This mobile application has not been tested before, but similar applications and content have been studied before with patients with cancer pain. This content has been reviewed and vetted by a team of pain psychologists, oncologists, nurses, and researchers. We have also used feedback from other cancer patients to help refine our content.
- These types of mobile apps are relatively new, but they seem to help patients learn about their symptoms and learn ways to self-manage better. They also seem to help keep their care team up to date about how the patients are doing. No specific apps for cancer pain have completed their testing yet.
- We are hoping to learn if this smartphone application is feasible and helpful for cancer patients.

B. WHAT IS INVOLVED IN THE RESEARCH STUDY?

Before the research starts: You will be asked to answer some questions to find out if you can be in the research study.

- **A medical history,** which includes questions about your health, current medications, and any allergies.

If these questions show that you are eligible to participate in the research study, you will be eligible to participate in the research study. If you do not meet the eligibility criteria, you will not be able to participate in this research study.

After the screening procedures confirm that you are eligible to participate in the research study:

Baseline assessments: After speaking with a research assistant and signing this consent form, if you wish to participate, we will ask that you complete a brief baseline questionnaire (10-15 minutes). This baseline survey includes questions about sociodemographics, barriers to pain management, pain severity, opioid use, mood, and quality of life.

Initial Study Visit: We will then ask to schedule a brief initial study visit (approximately 30 minutes). This visit will be either in-person or virtual (via phone call or Zoom) and will be to download the application on your phone or a phone provided to you by our team, then we will orient you to the application and make sure that it is working properly.

At home application use: While using the application, you will respond to questions and review educational content to learn pain self-management. The application will send you a daily, 5-minute survey about your mood, stress, and sleep, and pain management. The application will send you a message with daily content to review each day (~3-5 minutes to learn about pain management). The application will also send you a weekly survey about mood, stress, sleep, pain management, and common side effects of opioids, specifically constipation. At the end of each daily or weekly survey, the application will provide short readings, videos, or audio-recordings to help you learn more about managing symptoms. Based upon your symptom reports, you may be advised to contact your care team for severe symptoms. Additionally, our research assistant will monitor the app dashboard twice daily (Mon-Fri), in the event that you report any severe symptoms. If you report severe symptoms (Mon-Fri), our research assistant will contact a nurse navigator, who is part of your care team, about your survey results. The nurse navigator may then contact you. You will also have the opportunity to set achievable goals, such as “I want to walk for 5 minutes per day”, and to track your progress towards your goals. We will ask that you use the app for 4 weeks, and then you may continue using the app for an additional 2 weeks after that.

At week 4: After using the app at home for 4 weeks, you will be asked to fill out another survey with similar questions to the baseline survey, as well as questions on your thoughts and experiences using the application. We will send this survey through a link in your email. After completing this survey, you may be invited to be interviewed about your experiences using the application, but this is not a requirement of the study. This interview will be conducted remotely (using a computer, smartphone, or tablet, through compliant and secure Zoom video conferencing), last about 30 minutes, and be audio and video recorded. What you say during the interview will be analyzed by the study team and used to improve the application. At the end of the 4 weeks, you will be offered to continue using the app for another 2 weeks if you want to , but this is not required. Upon completion of this survey you will be offered a $25 gift card as a token of our appreciation.

At week 6: After being a study participant for 6 weeks we will send you a final brief survey that is similar to the survey you complete at 4 weeks. At this point you will have completed all study procedures and will be offered an additional $25 gift card as a token of our appreciation, for a total of up to $50 for participating in this study.

C. WHAT ARE THE RISKS OR DISCOMFORTS OF THE RESEARCH STUDY?

There are risks to taking part in any research study.

We anticipate that the risks involved in this study will be minimal. Risks of participating in this study include the possibility of a breach of confidentiality and emotional distress or discomfort answering certain questions. However, we will take steps to minimize the risk.

To reduce the potential risk of loss of privacy or confidentiality, all study staff have been trained in the proper conduct of human subjects' research. Additionally, your responses will be recorded using unique ID numbers, instead of names or other identifiable information. All data collected during the course of the study will be stored on secure password protected computers, in password protected files or in locked filing cabinets.

Reporting pain and psychological symptoms daily may be distressing for some participants. It may also be the case that reviewing psychological content may be distressing as awareness of cognitive and emotional factors relevant to pain will be acknowledged. If you experience significant distress, please contact the study staff or your care team to connect with a social worker for further support.

To reduce the risk of possible emotional discomfort or distress answering certain questions or reviewing content, please know that your responses are always voluntary. At any time, you may choose to not answer questions that make you uncomfortable.

During the research study, you will be provided with new information that may affect your health or willingness to participate. You may be asked to sign a new consent form that shows that you have been informed of new information relating to this research study.

There are no physical risks involved with participating in this study.

D. WHAT WILL HAPPEN IF I AM REMOVED FROM THE STUDY OR DECIDE TO END MY PARTICIPATION IN THE RESEARCH?

You may be taken off the research study for any reason including:

- You do not complete app onboarding within 3 weeks of agreeing to participate in the study
- It is considered to be in your best interest
- The study intervention or procedures are found to be unsafe or ineffective
- There is any problem with following study intervention and procedures
- You are a female and become pregnant or plan to become pregnant
- Your condition worsens
- A decision is made to end the study
- Or for other unforeseen reasons that make it necessary to stop your participation in the research study

You can also choose to stop participating in the research study at any time. Tell a member of the research team if you are thinking about stopping or decide to stop. He or she will tell you how to stop. Leaving the research study will not affect your medical care outside of the research study.

If you decide to withdraw from a study that involves de-identified data, it will not be possible to remove the data that has already been submitted to a database.

E. WHAT ARE THE BENEFITS OF THIS RESEARCH STUDY?

Taking part in this research study may or may not benefit you. We hope that by reviewing the content in the app, you are able to better manage your pain. We

hope the information learned from this research study may determine that the app, a new pain intervention, can help future patients experience less pain and discomfort.

F. WILL I BE PAID TO TAKE PART IN THIS RESEARCH STUDY?

As a token of appreciation, you will be offered a $25 gift card after completion of the 4-week survey. Additionally, upon completion of the final survey, at 6 weeks you will be offered another $25 gift card, earning $50 in total for participating.

G. WHAT ARE YOUR COSTS?

Taking part in this research study may lead to added costs to you. Participating in this study you will be asked to complete online surveys using an internet-enabled device. Participants will have to use their own phone (e.g. smartphone, tablet, computer) and their own WIFI or Data Plan which may cost them money, participants are responsible for these costs. Devices and/or data plans may also be provided by the study staff to interested participants who do not own an eligible device. Please ask your study team if you would prefer to use a phone provided by the research team.

You may:

- Have additional personal costs, such as cell phone data usage if you agree to use the application on your smartphone

You will not be charged for study visits or for downloading the smartphone application.

H. WHAT HAPPENS IF I AM INJURED BECAUSE I TOOK PART IN THIS RESEARCH STUDY?

If you think you have been injured as a result of taking part in this research study, tell the person in charge of this research study as soon as possible. The research doctor's name and phone number are listed in this consent form.

The treating hospital will offer you the care needed to treat injuries directly resulting from taking part in this research. These treatments may be billed to you or your insurance company. You will be responsible for

deductibles, co-payments and co-insurance. There are no plans to pay you or give you other compensation for the injury.

You do not give up your legal rights by signing this form.

We will need to collect certain personal information about you for insurance or payment reporting purposes, such as your name, date of birth, gender, social security number or Medicare identification number and information related to this research study. We may be required to report this information to the Centers for Medicare & Medicaid Services. We will not use this information for any other purpose.

If you go to the Emergency Room or to another hospital or doctor it is important that you tell them that you are in this research. If possible, you should give them a copy of this consent form.

I. WHOM DO I CONTACT IF I HAVE QUESTIONS ABOUT THE RESEARCH STUDY?

If you have questions about the study, please contact the lead investigator or study staff as listed below:

Lead Investigator, Dr. Desiree Azizoddin: (626) 826-7984
Merrimack Valley Contact, Hilary McGuire: 978-620-2020
Study Staff, Madeline Gorra: (617) 632-5639

For questions about your rights as a research participant, please contact a representative of the Office for Human Research Studies at Dana-Farber Cancer Institute (617) 632-3029. This can include questions about your participation in the study, concerns about the study, a research related injury, or if you feel/felt under pressure to enroll in this research study or to continue to participate in this research study.

J. RETURN OF RESEARCH RESULTS

Tests done on samples in this research study are only for research and have no clear meaning for your health care. For this reason, your study doctor will not share the results with you. If you are interested, the researcher will provide you with a summary of the results from this study. Please ask for this information at the end of your involvement and the research team will follow up with your when data analysis is complete.

K. CLINICALTRIALS.GOV

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

L. FUTURE USE OF DATA AND SPECIMENS

Your personal information collected during this study may be stored and used for future research. Any personal identifiers will be removed, before they are shared, so that the information or samples cannot be linked back to you. As a result, we will no longer be able to identify and destroy them. For the patients engaging in debriefing interviews, your video recorded data will be destroyed after manuscript publication.

Investigators, including investigators from collaborating institutions, can request this data for new research. Data may also be shared with outside non-profit academic investigators as well as with for-profit pharmaceutical investigators or commercial entities, with whom we collaborate.

You will not be asked to provide additional informed consent for the use of your de-identified information in future research.

M. CONFIDENTIALITY

We will take measures to protect the privacy and security of all your personal information, but we cannot guarantee complete confidentiality of study data.

The study team plans to publish the results of this research study and when we do, we may be asked to make the data we collect available to other researchers. We will not include information that identifies you in any publications or to the researchers who request the data to do additional research.

Your de-identified data may also be placed into one or more publicly accessible scientific databases. Through such databases, researchers from around the world will have access to de-identified data for future research.

There is a risk that deidentified research data that is shared with outside collaborators may be reidentified. When deidentified data and specimens are

shared with outside collaborators agreements limit what the outside collaborators can do with the information to help prevent reidentification.

N. FINANCIAL DISCLOSURES

It is possible that certain researchers on this study may have earned money from or own some publicly traded stock in, the company that makes or is developing the study intervention. The amount of money that a researcher may earn and still take part in research is limited by the Harvard Medical School Faculty of Medicine Policy on Conflicts of Interest and Commitment. If you have further questions, please speak with a member of the study team or contact the Dana-Farber Cancer Institute Office of Research Integrity at 617-432-4557 or researchintegrity@dfci.harvard.edu.

O. CERTIFICATE OF CONFIDENTIALITY (COC)

To help protect your privacy, we have been issued a Confidentiality Certificate from the National Institutes of Health (NIH). With this Certificate, the researchers on this study cannot be forced (for example, by court subpoena) to disclose information that may identify you in federal, state, or local civil, criminal, administrative, legislative, or other proceedings.

Disclosure will be necessary upon request of a United States federal or state government agency sponsoring the project that will be used for audit or program evaluation purposes or to meet the requirements of the federal Food and Drug Administration (FDA).

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family or even the research doctor from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medical care provider, or employer learns about your participation, and obtains your consent to receive research information, then we cannot use the Certificate of Confidentiality to withhold this information. This means that you and your family must actively protect your own privacy.

The Certificate of Confidentiality cannot be used to prevent disclosure to state or local authorities when there is a duty to report concerns of abuse, neglect, self-harm, or a danger to others.

P. PRIVACY OF PROTECTED HEALTH INFORMATION (HIPAA AUTHORIZATION)

The Health Insurance Portability and Accountability Act (HIPAA) is a federal law that requires Dana-Farber/Harvard Cancer Center (DF/HCC) and its affiliated research doctors, health care providers, and physician network to protect the privacy of information that identifies you and relates to your past, present, and future physical and mental health conditions ("protected health information"). If you enroll in this research study, your "protected health information" will be used and shared with others as explained below.

1. What protected health information about me will be used or shared with others during this research?

- Existing medical records, including mental health records.
- New health information created from study-related tests, procedures, visits, and/or questionnaires

2. Why will protected information about me be used or shared with others?

The main reasons include the following:

- To conduct and oversee the research described earlier in this form;
- To ensure the research meets legal, institutional, and accreditation requirements;
- To conduct public health activities (including reporting of adverse events or situations where you or others may be at risk of harm); and
- To provide the study sponsor with information arising from an adverse event or other event that relates to the safety or toxicity of the drug(s) used in the study and for the purpose of this or other research relating the study drug(s) and their use in cancer;
- To better understand the diseases being studied and to improve the design of future studies; and,
- Other reasons may include for treatment, payment, or health care operations. For example, some medical information produced by this research study may become part of your hospital medical record because the information may be necessary for your medical care. (You will also be given a notice for use and sharing of protected health information.)

3. Who will use or share protected health information about me?

- DF/HCC and its affiliated research doctors and entities participating in the research will use and share your protected health information. In addition, other DF/HCC offices that deal with research oversight, billing or quality assurance will be able to use and share your protected health information.

4. With whom outside of DF/HCC may my protected health information be shared?

While all reasonable efforts will be made to protect the confidentiality of your protected health information, it may also be shared with the following entities:

- Outside individuals or entities that have a need to access this information to perform functions relating to the conduct of this research such as analysis by outside laboratories on behalf of DF/HCC and its affiliates (for example, data storage companies, insurers, or legal advisors).
- The sponsor(s) of the study, its subcontractors, representatives, business partners, and its agent(s): National Palliative Care Research Center, Microsoft Azure, University of Oklahoma Health Sciences Center - Insight mHealth Shared Research Center.
- Other research doctors and medical centers participating in this research, if applicable
- Federal and state agencies (for example, the Department of Health and Human Services, the Food and Drug Administration, the National Institutes of Health, and/or the Office for Human Research Protections), or other domestic or foreign government bodies if required by law and/or necessary for oversight purposes. A qualified representative of the FDA and the National Cancer Institute may review your medical records.
- Hospital accrediting agencies
- A data safety monitoring board organized to oversee this research, if applicable

Some who may receive your protected health information may not have to satisfy the privacy rules and requirements. They, in fact, may share your information with others without your permission.

5. For how long will protected health information about me be used or shared with others?

- There is no scheduled date at which your protected health information that is being used or shared for this research will be destroyed, because research is an ongoing process.

6. Statement of privacy rights:

- You have the right to withdraw your permission for the research doctors and participating DF/HCC entities to use or share your protected health information. We will not be able to withdraw all the information that already has been used or shared with others to carry out related activities such as oversight, or that is needed to ensure quality of the study. To withdraw your permission, you must do so in writing by contacting the researcher listed above in the section: "Whom do I contact if I have questions about the research study?"
- You have the right to request access to your protected health information that is used or shared during this research and that is related to your treatment or payment for your treatment, but you may access this information only after the study is completed. To request this information, please contact the researcher listed above in the section: "Whom do I contact if I have questions about the research study?"

Q. DOCUMENTATION OF CONSENT

My signature below indicates:

- I have had enough time to read the consent and think about participating in this study;
- I have had all of my questions answered to my satisfaction;
- I am willing to participate in this study;
- I have been told that my participation is voluntary and I can withdraw at any time

_____ _____

Signature of Participant or Legally Authorized Representative | Date

_____

Relationship of Legally Authorized Representative to Participant

To be completed by person obtaining consent:

Adult Participant

The consent discussion was initiated on _____ (date).

Signature of individual obtaining consent: _____

Printed name of above: _____

Date: _____

☐ A copy of this signed consent form will be given to the participant or legally authorized representative.

☐ 1) The participant is an adult and provided consent to participate.

☐ 1a) Participant (or legally authorized representative) is a non-English speaker and signed the translated Short Form in lieu of English consent document:

☐ *As someone who understands both English and the language used by the participant, I interpreted and/or witnessed, in the participant's language, the researcher's presentation of the English consent form. The participant was given the opportunity to ask questions.*

Signature of Interpreter/Witness: _____

Printed Name of Interpreter/Witness: _____

Date: _____

☐ 1b) Participant is physically unable to sign the consent form because:

☐ The participant is illiterate.

☐ The participant has a physical disability.

☐ Other (please describe): _____

The consent form was presented to the participant who was given the opportunity to ask questions and who communicated agreement to participate in the research.

Signature of Witness: _____

Printed Name of Witness: _____

Date: _____

☐ 2) The participant is an adult who lacks capacity to provide consent and his/her legally authorized representative:

☐ 2a) gave permission for the adult participant to participate

☐ 2b) did not give permission for the adult participant to participate