Protocol Title:

Feasibility and Acceptability of a Smart Phone Application Intervention to Enhance Coping for Young Adults with Cancer

DF/HCC Principal Research Doctor / Institution:

Hanneke Poort, PhD/Dana-Farber Cancer Institute

Main Consent

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 been diagnosed with cancer. This study will be offered to young adult patients who are diagnosed between the age of 18 and 39 years.

2. Why is this research being done?

This research study is being done to determine how easy it is to use and accept a smartphone application intervention to enhance coping with cancer as a young adult.

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

This research study involves a smartphone application intervention for coping with cancer that includes exercises aimed at identifying and changing thoughts and behaviors. The smartphone application teaches emotional coping skills, aims to improve resilience, and provides access to a community of young adult peers with cancer at DFCI. Participants can decide whether or not they want to share or post content on the smartphone application. Additional features of the

smartphone application which may be utilized as a participant include: a geolocation capacity to show the user is at DFCI, ability to instant message other users, a rotating community question, resource posts by the Young Adult Program each day, ability to comment on other users posts, ability to set notifications to practice skills, and a personal private space for saving preferred content.

The names of the study intervention and research activities involved in this study are:

- Cognitive Behavior Therapy
- Acceptance and Commitment Therapy
- Dialectical Behavior Therapy
- Mindfulness-based Stress Reduction
- Questionnaires
- Post-study interview

The research study procedures include: screening for eligibility, access to the smartphone intervention, 2 evaluations, 4 reminder phone calls, and a post-study interview that will be audio recorded. All audio recordings of study interviews will be stored in secure locations in password-protected folders on Partners servers. Recordings will be tied only to a study ID number. We will transcribe audiotapes of interviews for analysis using a DFCI-approved, HIPAA-compliant transcription vendor. All patient information will be removed when the audio recordings are transcribed. Audio recordings will be destroyed when analyses are complete.

You will receive access to the smartphone intervention and will be followed for 12 weeks. We recommend using the smartphone application at least three times a week. The study team will be able to track participants' usage of the smartphone application. The study will include 4 reminder phone calls, 3 weekly calls in the week 1-3 of the study, and a midpoint phone call in week 6.

It is expected that about 30 people will take part in this research study. As a participant, you will be part of a larger community of young adult patients with cancer at DFCI that can use the smartphone application. You can decide to share content in the app with other users of the smartphone application.

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.

4. 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 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 is a loss of privacy
- Possible emotional distress due to personal questions
- Significant amount of time required to complete questionnaires
- Significant amount of time required to attend study visits

5. Will being in this study benefit me in any way?
We do not know if taking part in this study will benefit you. This study may help researchers learn information that could help people in the future.

6. 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. The smartphone application can be used without participating in this study.

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 smartphone application intervention in young adults with cancer.

This study is being conducted to determine feasibility and acceptability of a smartphone application intervention specifically developed for young adults with cancer. The purpose of this study is to determine how practical this intervention is, to determine patient satisfaction, and test the study procedures. The aims are

to: (1) determine whether this intervention will be appropriate for further testing; (2) identify which parts of the intervention need to be modified; and (3) assess patients' reactions to this intervention.

B. WHAT IS INVOLVED IN THE RESEARCH STUDY?

Before the research starts: After signing this consent form, 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 and current medications.

If your answers 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:
You will complete a series of questionnaires and surveys. You can choose not to answer certain questions. You will then be provided access to the smartphone application intervention to which you will have access for 12 weeks. It will take approximately 20 minutes to complete the questionnaires and surveys.

After the final intervention:
After 12 weeks, you will complete the same questionnaires and surveys, with the choice not to answer certain questions. You will have an individual post-study interview with a member of the study team to evaluate your thoughts and reactions to this smartphone application intervention. The interview will take about 45 minutes and can be conducted in-person at Dana-Farber or over the phone using video-conferencing depending on your preference. The interview will be audio recorded.

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

There are risks to taking part in any research study. You might experience some discomfort or distress thinking about and answering questions about your experiences with cancer and psychological symptoms. Further, participating in a smartphone application intervention will involve thinking about and discussing your thoughts, emotions, feelings, and memories, which may feel uncomfortable at times. Participation in this study is completely voluntary and will not have any effect on the care you receive from your cancer treatment team. If you begin the

study and then decide that you are uncomfortable, you may stop the study at any time.

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:

- It is considered to be in your best interest
- The study treatment or procedures are found to be unsafe or ineffective
- There is any problem with following study treatments and procedures
- 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 the research doctor 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.

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

You will not be paid for participating in this study. The study team will provide parking vouchers for qualifying study-related parking costs.

F. WHAT ARE YOUR COSTS?

Taking part in this research study will not lead to added costs to you or your insurance company. You may need to make 2 more visits to the clinic or hospital than if you were not participating in this study.

G. WHAT HAPPENS IF I AM INJURED OR BECOME SICK 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.

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

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

Dana-Farber Cancer Institute

- Hanneke Poort, PhD: 617-582-7617; Hanneke_Poort@dfci.harvard.edu

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.

I. RETURN OF RESEARCH RESULTS

This research will not involve tests done on samples.

J. FUTURE USE OF DATA

Your personal information collected during this study will not be used or distributed for future research even if the information is de-identified and cannot be linked back to you.

K. 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.

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.

L. GENETIC RESEARCH

This research will not involve genomic or germline testing.

M. 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).
- 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

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?”

N. 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

DFCI Protocol Number: 19-333	Approved Date (DFCI IRB Approval): 02/10/2020
Date Posted for Use: 02/11/2020	

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