Protocol Title:

DEVELOPMENT AND PILOTING AN AVATAR-BASED INTERVENTION TO SUPPORT PATIENTS UNDERGOING STEM CELL TRANSPLANTATION

DF/HCC Principal Investigator(s) / Institution(s):

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Consent for Patients to Participate in Developing and Piloting of an Avatar-Based Intervention Study : Aim 2

INTRODUCTION AND KEY INFORMATION

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 this research study because you have been admitted to the hospital for reduced-intensity conditioning (RIC) allogeneic transplant and you are over the age of 18.

2. Why is this research being done?

The goal of this research study is to provide an avatar-based technology while you are staying in the hospital and to determine if using this technology in a hospital setting is practical.

3. Who is supporting this research?

The company that makes the avatar-based technology, care.coach, is supporting this research by providing Dana-Farber access to its technology. The National Cancer Institute (NCI) also supports this research.

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

If you decide to participate in this research study, you will be provided with a Samsung tablet during you stay at the hospital. Dana-Farber Cancer Institute has

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a partnership with care.coach, a company that has developed a digital avatar-based technology that communicates with you using natural speech software. This software is powered by trained human staff, called health advocates.

You will receive the tablet during your admission. The research assistant will either from the hospital pick up the device from your room one day before you leave the hospital or after you have had the device for 3 weeks, whichever comes first.

It is expected that about 18 people will take part in this research study.

The research study procedures include screening for eligibility, a brief call with a research assistant while you are using the technology, and a survey after you are done with the study.

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 common risks right now. More information about is provided in "Section C. What are the risks or discomforts of the research study?"

Some of the potential risks to participating in this research study include:

- Possible emotional distress
- Disclosure of sensitive personal information may result in a lack of privacy

6. 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.

7. What are my costs for participating in this study?

Your participation comes at no additional costs to you.

8. 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

9. Do I have to take part in this research?

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.

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?

People who are receiving reduced-intensity conditioning (RIC) allogeneic HCT have unique needs during their stay at the hospital. This study is being done to determine if giving this technology to people who are receiving transplants is acceptable and useful to you.

This research study is a Pilot Study, which means we are studying the application in a smaller group of people to understand whether the technology is easy to use. If you consent to this study, you will be asked to use the care.coach technology.

In this research study:

- *We hope to learn through this research if providing people who are in the hospital after receiving an RIC HCT transplant with a digital avatar is feasible.*

- *If you decide to participate in this research study, you will be provided with a Samsung tablet during you stay at the hospital. The tablet with feature a talking animated dog or cat that you will interact with during your stay. Dana-Farber Cancer Institute has a partnership with care.coach, a company that has developed this digital avatar-based technology that communicates with you using natural speech software. This software is powered by trained human staff, called health advocates.*

- *Based on prior research outcomes with similar avatars, this study may benefit you by engaging you throughout your hospital stay to have a better and more pleasant experience at the hospital and learn more about the transplant process.*

B. WHAT IS INVOLVED IN THE RESEARCH STUDY?

Before the research starts (screening):

After signing this consent form, you will be asked to undergo some screening. We will ask a **brief medical history,** which includes questions about your health.

If this shows that you are eligible to participate in the research study, you may begin the study treatment. 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: You will meet with a research assistant to review the study. If you wish to participate, you will be asked to sign informed consent (should take around 10-15 minutes).

The study assistant will then set up the avatar device for you and answer any questions that you may have, this will take approximately 10 minutes.

The avatar has two states: awake and asleep. To wake up the avatar, you must tap on the avatar on the touchscreen device. When the animal avatar is awake, then you are able to talk to the avatar. Since this technology is powered by health advocates, this means that whenever you are talking to the avatar, you are talking to a health advocate in real time.

This technology is a conversational agent, which means that you can ask it questions. You can ask the avatar to play games with you such as trivia, or you can ask it to play your favorite music. Several times a day, the avatar will attempt to engage with you. It may ask you how you are doing or remind you to drink water. It may also ask you if you want to participate in an educational module about your transplant. This information may include what foods you can and cannot eat in the hospital, and how to flush your catheter. Other programs that the technology has includes meditation exercises and stretching exercises.

If at any point you want to stop talking to the avatar, you can tell it to “go to sleep”. Once the animal avatar is asleep, it will not be able to hear you. We will also provide you with a camera cover if you desire.

Study Visit #1: The research assistant will call you approximately one week after you have had the device to see how you are doing, and if you have any questions about the device.

Surveys: You will be asked to complete a 10- 15 minute survey 1 week after you have left the hospital or stopped using the avatar.

Study Completion: You will be notified that your participation in this research study is complete. The study team will not contact you again for these research purposes.

Research Study Plan:

Study Procedures	Baseline	Day 5	-1 to 0 days prior to discharge	One week after pilot
Informed Consent of participant	X			
Demographic data: self-report and EHR review	X			
Setting up avatar device	X			
RA check in		X	X	
Disenroll patients and retrieve avatar device from participants			X	
Post-pilot survey				X

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

There are risks to taking part in any research study.

We want to make sure you know about a few common risks right now. We consider risks or discomforts from this research to be minimal. Some risks are unforeseeable but may include falling due to inappropriate interaction with the avatar, embarrassment due to difficulty interacting with the avatar, and sadness at losing a friendship with the avatar at the end of the hospital stay.

The study team has taken measures to minimize these risks, including manual confirmation of any avatar prompts to perform exercises out of bed, physical, technical, and administrative security and privacy safeguards, and emphasis on the short-term nature of the avatar relationship which will be discontinued when you are discharged from the hospital. If you feel separation anxiety or distress after the conclusion of the study, please reach out the principal investigator.

Only meta-data will be collected through the avatar device. If you consent to participate in this study, the research assistant will set up a profile with your first name and in-hospital location for safety functions. Upon completion of the study, name and in-hospital location data will be decoupled from other data and destroyed by care.coach. Audiovisual streams are recorded for immediate language processing and understanding but will not be stored post-processing.

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
- If you have any problems 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. They 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 involved de-identified data, it will not be possible to remove the data that have already been submitted.

E. WHAT ARE THE BENEFITS OF THIS RESEARCH STUDY?

Taking part in this research study may or may not benefit you. We hope the information learned from this research study will provide more information about the practicality of providing digital avatars to people who are undergoing HCTs.

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

Participants in the third cohort will receive a $20 Dana-Farber gift card for completion of at least 4 out of 7 educational modules presented by the device.

G. WHAT ARE YOUR COSTS?

Taking part in this research study will not lead to added costs to you or your insurance company

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 Investigator'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.

We anticipate no physical risks associated with participating in this research study. However, in the unlikely event that physical injury occurs, we will offer you the care needed to treat injuries directly resulting from taking part in this research. We may bill your insurance company or other third parties, if appropriate, for the costs of the care you get for the injury, but you may also be responsible for some of them.

Providing your care does not mean that DF/HCC or the research investigators are at fault, or that there was wrongdoing. There are no plans for DF/HCC to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form.

I. 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

- Gregory A. Abel, MD, MPH: 617-632-2304 (PI)
- Amar Kelkar, MD (Co- Investigator): 857-215-6105
- Isabella Kallassy (Research Assistant): 857-215-1565

24-hour contact: DFCI: Gregory A. Abel, MD, MPH at 617-632-3000 beeper 44032. For questions about your rights as a research participant, please contact a representative of the Office for Human Research Studies at DFCI (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

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

Results from this research study have no clear meaning for your health care. For this reason, your study doctor will not share the results with you.

K. CONFIDENTIALITY

The study team may 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 are shared with outside collaborators agreements limit what the outside collaborators can do with the information to help prevent reidentification.

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.

L. 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).
- Limited information with be shared with care.coach while enrolled with the avatar
- 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.

M. 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: _____

Signature of Witness: _____
Interpreter may also serve as Witness if present

Printed Name of Interpreter: _____

Printed Name of Witness: _____

Date: _____

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

☐ The participant is unable to read and write.

☐ 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 Interpreter: _____

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Signature of Witness: _____
Interpreter may also serve as Witness if present

Printed Name of Interpreter: _____

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

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