Protocol Title: A Randomized Controlled Trial of an Avatar-based Supportive Care Intervention for Patients Undergoing Outpatient Stem Cell Transplantation

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Main Consent

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.

We are seeking to test the effectiveness of an intervention in improving the quality of life and anxiety for patients undergoing outpatient allogeneic stem cell transplantation at Dana-Farber Cancer Institute through a randomized clinical trial.

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 will be undergoing outpatient transplant treatment for reduced intensity conditioning allogeneic stem cell transplantation at Dana-Farber Cancer Institute and you are over the age of 18.

2. Why is this research being done?

The goal of this study is to provide an avatar-based, artificial intelligence software on a tablet device supervised by trained health advocates while you are undergoing outpatient transplant and to assess its effectiveness at improving your quality of life and transplant education during your procedure.

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3. Who is supporting this research?

Dana-Farber Cancer Institute has a partnership with care.coach Corporation, the company that makes the avatar-based technology. Dana-Farber Cancer Institute is acting as a study collaborator, while care.coach Corporation is acting as the primary sponsor and funder of this study. care.coach Corporation is funding this research study through a grant from The National Cancer Institute.

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

The study intervention is called the care.coach Avatar™ device. If you agree to participate in this study, you will be randomly assigned by a computer to receive one of two options:

Option 1: The care.coach Avatar™ device intervention. This includes the following:

- Completion of a set of questionnaires at baseline.
- Receive the tablet device six days (D-6) preceding your transplant to take home with you for the duration of your outpatient transplant in addition to the standard of care, which is supportive care from your transplant team.
- Follow-up Questionnaires: You will be asked to complete additional questionnaires at 3 follow-up time points: (1) six days after your transplant (D+6), (2) twenty days after your transplant (D+20), and (3) ninety days after your transplant (D+90).

Option 2: Standard-of-care. This includes the following:

- Completion of a set of questionnaires at baseline.
- Supportive care from your transplant team (standard-of-care) without a tablet device.
- Follow up Questionnaires: You will be asked to complete additional questionnaires at 3 follow-up time points: (1) six days after your transplant (D+6), (2) twenty days after your transplant (D+20) and (3) ninety days after your transplant (D+90).

It is expected that approximately 90 people will take part in this research study. The research study procedures include screening for eligibility, randomization to receive the intervention, receipt of the tablet device and enrollment, retrieval of the tablet device, and follow-up surveys at three specified time points.

If randomized to the care.coach Avatar™ device intervention arm, you will receive the avatar intervention for approximately four weeks and asked to complete surveys at three additional time points while you are monitored for 90 days after the transplant.

If randomized to the standard-of-care arm, you will not receive the avatar intervention, but you will be asked to complete additional surveys at three time points while you are monitored for 90 days after the transplant.

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. Some potential risks include emotional distress, embarrassment, and stigmatization if there is inadvertent disclosure of confidential information, and distress due to losing a friendship with the care.coach Avatar™ at the end of the outpatient transplant.

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 whether this intervention 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.

8. 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?

This research study is a Phase II clinical trial. Phase II clinical trials test the safety and effectiveness of an investigational intervention to learn whether the intervention works in treating a specific disease. “Investigational” means that the intervention is being studied.

Transplant outside of the hospital, also known as outpatient transplant, is a relatively new treatment setting that is becoming more widely available to patients; with improving availability of health services, preventative medications, and lower infection risks, expected outcomes can be comparable to transplant in the hospital for many people. However, for patients undergoing outpatient transplant, anxiety and stress is more common, so social support networks are important to patient success. With improved supportive care, more patients could benefit from outpatient transplant.

In an inpatient pilot study, we adapted the care.coach Avatar™ device for use during transplant. The study demonstrated the feasibility of using the care.coach Avatar™ device to support patients undergoing reduced intensity condition allogeneic stem cell transplant. This research study builds on that work to better understand how this intervention could improve quality of life during outpatient transplant.

In this research study:

- *We hope to learn through this if providing people who receive a reduced intensity condition allogeneic stem cell transplant in the outpatient setting the digital avatar improves their anxiety and quality of life.*
- *If you decide to participate in this research study, you will be randomly assigned to be provided with a tablet device or to receive standard supportive care during your outpatient transplant at Dana-Farber Cancer Institute.*
- *Based on prior research outcomes with similar technologies, if you are randomized into the intervention group receiving the care.coach Avatar™ device, this study may benefit you by engaging you throughout your transplant treatment to have a better and more pleasant experience and learn more about the transplant process.*

B. WHAT IS INVOLVED IN THE RESEARCH STUDY?

Because no one knows which of the study options is best, you will be “randomized” into one of the study groups: The care.coach Avatar™ device intervention group or the standard-of-care group. Randomization means that you

are put into a group by chance. It is like flipping a coin. Neither you nor the research doctor will choose what group you will be in.

By signing this consent form, you acknowledge that you have been informed about the randomization process and understand that your assignment to a intervention group will be determined randomly.

Before the research starts (screening): After signing this consent form, you will be asked to undergo a screening procedure to find out if you can participate in this research study. This procedure is likely to be part of regular cancer care and may be done even if it turns out that you do not take part in the research study. If you have this procedure recently, it may or may not have to be repeated.

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

If this shows that you are eligible to participate in the research study, you may begin the study intervention. 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:

Randomization Process: If the screening process determines that you meet the eligibility criteria and you choose to participate, you will be randomized to one of the intervention groups. The randomization process will be conducted by the computer program REDCap. Participants will be assigned a unique identification number, and this number will be used to determine their intervention group. Please be aware that even after being confirmed as eligible, there is no guarantee that you will be assigned to a specific intervention group. If you are randomized to the standard-of-care arm, you will receive standard care supportive care, while still completing the study surveys.

Baseline Assessments: After consenting to the study, you will meet with a research assistant to review the study. If you wish to participate, you will be asked to complete a baseline assessment (this should take around 20-25 minutes). Participants in both the standard-of-care intervention arm and the care.coach Avatar™ device intervention arm will complete the baseline assessment.

Setting up the care.coach Avatar™: If you are not randomized to the care.coach Avatar™ device intervention arm and assigned to the standard-of-

care intervention arm, then the information directly under this header will not be applicable to you.

If randomized to the care.coach Avatar™ device intervention arm, the research assistant will then help you set up the tablet device and answer any questions that you may have. This will take approximately 10 minutes.
After your clinic visit the day you receive the device, you will set it up at your residence with the assistance of the care.coach Avatar™.

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 avatar is awake, you are able to talk to the avatar. This technology listens and speaks using artificial intelligence and text-to-speech software but is being supervised at all times by health advocates.

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 how you are doing or remind you to drink water. It may also ask if you want to participate in an educational module about your transplant. This information may include what foods you can and cannot eat, or how to flush your catheter. Other programs that the technology has includes meditation exercises and stretching exercises.

Health advocates will be able to monitor video and audio streams when the device is awake by the device's default settings. 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 or see you. We will also provide you with a camera cover if you desire to not have the video stream observable by the health advocates.

RA Check-ins: Regardless of which intervention arm you are assigned to, the research assistant will contact you at the Dana-Farber Cancer Institute transplant clinic on Day+6 after the transplant to see how you are doing and to answer any questions you have at that time.

If you are assigned to the care.coach Avatar™ device intervention arm, the research assistant will meet with you at the Dana-Farber Transplant Clinic on Day+20 after the transplant to disconnect the tablet device, answer any questions, and see how you are doing. If you are assigned to the standard-of-care arm, you will meet with the research assistant to complete the D+20 survey, but no device will be collected.

Surveys: Regardless of which study arm you are assigned to, you will be asked to complete 10–20-minute surveys four times during the course of the study. At baseline on D-6, you will be asked to complete a 91-item survey. On Day+6, you will be asked to complete an 88-item survey. On D+20, you will be asked to complete a 102-item survey. On D+90, you will be asked to complete a 64-item survey.

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	D-6 (Baseline)	Day+6	Day+20 (Disconnect Avatar)	Day+90
Informed consent of participant	X			
Demographic data: self-report and EHR review	X			
Setting up care.coach Avatar™*	X			
Surveys	X	X	X	X
RA check-in		X	X	X
PROs	X		X	X
Disenroll patients and retrieve avatar device from participants*			X	

**Only participants randomized to the Avatar™ device intervention arm of the study, and not the standard-of-care arm participants, will set up the care.coach Avatar™ on D+6 and have the device retrieved from them on D+20.*

Data Collection: For all study participants, in both the care.coach Avatar™ device intervention arm and the standard-of-care intervention arm, data will be collected and shared with the study sponsor (care.coach Corporation) for analysis. The data used in the analysis will not be identifiable.

For participants assigned to the care.coach Avatar™ device intervention arm, identifiable data will be shared with the study sponsor, care.coach Corporation, while on the study intervention. After disenrolling from the avatar device, all participant identifiers will be decoupled and destroyed, making the data deidentified. First name, date of birth (DOB), name of transplant physician, residing address during transplant treatment, and study-assigned patient number

will be shared with care.coach Corporation. Identifying information is provided to care.coach Corporation for emergency or life-threatening situations only, where care.coach will contact the transplant physician on your behalf.

For participants assigned to the standard-of-care intervention arm, no identifiable data will be shared with care.coach Corporation; only study assigned patient numbers and recorded survey responses from this group will be shared with care.coach Corporation.

FOR DETAILS REGARDING CONFIDENTIALITY PLEASE SEE THE "FUTURE USE OF DATA AND SPECIMENS" AND THE "CONFIDENTIALITY" SECTIONS BELOW.

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 direction from the avatar, embarrassment due to difficulty interacting with the avatar, and separation anxiety or distress due to losing contact with the avatar at the end of the study.

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

For participants assigned to the standard-of-care intervention arm, meta-data will not be collected by care.coach Corporation. For participants assigned to the care.coach Avatar™ device intervention arm, meta-data will be collected through the avatar device while participants are on the study intervention to be used in data analysis. Meta-data is data about data. The meta-data for this study is descriptive information about participant interactions with the device, such as frequency of interactions, length of interactions, and categorization of such interactions (music, games, educational modules, etc.).

If you consent to participate in this study, the research assistant will set up a profile with your first name, date of birth (DOB), residing address during transplant treatment, and name of transplant physician for safety functions. If you are assigned to the care.coach Avatar™ device intervention arm, this information will be shared with care.coach Corporation. Upon completion of the study first name, date of birth (DOB), residing address during transplant treatment, and name of transplant physician data will be decoupled from other data and destroyed by care.coach Corporation. Audiovisual streams are recorded for immediate language processing and understanding but will not be stored after post-processing.

The questionnaires used in this study may be upsetting. If you find the questionnaires upsetting, you may speak with the research doctor or ask to be referred for additional emotional support. You may also skip any question that you do not wish to answer.

During the research study, you will be notified of newly discovered side effects or significant findings, which 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.

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 intervention or procedures are found to be unsafe or ineffective
- If you have any problems following study interventions 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 to the data bank.

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 benefits and practicality of providing digital avatars to people who are undergoing outpatient transplant.

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

You will not be paid for participating in this study.

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 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.

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 (Principal Investigator): 617-632-2304
- Amar Kelkar, MD, MPH (Co-investigator): 857-215-6105
- Nicholas Groblewski (Clinical Research Coordinator): 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.

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. 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

This study is collecting data from you. We would like to make your data available for other research studies that may be done in the future. The research may be about similar diseases or conditions to this study. However, research could also be about unrelated diseases, conditions, or other types of research. These studies may be done by researchers at this institution or other institutions, including for-profit entities, such as biotechnology companies. Our goal is to make more research gains possible from your contribution.

De-identified refers to data that used to be fully identifiable or coded, until the researcher destroyed or no longer has access to all the identifiers linking the data to study participants. Your name and identifying information will be removed from

any data you provide before they are shared with other researchers. Researchers cannot easily link your identifying information to the data. The researchers must agree not to try to identify you.

We plan to keep your data indefinitely. The decision to share your data is controlled by care.coach Corporation. To get your data, future researchers must seek approval from care.coach Corporation.

We may use your information to develop a new product that has commercial value. The sponsor and/or hospital may benefit if this happens. There are no plans to pay you if your information is used for this purpose.

We will do our best to protect your data during storage. However, there remains a possibility that someone could identify you. There is also the possibility that unauthorized people might access your data. In either case, we cannot reduce the risk to zero.

You will not receive any direct benefit from sharing your data. However, sharing your data may contribute to research that could help others in the future.

You will not be asked to provide additional informed consent for the use of your 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 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.

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.

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 study 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 transplant 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): care.coach Corporation. 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 transplant treatment or payment for your transplant 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	Date

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 who received and signed the translated Short Form in lieu of English consent document, and was provided a copy

☐ *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 or legally authorized representative is a non-English speaker who received and signed a translated consent form in the language they understand, and was provided a copy

☐ 1c) 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: _____

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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