Principal Investigator: Nilanjan Sarkar, PhD **Revision Date: 8.14.23**
Study Title: Reducing Loneliness of Older Adults in Long Term Care Facilities through Collaborative Augmented Reality
Institution/Hospital: Vanderbilt University

Comparing Augmented Reality to Video Chat Technology for Family Visits with Older Adult – Staff Participant

This informed consent document applies to individuals 18 years or older.

Name of participant: _____
Age: _____

The following information is provided to inform you about the research project and your participation in it. Please read this form carefully and feel free to ask any questions you may have about this study and the information given below. You will be given an opportunity to ask questions, and your questions will be answered. Also, you will be given a copy of this consent form.

Key Information:
The first section of this document contains some key points that the research team thought you would find important. The study is described in more detail after this section. If you do not understand something, please ask someone.

Key information about this study:

Why is this research being done?

This research will involve 24 older adults who reside in long term care (LTC) communities and their designated family member (24 people) in testing two types of interactive technology: augmented reality or video chat, such as Facetime. Augmented reality combines the real world with virtual objects and lets you participate in real-time interaction with another person. Video chat involves use of a screen to see and hear your family member. We will examine the feasibility, acceptability and degree to which either technology makes you feel the presence of your family member.

Detailed Information:
The rest of this document includes detailed information about this study (in addition to the information listed above).

You are being asked to take part in this research study because you are employed at the long term care residence and had interactions with the older adult and their family member during the experiment.

Date of IRB Approval: 11/11/2024
Date of Expiration: 11/10/2025

Institutional Review Board
VANDERBILT

You do not have to be in this research study. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether you still want to be in this study.

Procedures to be followed and approximate duration of the study:

- Twice a week, older adults and their family members will have visits using either the augmented reality or the video chat technology. The experiment will last for 4 weeks, 8 sessions.
- All sessions will be videotaped. You may be present in these recordings when in attendance at the sessions.
- After the experiment, you will participate in an interview with the research staff letting us know the feasibility, acceptability, barriers and facilitators to the technology. You will complete a short questionnaire (8 items) on feasibility and acceptability. The interview will take 30 minutes.

Expected costs: There are no costs to you for participating.

Description of the discomforts, inconveniences, and/or risks that can be reasonably expected as a result of participation in this study:

Questionnaire: After the experiment ends we will interview you regarding your perceptions of the technology and visits you observed. You may find this inconvenient or bothersome. We will arrange the time of the interview at your convenience.

Compensation in case of study-related injury:

If it is determined by Vanderbilt and the Investigator with input from the National Institutes of Health that an injury occurred, then you and/or your insurance may be billed for the cost of medical care provided at Vanderbilt to treat the injury. You will be responsible for any copayments or deductibles associated with the treatment of that injury.

There are no plans for Vanderbilt or the National Institutes of Health to pay for the costs of any additional care. There are no plans for Vanderbilt or the National Institutes of Health to give you money for the injury.

Good effects that might result from this study:

Date of IRB Approval: 11/11/2024
Date of Expiration: 11/10/2025

Institutional Review Board
VANDERBILT

a) **The benefits to science and humankind that <u>might</u> result from this study.** Results might lead to augmented reality technology that allows multiple people who do not live together to have collaborative and interactive experiences.

b) **The benefits you might get from being in this study.** There may be no direct benefits to you for participating in this study.

Study Results:
Once we have completed the analyses, we will provide you with the final results.

Alternative treatments available: There are no alternative treatments. You have the option to not participate.

Compensation for participation:

For your time and effort, we will provide you a $25 gift card.

You are not allowed to accept any money for taking part in this study if you are not eligible to receive money from a U.S. person or company or the U.S. government because of U.S. national security and/or foreign policy laws. You can still take part in the study however, you will not be paid if you are a resident of a country restricted by the U.S. government's comprehensive territorial sanctions or if you are listed on the U.S. Treasury Department's Office of Foreign Assets Control's Specially Designated Nationals (SDN) list of prohibited individuals. You do not have to say why you choose not to be paid.

What happens if you choose to withdraw from study participation?
Leaving the study will not result in any penalty or loss of benefits to which you are entitled. You can withdraw at any time at not cost to yourself.

Contact Information.

If you should have any questions about this research study or possibly injury, please feel free to contact **Kelley Colopietro, B.S.** at (443) 617-6792 or kelley.j.colopietro@vanderbilt.edu or **Nilanjan Sarkar, Ph.D.** at (615) 936-0267 or nilanjan.sarkar@vanderbilt.edu.

For additional information about giving consent or your rights as a participant in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to contact the Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

Confidentiality:

All data obtained in this study will be confidential to the extent allowed by law. All efforts, within reason, will be made to keep your personal information in your research record confidential but total confidentiality cannot be guaranteed. Your records may be reviewed by the following groups:

- Office for Human Research Protections
- Vanderbilt University Institutional Review Board
- Ohio State University
- The sponsor, National Institutes of Health, supporting the study.

Questionnaires, field notes of the sessions and videotapes of the session will be stored on a password protected computer at Vanderbilt University and access will be limited to Dr. Nilanjan Sarkar and his research team. Your name will be removed from all files and instead you will be assigned a unique study number. Data will be kept for 7 years at which time it will be erased from the computer database.

Certificate of Confidentiality

This study has support from the National Institutes of Health (NIH). Your study information is protected by a Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give out your information even if requested using legal means.

It does not protect information that we have to report by law, such as child abuse or some infectious diseases. The Certificate does not prevent us from disclosing your information if we learn of possible harm to yourself or others, or if you need medical help.

Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study or future research. Disclosures that you make yourself are also not protected.

You may also visit the NIH website at https://grants.nih.gov/policy/humansubjects/coc.htm to learn more.

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

VUMC Institutional Review Board
Informed Consent Document for Research

Principal Investigator: Nilanjan Sarkar, PhD **Revision Date: 8.14.23**
Study Title: Reducing Loneliness of Older Adults in Long Term Care Facilities through Collaborative Augmented Reality
Institution/Hospital: Vanderbilt University

STATEMENT BY PERSON AGREEING TO PARTICIPATE IN THIS STUDY

I have read this informed consent document and the material contained in it has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to participate.

Date _____ Signature of participant/volunteer _____

Consent obtained by:

Date _____ Signature _____

Printed Name and Title _____

Date of IRB Approval: 11/11/2024
Date of Expiration: 11/10/2025

Institutional Review Board

VANDERBILT

Comparing Augmented Reality to Video Chat Technology for Visits with Older Adult – Family Participant

This informed consent document applies to individuals 18 years or older.

Name of participant: _____
Age: _____

The following information is provided to inform you about the research project and your participation in it. Please read this form carefully and feel free to ask any questions you may have about this study and the information given below. You will be given an opportunity to ask questions, and your questions will be answered. Also, you will be given a copy of this consent form.

Key Information:
The first section of this document contains some key points that the research team thought you would find important. The study is described in more detail after this section. If you do not understand something, please ask someone.

Key information about this study:

Why is this research being done?

This research will involve 24 older adults who reside in retirement or long-term care (LTC) communities and their designated family member (24 people) in testing two types of interactive technology: augmented reality or video chat, such as Facetime. Augmented reality combines the real world with virtual objects and lets you participate in real-time interaction with another person. Video chat involves use of a screen to see and hear your family member. We will examine the feasibility, acceptability and degree to which either technology makes you feel the presence of your family member.

Detailed Information:
The rest of this document includes detailed information about this study (in addition to the information listed above).

You are being asked to take part in this research study because your older adult family member resides in a retirement or long term care community.

You do not have to be in this research study. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether you still want to be in this study.

Procedures to be followed and approximate duration of the study:

- An engineer from Vanderbilt University will visit your home to measure the bandwidth. If needed, a hotspot will be created to allow for the data streaming.

- Twice a week, you will be asked to participate in a virtual visit with your older adult relative using one of the two methods described below. At one session per week, we would like you to drink and/or eat something while doing your visit. Other activities you do with your family member is at your choice. There is no set time for the family visit, but each session will end after 1 hour. If you get tired, we can take a break during the session.

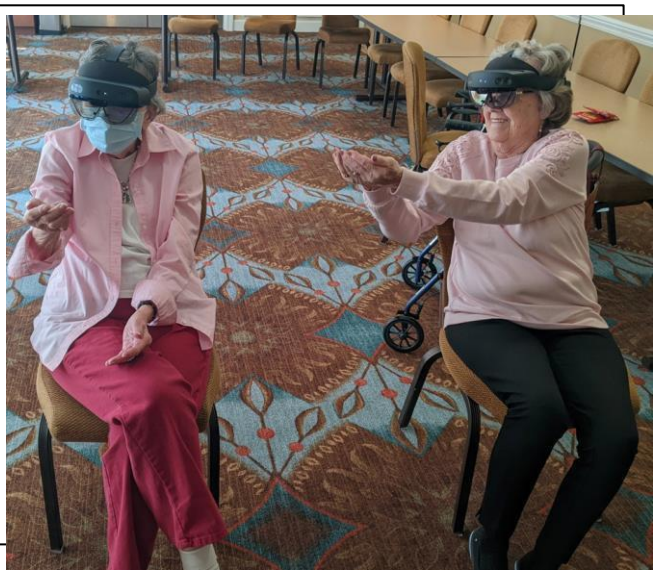
- These sessions will take place over 1 month for a total of 8 sessions (two sessions per week). All sessions will be videotaped. At each session, a Vanderbilt researcher will be in attendance with the older adult. They will assist you and your family member with the technology and troubleshoot any problems.

- After the experiment, the Vanderbilt engineer or research staff will visit your home to retrieve the equipment. You and your older adult relative will tell us what worked, what didn't work and what could be done in the future to improve the technology.

We have two types of technology that we are testing. We do not know which technology you will be assigned. Participants will be randomized to either augmented reality or video chat technology, like a flip of a coin.

<u>Augmented Reality Technology</u>

- Before beginning the design sessions, you will try out the HoloLens2 headset (see photos). The headset has a headband with battery at the back. It has clear lenses that allows you to clearly see your surroundings while displaying virtual objects on the environment. The headset weighs 1.25 pounds.



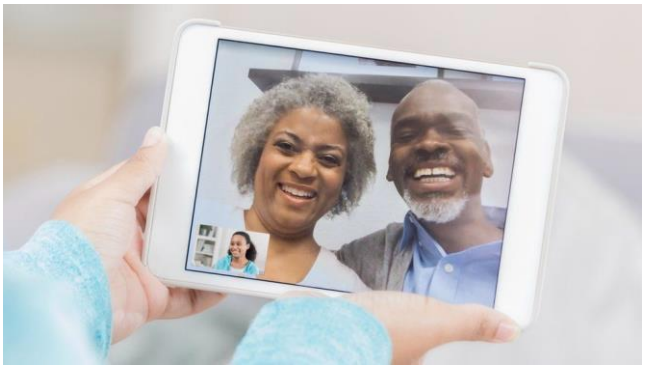
- You will use the headset to interact with three augmented reality activities: playing with a hummingbird (photo), painting and playing a piano. This is to see if you can tolerate the headset and the virtual objects. If it causes you distress, then you will not be able to participate.

- Equipment for the augmented reality includes two cameras and one headset. The Vanderbilt engineer will come to your home to consult with you where to place the cameras (e.g., kitchen).

- You will have control over the cameras to turn them off when not in use for the experiments.

Video Chat Technology

- Your older relative will use a monitor and headset set up at the long term care residence. (see photo example)
- If you do not own a device (e.g., smart phone, iPad, etc.) to use for the video chat, we will lend you a computer table for the 4 weeks.



Expected costs: There are no costs to you for participating.

Description of the discomforts, inconveniences, and/or risks that can be reasonably expected as a result of participation in this study:

Questionnaire: After the experiment ends we will interview you and your older relative regarding the experience. You may find this inconvenient or bothersome. We will arrange the time of the interview at your convenience.

Activity Sessions: Spending the time with the visits may be tiring. You may become bored, annoyed or anxious with some of the activities. If at any time you get tired or annoyed, let us know and we will stop the session. You can leave the session at any time.

HoloLens2 Headset and Augmented Reality: There is a slight risk of nausea, dizziness, eye strain, neck discomfort or headache from using augmented reality.

Privacy: There is a small risk that your video calls or augmented reality visits can be hacked.

Compensation in case of study-related injury:

If it is determined by Vanderbilt and the Investigator with input from the National Institutes of Health that an injury occurred, then you and/or your insurance may be billed for the cost of medical care provided at Vanderbilt to treat the injury. You will be responsible for any copayments or deductibles associated with the treatment of that injury.

There are no plans for Vanderbilt or the National Institutes of Health to pay for the costs of any additional care. There are no plans for Vanderbilt or the National Institutes of Health to give you money for the injury.

Good effects that might result from this study:

a) **The benefits to science and humankind that might result from this study.** Results might lead to augmented reality technology that allows multiple people who do not live together to have collaborative and interactive experiences.

b) **The benefits you might get from being in this study.** There is the potential for you to enjoy visiting with your older relative using one of these technologies. There may be no direct benefits to you for participating in this study.

Study Results:

Once we have completed the analyses, we will provide you with the final results.

Alternative treatments available: There are no alternative treatments. You have the option to not participate.

Compensation for participation:

For your time and effort, we will provide you a gift card for each session you participate (total $250). The compensation schedule for this study is listed below:

Completes 1 session ($25)
Completes 2 sessions ($50)
Completes 3 sessions ($75)
Completes 4 sessions ($100)
Completes 5 sessions ($125)
Completes 6 sessions ($150)
Completes 7 sessions ($200)
Completes 8 sessions ($250)

You are not allowed to accept any money for taking part in this study if you are not eligible to receive money from a U.S. person or company or the U.S. government because of U.S. national security and/or foreign policy laws. You can still take part in the study however, you will not be paid if you are a resident of a country restricted by the U.S. government's comprehensive territorial sanctions or if you are listed on the U.S. Treasury Department's Office of Foreign Assets Control's Specially Designated Nationals (SDN) list of prohibited individuals. You do not have to say why you choose not to be paid.

Circumstances under which the Principal Investigator may withdraw you from study participation:

The Principal Investigator may withdraw you from the study if you or your older relative are having difficulties with the augmented reality activities, such as headaches, nausea, or anxiety. The Principal Investigator may withdraw you from the study if the sessions make you or your relative too anxious or upset.

What happens if you choose to withdraw from study participation?

Leaving the study will not result in any penalty or loss of benefits to which you are entitled. You can withdraw at any time at not cost to yourself.

Contact Information.

If you should have any questions about this research study or possibly injury, please feel free to contact **Kelley Colopietro, B.S.** at (443) 617-6792 or kelley.j.colopietro@vanderbilt.edu or **Nilanjan Sarkar, Ph.D.** at (615) 936-0267 or nilanjan.sarkar@vanderbilt.edu.

For additional information about giving consent or your rights as a participant in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to contact the Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

Confidentiality:

All data obtained in this study will be confidential to the extent allowed by law. All efforts, within reason, will be made to keep your personal information in your research record confidential but total confidentiality cannot be guaranteed. Your records may be reviewed by the following groups:

- Office for Human Research Protections
- Vanderbilt University Institutional Review Board
- Ohio State University
- The sponsor, National Institutes of Health, supporting the study.

Questionnaires, field notes of the sessions and videotapes of the session will be stored on a password protected computer at Vanderbilt University and access will be limited to Dr. Nilanjan Sarkar and his research team. Your name will be removed from all files and instead you will be assigned a unique study number. Data will be kept for 7 years at which time it will be erased from the computer database.

Certificate of Confidentiality

This study has support from the National Institutes of Health (NIH). Your study information is protected by a Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give out your information even if requested using legal means.

It does not protect information that we have to report by law, such as child abuse or some infectious diseases. The Certificate does not prevent us from disclosing your information if we learn of possible harm to yourself or others, or if you need medical help.

Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study or future research. Disclosures that you make yourself are also not protected.

You may also visit the NIH website at https://grants.nih.gov/policy/humansubjects/coc.htm to learn more.

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

Privacy:

We will use encrypted programs to prevent hackers from breaking into your calls in progress.

VUMC Institutional Review Board
Informed Consent Document for Research

Principal Investigator: Nilanjan Sarkar, PhD **Revision Date: 9.17.24**
Study Title: Reducing Loneliness of Older Adults in Long Term Care Facilities through Collaborative Augmented Reality
Institution/Hospital: Vanderbilt University

STATEMENT BY PERSON AGREEING TO PARTICIPATE IN THIS STUDY

I have read this informed consent document and the material contained in it has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to participate.

Date	Signature of participant/volunteer

Consent obtained by:

Date	Signature
	Printed Name and Title

Date of IRB Approval: 11/11/2024
Date of Expiration: 11/10/2025

Institutional Review Board
VANDERBILT

Comparing Augmented Reality to Video Chat Technology for Family Visits

This informed consent document applies to individuals 60 years or older.

Name of participant: _____
Age: _____

The following information is provided to inform you about the research project and your participation in it. Please read this form carefully and feel free to ask any questions you may have about this study and the information given below. You will be given an opportunity to ask questions, and your questions will be answered. Also, you will be given a copy of this consent form.

Key Information:
The first section of this document contains some key points that the research team thought you would find important. The study is described in more detail after this section. If you do not understand something, please ask someone.

Key information about this study:

Why is this research being done?

Many older adults become lonely and miss visiting with their family. This research will involve 24 older adults who reside in either retirement communities or long term care (LTC) communities and their designated family member (24 people) in testing two types of interactive technology: augmented reality or video chat, such as Facetime. Augmented reality combines the real world with virtual objects and lets you participate in real-time interaction with another person. Video chat involves use of a screen to see and hear your family member. We will examine the feasibility, acceptability and degree to which either technology makes you feel the presence of your family member.

Detailed Information:
The rest of this document includes detailed information about this study (in addition to the information listed above).

You are being asked to take part in this research study because you reside in a retirement community or long term care community.

You do not have to be in this research study. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether you still want to be in this study.

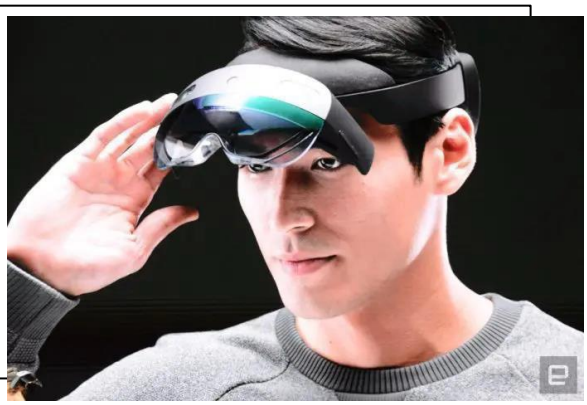
Procedures to be followed and approximate duration of the study:

- You will be asked to complete questionnaires about a) your degree of loneliness and b) the number and frequency of your social contacts. This will take about 10 minutes.
- You will be asked to complete one questionnaire about your thinking and memory. This will take approximately 10 minutes.
- You will complete these questionnaires before you start the family visit sessions. Total time for these questionnaires will take about 20-30 minutes.
- We will gather information from the nursing staff on your diseases and medications and physical activity. By consenting, you are agreeing to have them obtain this information from your medical records and provide to the study team for research purposes.
- Twice a week, you will be asked to participate in a family visit using one of the two methods described below. At one session per week, we would like you to drink and/or eat something while doing your visit. Other activities you do with your family member is at your choice. There is no set time for the family visit, but each session will end after 1 hour. If you get tired, we can take a break during the session.
- These sessions will take place over 1 month for a total of 8 sessions. All sessions will be videotaped. At each session, a Vanderbilt researcher will be in attendance. They will assist you with the technology and troubleshoot any problems.
- We will monitor your body's responses constantly during the activity session. We will ask you to wear a wristband that will give us your heart rate and skin temperature.
- After the experiment, you and your family member will tell us what worked, what didn't work and what could be done in the future to improve the technology.

We have two types of technology that we are testing. We do not know which technology you will be assigned. Participants will be randomized to either augmented reality or video chat technology, like a flip of a coin.

<u>Augmented Reality Technology</u>

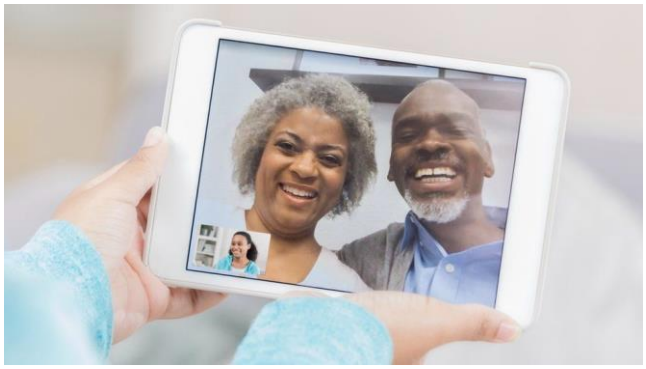
- Before beginning the design sessions, you will try out the HoloLens2 headset (see photos). The headset has a headband with battery at the back. It has clear lenses that allows you to clearly see your surroundings while displaying virtual objects on the environment. The headset weighs 1.25 pounds.

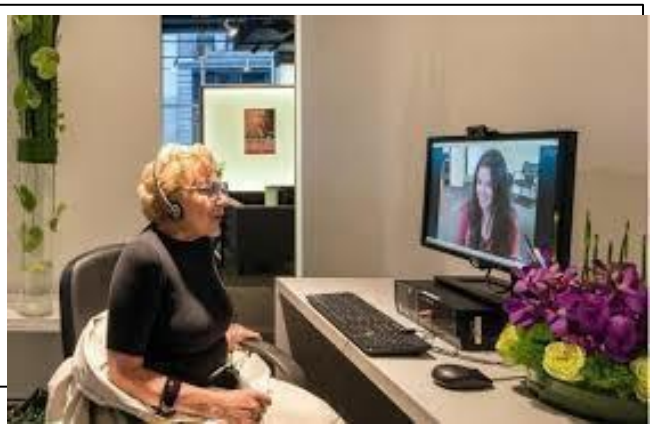


- You will use the headset to interact with three augmented reality activities: playing with a hummingbird (photo), painting and playing a piano. This is to see if you can tolerate the headset and the virtual objects. If it causes you distress, then you will not be able to participate.

Video Chat Technology

- A monitor and headset will be set up for you to use at each visit. (see photo examples)





Expected costs: There are no costs to you for participating.

Description of the discomforts, inconveniences, and/or risks that can be reasonably expected as a result of participation in this study:

Questionnaires: Before the first session, you will be asked a series of questions on your thinking and memory and social contacts. These topics may make you upset. You can skip questions if you do not want to answer them. There is a potential risk of loss of confidentiality; we will make every effort to keep your information secured.

Activity Sessions: Spending the time with the visits may be tiring. You may become bored, annoyed or anxious with some of the activities. If at any time you get tired or annoyed, let us know and we will stop the session. You can leave the session at any time.

Rarely, people may have itching or skin reddening from the wristband. If the wristband feels uncomfortable, you can remove it.

HoloLens2 Headset and Augmented Reality: There is a slight risk of nausea, dizziness, eye strain, neck discomfort or headache from using augmented reality.

Privacy: There is a small risk that your video calls or augmented reality visits can be hacked.

Compensation in case of study-related injury:

If it is determined by Vanderbilt and the Investigator with input from the National Institutes of Health that an injury occurred, then you and/or your insurance may be billed for the cost of medical care provided at Vanderbilt to treat the injury. You will be responsible for any copayments or deductibles associated with the treatment of that injury.

There are no plans for Vanderbilt or the National Institutes of Health to pay for the costs of any additional care. There are no plans for Vanderbilt or the National Institutes of Health to give you money for the injury.

Good effects that might result from this study:

a) **The benefits to science and humankind that might result from this study.** Results might lead to augmented reality technology that allows multiple people who do not live together to have collaborative and interactive experiences.

b) **The benefits you might get from being in this study.** There is the potential for you to enjoy visiting with family members using one of these technologies. There may be no direct benefits to you for participating in this study.

Study Results:

Once we have completed the analyses, we will provide you with the final results.

Alternative treatments available:

There are no alternative treatments. You have the option to not participate.

Compensation for participation:

For your time and effort, we will provide you a gift card for each session you participate (total $250). Below is the compensation schedule for this study:

Complete 1 session ($25)
Complete 2 sessions ($50)
Complete 3 sessions ($75)
Complete 4 sessions ($100)
Complete 5 sessions ($125)
Complete 6 sessions ($150)
Complete 7 sessions ($200)
Complete 8 sessions ($250)

You are not allowed to accept any money for taking part in this study if you are not eligible to receive money from a U.S. person or company or the U.S. government because of U.S. national security and/or foreign policy laws. You can still take part in the study however, you will not be paid if you are a resident of a country restricted by the U.S. government's comprehensive territorial sanctions or if you are listed on the U.S. Treasury Department's Office of Foreign Assets Control's Specially Designated Nationals (SDN) list of prohibited individuals. You do not have to say why you choose not to be paid.

Circumstances under which the Principal Investigator may withdraw you from study participation:

The Principal Investigator may withdraw you from the study if you are having difficulties with the augmented reality activities, such as headaches, nausea, or anxiety. The Principal Investigator may withdraw you from the study if the sessions make you too anxious or upset.

What happens if you choose to withdraw from study participation?

Leaving the study will not result in any penalty or loss of benefits to which you are entitled. You can withdraw at any time at not cost to yourself.

Principal Investigator: Nilanjan Sarkar, PhD **Revision Date: 9.17.24**

Study Title: Reducing Loneliness of Older Adults in Long Term Care Facilities through Collaborative Augmented Reality
Institution/Hospital: Vanderbilt University

Contact Information.

If you should have any questions about this research study or possibly injury, please feel free to contact **Kelley Colopietro, B.S.** at (443) 617-6792 or kelley.j.colopietro@vanderbilt.edu or **Nilanjan Sarkar, Ph.D.** at (615) 936-0267 or nilanjan.sarkar@vanderbilt.edu.

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Confidentiality:

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- Office for Human Research Protections
- Vanderbilt University Institutional Review Board
- Ohio State University
- The sponsor, National Institutes of Health, supporting the study.

Questionnaires, field notes of the sessions and videotapes of the session will be stored on a password protected computer at Vanderbilt University and access will be limited to Dr. Nilanjan Sarkar and his research team. Your name will be removed from all files and instead you will be assigned a unique study number. Data will be kept for 7 years at which time it will be erased from the computer database.

Certificate of Confidentiality

This study has support from the National Institutes of Health (NIH). Your study information is protected by a Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give out your information even if requested using legal means.

It does not protect information that we have to report by law, such as child abuse or some infectious diseases. The Certificate does not prevent us from disclosing your information if we learn of possible harm to yourself or others, or if you need medical help.

Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study or future research. Disclosures that you make yourself are also not protected.

You may also visit the NIH website at https://grants.nih.gov/policy/humansubjects/coc.htm to learn more.

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

Privacy:

We will request the staff to provide us with information from your medical record based at your long term care community. Information gathered for this research includes:

- Your age and gender
- Your physical function
- Your medical conditions
- Medications you take

Authorization to Use/Disclose Protected Health Information

What information is being collected, used, or shared?

To do this research, we will need to collect, use, and share your private health information. By signing this document, you agree that your health care providers may release your private health information to us, and that we may use any and all of your information that the study team believes it needs to conduct the study. Your private information may include things learned from the procedures described in this consent form, as well as information from your medical record.

Who will see, use or share the information?

The people who may request, receive or use your private health information include the researchers and their staff. By signing this form, you give permission to the research team to share your information with others outside of Vanderbilt University. This may include the sponsor of the study and its agents or contractors, outside providers, study safety monitors, government agencies, other sites in the study, data managers and other agents and contractors used by the study team. We try to make sure that everyone who sees your

information keeps it confidential, but we cannot guarantee that your information will not be shared with others. If your information is disclosed by your health care providers or the research team to others, federal and state confidentiality laws may no longer protect it.

Do you have to sign this Authorization?
You do not have to sign this Authorization, but if you do not, you may not join the study.

How long will your information be used or shared?
Your Authorization for the collection, use, and sharing of your information does not expire. Additionally, you agree that your information may be used for similar or related future research studies.

What if you change your mind?
You may change your mind and cancel this Authorization at any time. If you cancel, you must contact the Principal Investigator in writing to let them know by using the contact information provided in this consent form. Your cancellation will not affect information already collected in
the study, or information that has already been shared with others before you cancelled your authorization.
If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.

STATEMENT BY PERSON AGREEING TO PARTICIPATE IN THIS STUDY

I have read this informed consent document and the material contained in it has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to participate.

_____ _____
Date Signature of participant/volunteer

Consent obtained by:

_____ _____
Date Signature

_____
Printed Name and Title

Principal Investigator: Nilanjan Sarkar, PhD **Revision Date: 9.17.24**
Study Title: Reducing Loneliness of Older Adults in Long Term Care Facilities through Collaborative Augmented Reality Institution/Hospital: Vanderbilt University

I, _____[name of decision-maker/surrogate], am the _____ [state relationship to participant] of _____ [state participant's name]. I have read the informed consent document or it has been explained to me. I have had the opportunity to ask any questions and all of my questions have been answered. I have been informed that an investigational treatment may be administered to _____[participant's name]. I believe receiving such treatment would be in the interests of _____ [participant's name] and is consistent with what he/she would have decided had he/she been able to do so.

Your decision to allow your family member/friend to participate in this research study is voluntary. You may choose not to allow his/her participation and he/she will receive alternative treatments without affecting his/her healthcare/services or other rights. You are also free to withdraw him/her from this study at any time. In the event new information becomes available that may affect the risks or benefits associated with this research study or your willingness to allow continued participation in this research study, you will be notified so that you can make an informed decision whether or not to continue your family member/friend's participation in this study.

Your family member/friend will periodically be re-evaluated for the capacity to give consent. If he/she is found to be capable, continued participation in this study would only occur with his/her consent.

_____ ___/___/___
Signature of Health Care Decision-Maker/Surrogate Date

_____ ___/___/___
Signature of Witness Date

_____ ___/___/___
Name and Signature of person obtaining consent Date

Date of IRB Approval: 11/11/2024
Date of Expiration: 11/10/2025

Institutional Review Board
VANDERBILT