Consent Forms - Cover Page

Protocol Title:	**Social Assistive Robot Interface for People with Alzheimer's and Other Dementias to Aid in Care Management**
Study C Title:	**SimpleC Wellness Platform With Social Robot Interaction**
NCT:	NCT05296239
Document Date:	Approved Verbal Consent Forms and Participant Information Sheets (2022-01-20). Combined PDF updated October 09, 2025.

- 7645C RESFAM Participant Info Sheet APPROVED 2022-01-20
- 7645C RESFAM VerbalConsent APPROVED 2022-01-20
- 7645C STAFF Participant Info Sheet APPROVED 2022-01-20
- 7645C STAFF VerbalConsent APPROVED 2022-01-20

PARTICIPANT INFORMATION SHEET

STUDY TITLE: SimpleC Wellness Platform with Social Robot Interaction (Study C)

STUDY INVESTIGATOR: Anne E Adams, PhD, SimpleC, LLC

CO-INVESTIGATOR: Jenay Beer, PhD, University of Georgia

SPONSOR: SimpleC, LLC

This document is for use in a research study which may involve both individuals who do and do not have the legal capacity to consent to their participation. Throughout this document, the pronouns "you" and "your" should be read as referring to the participant rather than the legally authorized representative who is giving consent for the participant.

Introduction

Thank you for your interest in taking part in this study. Our work could not be done without your help.

You are being asked to take part in a research study. This form is designed to tell you everything you need to think about before you decide if you want to be part of the study. **It is entirely your choice. If you decide to take part, you can change your mind later and withdraw from the study.** If you decide not to take part in this study, your relationship with your community will not be affected.

Before making your decision:

- Carefully read this form or have it read to you,
- Listen to the study staff explain the study to you, and
- Ask questions about anything that is unclear.

You will receive a copy of this form to review at your leisure or to ask advice from others. After reading this information, if you would like to participate, you will be asked to verbally consent to participate in the study.

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.

What is the purpose of this study?

This research evaluates new technology for community living. Our goal is to support daily wellness by stimulating healthy routines and providing enjoyment and engagement. The overall goal is to support aging in place and promote connectedness. We want to learn how our wellness programs can be most useful and what changes we need to make to optimize results for individual residents, their families, and staff. We also want to learn about your experiences and opinions of a social robot as part of SimpleC wellness services. We expect to enroll about 30 men and women age 18 and older.

How long will the study last?

Your participation in this study will last approximately 3 weeks.

What will I be asked to do?

You will be asked to take part in one or more of the following activities:

- Complete questionnaires at the beginning and end of the study.
- Join a robot group activity at least once.
- Use the SimpleC Wellness Platform. For Residents, this is the *SimpleC Companion* app on a tablet provided for the duration of the study. For family & friends, this is the *Family Connect* app. For staff, this is the *Clinical Connect* app and/or robot (as applicable).
- Participate in two of our study check-ins (call or in-person).

What are the potential risks, and discomforts?

The risks associated with this study are minimal and no greater than normal office work. Some of the questions we ask may be personal in nature. You may be uncomfortable answering the questions we ask. You do not have to answer any questions that you do not want to answer. We cannot guarantee that your study participation will remain confidential. The study staff will inform you of any new findings about our technology that may affect your willingness to continue in the study.

Will I benefit directly from the study?

You may or may not experience improved wellness and connectedness. You will help researchers learn new things that may help other people in the future.

What are my other options?

Your alternative is to not participate. If you choose to not participate, you can still interact with the robot in the community area.

Will I be compensated for my time and effort?

At the end of the study you will receive either a $20.00 Amazon or Target gift card as a Thank-You for your time and feedback. If you choose to withdraw early, you will be compensated in proportion of your time invested in the study.

Costs to you

There is no cost to you for being in this study. SimpleC, LLC will cover costs of all procedures associated with this study as described in this document. Emergency care will be made available to you to treat any injury incurred by you as a direct result of the study procedures while following all instructions and guidelines. The cost of such care will be covered by SimpleC, LLC. SimpleC, LLC will not be responsible for the cost of referrals or additional services requested by you as a result of participation in this study (such as seeking further medical guidance or help).

Withdrawal from the Study

Your decision to take part in this study is entirely voluntary. You may refuse to participate and withdraw from the study at any time. Tell the study staff if you no longer want to be in the study.

The study staff may stop your participation without your consent for any reason, especially if they believe it is in your best interest. If your participation ends early, we will keep the data collected up to the point of the withdrawal. We may continue to analyze the information.

Confidentiality

As a part of this research, records that contain information or data about you may be collected and used. This includes data collected through our applications. These records may identify you and will be kept as confidential as possible. To the extent permitted by applicable laws and regulations, the records identifying you will not be made publicly available or be disclosed to anybody outside the research team without your written consent. There is a small risk of a breach of confidentiality. This will be minimized by the procedures described in this section below.

Under the privacy laws, you have the rights to decide who can use your protected health information (called PHI). When you verbally agree to be in this study, you are saying that you allow the use of your protected health information for this study. The information that will be collected about you as part of this research includes:

- Name, Address, Email, Telephone number
- Birth date and/or Age
- Race, Ethnicity, Sex
- Your answers to questions and results of study procedures
- Information you share through the SimpleC Platform
- Video and/or Audio recordings

We currently **do not** collect any information from doctors' offices, clinics and/or hospitals about you, and have no intention of doing so. If we need this information, we will let you know and request your approval at that time.

We will use and share your PHI for the conduct and oversight of this research as well as to conduct normal business operations. We will share the minimum necessary to complete a task. All physical files collected about you will be kept in a locked file in a locked office. Digital information collected from you will be stored on a password protected server. Your research records will be labeled and kept under a random code number rather than by name. Your name and any other fact that might point to you will not appear when results of this study are presented and published.

The following groups may review some or all of your study information. They may review your information to make sure that it is correct, assure quality of the data, analyze data. They may also review your information to make sure that the study is being conducted properly. Other reasons include providing of services or product design.

- SimpleC, LLC
- The University of Georgia
- AME, LLC
- Data Processing Services contracted by SimpleC, LLC
- The study sponsor (or representatives such as monitors and/or auditors)
- The U.S. Food and Drug Administration (FDA)
- Sterling Institutional Review Board (IRB)
- The Department of Health and Human Service (DHHS)
- Other government agencies in other countries

RECORDINGS

We may record sessions on both audio and video. Once the study is complete, your audio recordings will be transcribed and labeled with your unique ID only. All identifying information that you give us will be removed from the transcript. Recordings will be viewed or listened to by members of the study team as part of data analysis and review. For development purposes, some identifiers may need

to be included, for example, voice samples to test the responsiveness of our system. We may use parts from the recordings in research presentations to other academics and the public. To protect your privacy, we will not share the raw recordings without your explicit permission.

By agreeing to participate in this study, you acknowledge that we may use information from your video or audio as described above.

Questions

If you have questions, concerns or complaints about the research study, please contact Dr. Adams (SimpleC) at (770) 290-0035 or Dr. Beer (UGA) at (706) 542-2539. For research-related injuries, please call 404-892-8945.

You may also contact Sterling IRB if you have questions about your rights as a research participant, have questions, concerns, or complaints about the research, or would like to have information or offer input: Sterling Institutional Review Board Regulatory Department, 6300 Powers Ferry Road, Suite 600-351 Atlanta, Georgia 30339 (mailing address), Telephone: 1-888-636-1062 (toll free).

VERBAL INFORMED CONSENT

We are inviting you to be in our research study. We want to learn how our wellness programs can be most useful and provide optimal results for individual residents, their families, and staff. We also want to learn about your experiences and opinions of a social robot as part of SimpleC wellness services.

Your participation is voluntary. You can choose to not participate. You can change your mind at any time and withdraw from this study. We may stop your participation for any reason.

The study will last approximately 3 weeks. We will ask you to complete questionnaires at the beginning and end of the study. Your community will receive a robot, and we ask that you (resident) join a robot group activity at least once. We will also ask you to use the SimpleC Wellness Platform. [For Residents, this is the *Companion* app. For family & friends, this is the *Family Connect* app.] Lastly, we would like to check- in twice with you, either in person or through a phone call.

The risks associated with participating in this study are minimal. If we learn of any other potential risks of being in this study, we will let you know as soon as possible. Your alternative is to not participate.

You may or may not experience improved wellness and connectedness. You will help researchers learn new things that may help other people in the future. There is no cost to you for being in this study, and you will receive a $20.00 Amazon or Target gift card as a thank you for your time and feedback.

You do not give up any of your legal rights by being in the study. As part of this research we may record audio and video. We also may share your protected health information (called PHI) as needed for the conduct and oversight of this research and to provide SimpleC services. We will share the minimum necessary and keep your answers confidential using random identifiers whenever possible. We may share a summary of the results at scientific meetings, scientific papers, or in materials for doctors and patients.

If you have questions, concerns, or complaints about the research study, please contact Dr. Anne Adams at (770) 290-0035 or Dr. Jenay Beer at (706) 542-2539. Information about this research study will also be posted to ClinicalTrials.gov.

Please see the Participant Information Sheet for the contact information of the Sterling Institutional Review Board Regulatory Department if you have questions regarding your rights as a research participant; questions, concerns, complaints about this study research; would like information; or offer input. The study's IRB ID is 7645.

Do you have any questions? Yes/No
Do you voluntarily agree to participate in this study? Yes/No
Do you agree to audio recording? Yes/No
Do you agree to video recording? Yes/No

PARTICIPANT INFORMATION SHEET

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CO-INVESTIGATOR: Jenay Beer, PhD, University of Georgia

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Will I benefit directly from the study?

You may not directly benefit from participating in this study, but you will help researchers learn new things that may help other people in the future.

What are my other options?

Your alternative is to not participate. If you choose to not participate, you can still interact with the robot in the community area.

Will I be compensated for my time and effort?

You will not be compensated for participating in this research.

Costs to you

There is no cost to you for being in this study. SimpleC, LLC will cover costs of all procedures associated with this study as described in this document. Emergency care will be made available to you to treat any injury incurred by you as a direct result of the study procedures while following all instructions and guidelines. The cost of such care will be covered by SimpleC, LLC. SimpleC, LLC will not be responsible for the cost of referrals or additional services requested by you as a result of participation in this study (such as seeking further medical guidance or help).

Withdrawal from the Study

Your decision to take part in this study is entirely voluntary. Participation is strictly voluntary and will not be tied to any preferential treatment or promotion within the organization. Likewise, there will be no penalty or drawbacks associated with not participating. You may refuse to participate and withdraw from the study at any time. Tell the study staff if you no longer want to be in the study.

The study staff may stop your participation without your consent for any reason, especially if they believe it is in your best interest. If your participation ends early, we will keep the data collected up to the point of the withdrawal. We may continue to analyze the information.

Confidentiality

As a part of this research, records that contain information or data about you may be collected and used. This includes data collected through our applications. These records may identify you and will be kept as confidential as possible. To the extent permitted by applicable laws and regulations, the records identifying you will not be made publicly available or be disclosed to anybody outside the research team without your written consent. There is a small risk of a breach of confidentiality. This will be minimized by the procedures described in this section below.

Under the privacy laws, you have the right to decide who can use your protected health information (called PHI). When you verbally agree to be in this study, you are saying that you allow the use of your protected health information for this study. The information that will be collected about you as part of this research includes:

- Name, Address, Email, Telephone number
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- Your answers to questions and results of study procedures
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We currently **do not** collect any information from doctors' offices, clinics and/or hospitals about you, and have no intention of doing so. If we need this information, we will let you know and request your approval at that time.

We will use and share your PHI for the conduct and oversight of this research as well as to conduct normal business operations. We will share the minimum necessary to complete a task. All physical files collected about you will be kept in a locked file in a locked office. Digital information collected from you will be stored on a password protected server. Your research records will be labeled and kept under a random code number rather than by name. Your name and any other fact that might point to you will not appear when results of this study are presented and published.

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