Informed Consent Form

E-training of Inmate Peer Caregivers for Enhancing Geriatric and End-of-life Care in Prisons Phase II

NCT05017129

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CONSENT FOR RESEARCH: CORRECTIONS ADMINISTRATIVE OFFICIALS

The Pennsylvania State University

Title of Project: Large-scale Usability Testing of "Just Care" E-Learning with Front-line Staff and Peer Caregivers

Principal Investigator: Susan J. Loeb, PhD, RN

Address: 201 Nursing Sciences Building, Penn State Ross & Carol Nese College of Nursing, University Park, PA 16802

Telephone Numbers: Weekdays: 8:00 a.m. to 5:00 p.m. (814) 863-2236

We are asking you to be in a research study.

Whether or not you take part is up to you. You can choose not to take part. You can agree to take part and later change your mind. Your decision will not be held against you, and there will be no penalty or loss of benefits to which you are entitled.

This form gives you information about the research. Please ask questions about anything that is unclear to you and take your time to make your choice.

1. Why is this research study being done?

The purpose of this project is to continue the research and development of the *Just Care* electronic learning (e-learning) system for training people living in prison to become Peer Caregivers in prison.

The qualitative interviews with Administrative Officials, such as yourself is being done, to determine facilitators and barriers to using the *Just Care* program in correctional settings, as well as to reveal needed modifications to the program.

Approximately 300 people nationally will take part in this study:

- 240 people who are incarcerated and 48 staff for usability testing;
- 12 administrative officials: 1 interview

2. What will happen in this research study?

- The procedure that you will take part in is one telephone or video-conference interview.
- The interview will be audio-recorded if permitted by the Department of Corrections.
- No screening is needed because you are the administrative official who has been working with us throughout our usability testing portion of our study, administrative officials are 18 or older, able to speak and understand English, and have the ability to provide consent.
- During the interview, the researcher will pose open-ended questions and other questions with a fixed array of responses to choose from. You are free to skip any questions that you prefer not to answer.
- The single interview will last 1-hour or less.
- The participant will interact with Principal Investigator, Susan J. Loeb or another IRB approved researcher on the team.
- This interview will take place over the telephone or a videoconference.

- The research study will be done in a private space (e.g., participant's office). PI Loeb (or another IRB-approved researcher on the team) will be in their private office.

What are my responsibilities if I take part in this research?
If you take part in this research, your major responsibilities will include:

- To provide verbal consent prior to the interview.
- Participate in a 1-hour interview that includes providing:
  - answers to open-ended questions about barriers and facilitators during the usability testing;
  - insights on needed modifications to the program;
  - global ratings of the program;
  - views on the commercial appeal of the product; and
  - responses to demographic questions.

3. What are the risks and possible discomforts from being in this research study?
There is a risk of loss of confidentiality if your information or your identity is obtained by someone other than the investigators, but precautions will be taken to prevent this from happening. The confidentiality of your electronic data created by you or by the researchers will be maintained as required by applicable law and to the degree permitted by the technology used. Absolute confidentiality cannot be guaranteed.

4. What are the possible benefits from being in this research study?

4a. What are the possible benefits to me?
You will not benefit from this research study.

4b. What are the possible benefits to others?
The results of this research will contribute to the refinement of a training program that may enhance the care and management of health needs of people who are older and/or dying in prisons and enhance quality of life and health equity.

5. What other options are available instead of being in this research study?
You may choose not to be in this research study.

6. How long will I take part in this research study?
It will take you ~ 1-hour to complete one interview.

7. How will you protect my privacy and confidentiality if I decide to take part in this research study?

7a. What happens to the information collected for the research?
Efforts will be made to limit the use and sharing of your personal research information to people who have a need to review this information. Reasonable efforts will be made to keep the personal information in your research record private. However, absolute confidentiality cannot be guaranteed, and there may be situations where disclosure is required by law.

- All paper copies of study related documents will be kept at Penn State University in a locked file cabinet in a locked office. This file cabinet will be a different file cabinet from where study related transcripts and other data collection instruments are stored.
- Audio-recordings (if permitted) of the qualitative interview and demographic questionnaire responses will be destroyed once the transcripts are typed up, verified line-by -line, and cleaned of any identifiers (e.g., Dr. Jones would instead become changed to [Corrections Provider]). This process will be completed within 1-2 weeks of your interview.

- Your research records will be deidentified. These records will be kept in a safe area in PI Loeb's research office.
- Research records are stored in Microsoft Teams secure storage system for use by our team of researchers at Penn State University and Klein Buendel, Inc. We will use a code number (e.g., Administrative Official Participant 001), and no personally identifiable data will be included.

This research is covered by a Certificate of Confidentiality from the NIH. This means that the researchers cannot disclose information that identifies you to anyone not connected with the research. This protection also prevents this information from being used or disclosed for legal proceedings, such as being accessed through a court order. The Certificate of Confidentiality however does not prevent disclosures required by law, such as information about child abuse or neglect and harm to yourself or others. Also, your information may be disclosed in accordance with any consent you provide, including for your medical treatment or use in other research. Additionally, the Certificate of Confidentiality does not prevent your information from being disclosed to the NIH/NIA in order for it to evaluate or audit the research. For additional information ask the principal investigator or a member of the study team or contact the Human Research Protection Program at (814) 865-1775.

In the event of any publication or presentation resulting from the research, no personally identifiable information will be shared.

We will do our best to keep your participation in this research study confidential to the extent permitted by law. However, the following people/groups may check and copy records about this research.

- The Office for Human Research Protections in the U. S. Department of Health and Human Services
- The research study sponsor, the NIH/NIA
- The Penn State Institutional Review Board (a committee that reviews and approves human research studies) and the Penn State Human Research Protection Program
- The investigator, Penn State study staff, and other Penn State professionals who may be evaluating the study.

7b. What will happen to my research information and/or samples after the study is completed?
We may use your research information in future studies or may share your information with other investigators for future research without your additional informed consent. Before we use or share your information we will remove any information that shows your identity.

8. What are the costs of taking part in this research study?
8a. What will I have to pay for if I take part in this research study?
There are no costs associated with taking part in this study.

9. Will I be paid to take part in this research study?
You will not receive any payment or compensation for being in this research study.

10. Who is paying for this research study?
The institution and investigators are receiving a grant from the NIH/NIA [grant # 2R44AG057239] to support this research.

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11. What are my rights if I take part in this research study?
Taking part in this research study is voluntary.

- You do not have to be in this research.
- If you choose to be in this research, you have the right to stop at any time.
- If you decide not to be in this research or if you decide to stop at a later date, there will be no penalty or loss of benefits to which you are entitled.

If you stop being in the research during the interview, you may request that the data collected to that point be removed. However, if the interview has concluded, the already collected data may not be removed from the study database, because there is no way for the investigator to determine which data are associated with which participant.

The person in charge of the research study or the sponsor can remove you from the research study without your approval. A possible reason for removal from this study is safety reasons. The criteria for removal would be a real or perceived threat to the individual's or others' safety in the location where the usability testing was taking place. Due to the nature of the environment, the correctional facility's policies and procedures would dictate precise steps taken in this process. Any study team members who were on-site at that time would not engage in the removal process.

During the course of the research, you will be provided with any new information that may affect your health, welfare or your decision to continue participating in this research.

12. If I have questions or concerns about this research study, whom should I call?
Please call the head of the research study, PI Loeb at (814) 863-2236, if you have:

- Questions, complaints, or concerns about the research.
- Believe you may have been harmed by being in the research study.

You may also contact the Penn State Human Research Protection Program (HRPP) at (814) 865-1775 or visit the HRPP website at https://www.research.psu.edu/irb/participants if you:

- Have questions or want information regarding your rights as a person in a research study.
- Have concerns, complaints, or general questions about the research.
- You may also call this number if you cannot reach the research team or wish to offer input or to talk to someone else about any concerns related to the research.

A description of this clinical trial will be available on https://www.ClinicalTrials.gov, as required by U.S. Law or policy. 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.

VERBAL/IMPLIED CONSENT TO TAKE PART IN RESEARCH
I have read this consent form and the research study has been explained to me. I agree to be in the research study described above. A copy of this consent form will be provided to me or I will print a copy for my records. By agreeing to participate, I have not given up any of the legal rights that I would have if I were not a participant in the study.