Penn logo

DATE:	01-Apr-2021	**Institutional Review Board**
TO:	Pamela Z Cacchione	3600 Civic Center Blvd., 9th Floor
CC:	Dougherty, Ashley	Philadelphia, PA 19104
	Chianese, Alexander	Phone: 215-573-2540
		(Federalwide Assurance # 00004028)

RE:
IRB PROTOCOL#: 833696
PROTOCOL TITLE: The Use of PARO to decrease agitation and restlessness in persons with dementia and or delirium

SPONSOR: NO SPONSOR NUMBER
REVIEW BOARD: IRB #5

IRB AMENDMENT: NOTICE OF APPROVAL

Dear Dr. Cacchione,

The documents noted below, for the above-referenced protocol, were reviewed by the Institutional Review Board using the expedited procedure set forth in 45 CFR 46.110 and approved on 31-Mar-2021.

Consistent with the regulations set forth in 45 CFR 46.109(f), continuing review of this research is not required. IRB approval of this protocol will not expire and continuing review applications should not be submitted. However, you are still required to submit modifications and reportable events to the IRB for review.

The documents included with the application noted below are approved:

HSERA Modification, Conf. code: ddeiigif, submitted on 3/23/2021

NOTE: Approval by the IRB at this time DOES NOT constitute authorization to initiate or continue in-person research during the COVID-19 pandemic. Please review Requirements for In-Person Research Resumption Guidance on the IRB website here for further details: https://irb.upenn.edu/mission-institutional-review-board-irb/guidance/covid19

Note: For participants in the intervention group and/or their legally authorized representatives who provide consent by telephone: The IRB reviewed and approved a waiver of written documentation of consent as

per HHS 45 CFR 46.117(c)(2) or FDA 21 CFR 56.109(c)(1): That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context {e.g. Telephone survey}.

Note: For control/usual care group participants only: As part of the review, an alteration of informed consent and the HIPAA authorization requirement was granted as authorized by 45 CFR 46.116(d) and 45 CFR 164.512 (i), respectively. An expedited review procedure was used for the alteration of HIPAA authorization because the research involves no more than minimal risk to the privacy of the individuals who are the subject of the protected health information for which use or disclosure is being sought. The review of the research has determined the following:
• An adequate plan has been presented to protect the identifiers from improper use and disclosure;
• An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research exists, unless there is a health or research justification for retaining the identifiers, or such retention is otherwise required by law; and,
• An adequate written assurance has been provided that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information would be permitted under the law.
• That the research cannot practicably be conducted without the waiver to access and use of the protected health information.

ONGOING REQUIREMENTS:

- You must obtain IRB review and approval under 45 CFR 46 if you make any changes to the protocol, consent form, or any other study documents subject to IRB review requirements. Implementation of any changes cannot occur until IRB approval has been given.
- Reportable event, such as serious adverse events, deviations, potential unanticipated problems, and reports of non-compliance must be reported to the IRB in accordance with Penn IRB SOP RR 404.
- When enrolling subjects at a site covered by the University of Pennsylvania's IRB, a copy of the IRB approved informed consent form with the IRB approved from/to stamp must be used unless a waiver of written documentation of consent has been granted.

COMMITTEE APPROVALS: You are responsible for assuring and maintaining other relevant committee approvals. This human subjects research protocol should not commence until all relevant committee approvals have been obtained.

If your study is funded by an external agency, please retain this letter as documentation of the IRB's determination regarding your proposal.

If you have any questions about the information in this letter, please contact the IRB administrative staff. A full listing of staff members and contact information can be found on our website: http://www.irb.upenn.edu

***This letter constitutes official University of Pennsylvania IRB correspondence. ***

UNIVERSITY OF PENNSYLVANIA
RESEARCH SUBJECT
INFORMED CONSENT AND HIPAA AUTHORIZATION FORM

Protocol Title:	The Use of PARO to Decrease Agitation and Restlessness in Persons with Dementia and/or Delirium
Principal Investigator:	Pamela Z. Cacchione, PhD, CRNP, BC, FGSA, FAAN *University of Pennsylvania School of Nursing* *Penn Presbyterian Medical Center*
Emergency Contact:	Pamela Z. Cacchione, PhD, CRNP, BC, FGSA, FAAN 215-746-5472

NOTE: This consent form is written from the point of view of a research participant. If the parent or legal guardian of a minor or a legally authorized representative will be providing consent, the words "you" and "your" should be read as ("your child" or "the research participant").

Research Study Summary for Potential Subjects
You are being invited to participate in a research study. Your participation is voluntary, and you should only participate if you completely understand what the study requires and what the risks of participation are. You should ask the study team any questions you have related to participating before agreeing to join the study. If you have any questions about your rights as a human research participant at any time before, during or after participation, please contact the Institutional Review Board (IRB) at (215) 898-2614 for assistance.

The research study is being conducted to determine if a one-hour interaction with PARO, a personal robotic seal, will decrease agitation and restlessness in persons with dementia and/ or delirium. In turn, we hope this will lead to a decrease the use of calming medications, sitters, and length of stay.

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The study involves two groups: one that will interact with PARO and a usual care control group. Which group you are assigned to depends on picking a card out of a hat.

If you agree to join the study and are assigned to the intervention group, you will be asked to complete the following research procedures: interact with a personal robotic seal for a maximum of 60 minutes out in the activity area on the ACE unit. You are willing to be videotaped interacting with the robotic seal. Interact with the robotic seal two days in a row for 60 minutes. The research team member will introduce you to the robotic seal and observe your observations completing three assessment tools (Cohen Mansfield Agitation Inventory, Pain in Dementia Scale and Social Interaction Tool) while observing you in real time. You will not be observed or videotaped during personal care. The videotaping will be completed in the activity area on the ACE Unit.

Your participation will last for a total of 140 minutes for the intervention group over two days. Dr. Cacchione will review your medical record following your discharge to determine the use of 1:1 sitters, calming medications, and how long you were in the hospital.

You may not receive any benefit to participating in this study other than the enjoyment of interacting with the robotic seal and having company for one hour two days in a row. The most common risks of participation are loss of privacy and confidentiality. There is also a slight risk of cross contamination between participants in the study. This research has a very detailed cleaning process to aid us in avoiding this potential complication.

Please note that there are other factors to consider before agreeing to participate such as additional procedures, use of your personal information, costs, and other possible risks not discussed here. If you are interested in participating, a member of the study team will review the full information with you. You are free to decline or stop participation at any time during or after the initial consenting process.

Why am I being asked to volunteer?

You are being invited to participate in a research study because you are a patient on the Acute Care for the Elderly Unit and have problems with your memory and thinking either due to dementia and or delirium.

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If you decide to participate, you will be asked to sign this form.

Your doctor may be an investigator in this research study. You do not have to participate in any research study offered by your doctor. If you choose not to participate, there will be no loss of benefits to which you are otherwise entitled. You may also decide to discuss the study with your family, friends, or family doctor. Being in a research study is different from being a patient. As an investigator, your doctor is interested both in your clinical welfare and in the conduct of this study.

What is the purpose of the study?
The purpose of the study is to learn if interaction with a robotic seal for one hour a day two days in a row decreases agitation and restlessness, need for 1:1 sitters, calming medication use and how long you stay in the hospital. We will also be testing our protocols to engage patients with the robotic seal and our extensive cleaning process for the robotic seal between participants.

Why was I asked to participate in the study?
You are being asked to join this study because you are a patient on the ACE Unit at Penn Presbyterian Medical Center and have problems with your memory and thinking either due to dementia and/or delirium.

How long will I be in the study?
The study will take place over a period of 2 days. This means for the next two days you will interact with the robotic seal for one hour and be observed for 70 minutes and videotaped for 60 minutes. Each session will last approximately 1 hour and 10 minutes.

How many people will be in the study?
We anticipate enrolling 51 participants for the usual care group and 51 participants in the intervention group.

What will I be asked to do?
Intervention participant: You will be asked to come out to the activity area on the ACE unit to interact with the robotic seal for one hour two days in a row. During this time, you will be watched by a member of our research team and videotaped for up to 60 minutes.

What are the risks?

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The research team will do everything possible to minimize the risks of this study. The main risk of this study to both groups is the risk of loss of confidentiality and privacy.

One additional risk is possible for the intervention group which is the risk of spread of bacteria from the seal. To minimize this risk, the seal is cleaned between each use and deep cleaned between each participant. Only one participant will interact with the seal at a time. The seal will be tested for bacteria after each deep cleaning. If bacteria are found the robot is deep cleaned until the seal no longer tests positive for bacteria.

What are the possible benefits of the study?
There may be no benefit to you. However, your participation could help us understand how best to engage older adults in the hospital with a robotic seal to improve outcomes for patients, which can benefit you indirectly. In the future, this may help other people to avoid long hospital stays and avoid sedating medications.

Will I receive the results of research testing?
Most tests done in research studies are only for research and have no clear meaning for participants. Research results will not be returned to you because they do not have bearing on your care nor will they be added to your medical record. If you are in the intervention group and would like a copy of the videotape of you interacting with the robotic seal. We can determine what format you would like a copy in and provide a copy to you.

What other choices do I have?
Your alternative to being in the study is to not be in the study.

Will I have to pay for anything?
There is not cost for you to participate in this study.

Will I be paid for being in this study?
You will be compensated with a $25 visa gift card for your participation in the study.

What happens if I do not choose to join the research study?
You may choose to join the study, or you may choose not to join the study. Your participation is voluntary.

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There is no penalty if you choose not to join the research study. You will lose no benefits or advantages that are now coming to you, or would come to you in the future. Your therapist, social worker, nurse, or doctor will not be upset with your decision.

If you are currently receiving services and you choose not to volunteer in the research study, your services will continue.

When is the study over? Can I leave the study before it ends?
The study is expected to end after all participants have completed all visits and all the information has been collected. The study may be stopped without your consent for the following reasons:

- The PI feels it is best for your safety and/or health-you will be informed of the reasons why.
- You have not followed the study instructions
- The PI, the sponsor or the Institutional Review Board (IRB) at the University of Pennsylvania can stop the study anytime

You have the right to drop out of the research study at any time during your participation. There is no penalty or loss of benefits to which you are otherwise entitled if you decide to do so. Withdrawal will not interfere with your future care.

If you no longer wish to be in the research study, please contact Dr. Pamela Cacchione, at 215-746-5472 and take the following steps: Leave a message that you would like to withdraw from the research study. Please let Dr. Cacchione know if any data that has already been collected can be used or if you would like it removed from the study. Dr. Cacchione will accommodate your request without any penalty to you. If you would like to talk with Dr. Cacchione directly please leave your name and number and she will return your call as soon as possible.

What happens if I am injured from being in the study?
We do not anticipate that anyone will be injured during this study. However, 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.

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There are no plans for the University of Pennsylvania to pay you or give you other compensation for the injury. If you feel this injury was caused by medical error on the part of the study doctors or others involved in the study, you have the legal right to seek payment, even though you are in a study. You do not give up your legal rights by signing this form.

If you think you have been injured as a result of taking part in this research study, tell the person in charge of the research study, Dr. Pamela Cacchione, 215-746-5472, as soon as possible.

How will my personal information be protected during the study?
We will do our best to make sure that the personal information obtained during the course of this research study will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used. The Institutional Review Board (IRB) at the University of Pennsylvania will have access to your records.

- Each participant is assigned a code number, your name nor any of your personal information will be linked to your study code number. All the data will be stored on password protected secure servers at the University.
- We will separate your consent forms and the list of participants and their code numbers.
- For the intervention participants, the videotapes will be uploaded the same day to the secure server then deleted from the videorecorder. The videotapes will be used for data collection and educational purposes. Examples of educational purposes include: in class lectures, presentations at conferences, and publications in scientific journals (images from videotape only). Your name will not be shared, just your likeness and your interaction with the robotic seal.

An exception to confidentiality is if you report child or elder abuse or neglect, or if you report suicidal or homicidal ideation or intent to the research team. Any information about child or elder abuse or intent to harm yourself or others will be reported to the authorities, as required by law.

What information about me may be collected, used or shared with others?

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We will be collecting your name, medical record number, age, race ethnicity, list of medical problems, medication lists, where you were residing prior to your hospitalization, and your type of insurance. This information is necessary to assist us in describing the participants as a group. If you would like a copy of your videotape mailed to you, we will also collect your name and address.

Why is my information being used?
Your information is used by the research team to contact you during the study. Your information and results of tests and procedures are used to:

- do the research
- oversee the research
- to see if the research was done right
- to evaluate and manage research functions.

Who may use and share information about me?
The following individuals may use or share your information for this research study:

- The investigator for the study and the study team
- Other authorized personnel at Penn, infection control department, including offices that support research operations
- Other research personnel with access to the databases for research and/or study coordination and as otherwise approved by the IRB

Who, outside of the School of Medicine, might receive my information?
Oversight organizations

- The U. S. Office of Human Research Protections (OHRP)

If future funding is received for this research the funding sponsor and their organizations supporting the sponsor may have access to your information.

Once your personal health information is disclosed to others outside the School of Nursing and Medicine, it may no longer be covered by federal privacy protection regulations.

The Principal Investigator or study staff will inform you if there are any additions to the list above during your active participation in the trial. Any additions will be subject to University of Pennsylvania procedures developed to protect your privacy.

How long may the School of Nursing or Medicine use or disclose my personal health information?
Your authorization for use of your personal health information for this specific study does not expire.

Your information may be held in a research database. However, the School of Nursing or School of Medicine may not re-use or re-disclose information collected in this study for a purpose other than this study unless:

- You have given written authorization
- The University of Pennsylvania's Institutional Review Board grants permission
- As permitted by law

Can I change my mind about giving permission for use of my information?
Yes. You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the investigator for the study. If you withdraw your permission, you will not be able to stay in this study.

What if I decide not to give permission to use and give out my health information?
Then you will not be able to be in this research study.

You will be given a copy of this Research Subject HIPAA Authorization describing your confidentiality and privacy rights for this study.

By signing this document, you are permitting the School of Nursing and School of Medicine to use and disclose personal health information collected about you for research purposes as described above.

What may happen to my information collected on this study?
Future Use of Data
The majority of your information will be de-identified. De-identified means that all identifiers have been removed. The information could be stored and shared for future research in this de-identified fashion. It would not be possible for future researchers to identify you as we would not share any

identifiable information about you with future researchers. This can be done without again seeking your consent in the future, as permitted by law. The future use of your information only applies to the information collected on this study.

Your identifiable video tapes will be stored for future research and educational purposes. Future researchers and educators may receive your video image that could identify you. This can be done without again seeking your consent in the future, as permitted by law. The future use of your information only applies to the information collected on this study.

We will not follow up with you to tell you about the specific research that will be done. We will not give you any results from these studies. It is possible that you may have chosen not to participate in these future research studies, had you been approached for participation.

There is a risk of breach of confidentiality (unintentional release of your information). We will do our best to make sure that this doesn't happen. However, we cannot guarantee total privacy. We will protect your confidentiality during storage and sharing by storing your de-identified data and videotapes on a password protected secure server.

You will likely not directly benefit from future research with your information Research with your identifiable information may help others by improving our understanding of health and disease, improving health care and making safer or more effective medical therapies, and developing new scientific knowledge.

If you have questions about the storage of your information or have changed your mind, you can contact Dr. Pamela Cacchione at 215-746-5472. If you change your mind, you can withdraw from the study at any time.

Who can I call with questions, complaints or if I'm concerned about my rights as a research subject?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with Dr. Pamela Z. Cacchione, 215-746-5472. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the IRB at (215) 898 2614.

When you sign this form, you are agreeing to take part in this research study. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer. Your signature also means that you are permitting the University of Pennsylvania to use your personal health information collected about you for research purposes within our institution. You are also allowing the University of Pennsylvania to disclose that personal health information to outside organizations or people involved with the operations of this study.

Printed Name of Subject	Signature of Subject	Date
Printed Name of Responsible Party	Signature of Responsible Party	Date
Nurse Signature for phone consent	2nd Nurse signature for phone consent	Date

Participant answered the following questions correctly		
1. What is the purpose of the study?	Yes	No
2. What are the risks to the study?	Yes	No
3. What are the benefits to the study?	Yes	No
4. What are they being asked to do?	Yes	No
5. How do they reach the investigator?	Yes	No

If they cannot answer all 5 questions they provide Assent and Responsible Party provides informed consent.

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