CONSENT TO ACT AS A PARTICIPANT IN A RESEARCH STUDY

TITLE: CareMedia: Automated Video and Sensor Analysis for Geriatric Care

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Why is this research being done?

Up to 90% of persons with dementia experience one or more behavioral problems during the course of their illness. These behaviors are often broadly labeled as “agitation,” and are the leading reason for psychiatric consultation in nursing homes. In particular, aggressive behaviors (verbal, physical, or sexual) are the most disruptive and interfere...
with provision of daily care, and jeopardize the safety of resident(s) and staff. Until now, we have not had technologies to accurately and efficiently detect such infrequent, but potentially dangerous, aggressive behaviors. Using novel video and audio recording technologies from Carnegie Mellon University we plan to record behaviors, activities, and day-to-day functioning of nursing home residents with dementia in order to estimate the frequency of aggressive behaviors and factors that contribute to their occurrence. By understanding these factors, we hope to develop more accurate assessment and treatment plans that minimize aggressive behaviors and enhance social interactions and safety of residents and staff.

Development of the CMU technologies will eventually augment subjective, cross-sectional staff accounts of residents’ lives with objectively collected data regarding their day-to-day functioning, activities, behaviors and social interactions, thus permitting more appropriately targeted behavioral and pharmacological treatments.

Who is being asked to take part in this research study?

All nursing personnel including support staff who report to the Asbury Heights Willow Dementia Unit will be asked to participate in the study. Your participation will not be that of a study subject but your presence will be included in the filming and recording of care rendered by you to the residents.

What procedures will be performed for research purposes?

If you decide to take part in this research study, the following procedures will be conducted:

Clinical procedures:

A clinical research associate who has experience working with the elderly will complete the following assessment instruments by interviewing the nursing staff that work most closely with the study patient. These assessments include the Cohen-Mansfield Agitation Inventory, Neuropsychiatric Inventory – Nursing Home version, Cornell Scale for Depression in Dementia, and the Physical Self-Maintenance Scale. The questions that will be asked will pertain to the patient’s mood, behavior, physical self-maintenance, and care. These interviews will require approximately one hour of time per week and will be completed over a four week period. One other instrument, the Ryden Aggression Scale will be completed twice a day at 1pm and 8pm. This scale will be necessary to record aggressive behaviors in both non-private and private spaces (bedrooms, bathrooms). This scale will be completed daily for a period of four weeks.

All patient information obtained from the staff interviews will remain strictly confidential and stringent standards of confidentiality must be maintained by staff. Only members of the research team will have access to the information.
Technical procedures:

The common areas of the dementia unit (hallways, an activity room, areas surrounding the nursing station but not the nursing station itself) will be filmed continually (24/7) for 4-weeks using ceiling-mounted video cameras and microphones. We will NOT record in bedrooms or bathrooms. Additionally, one activity room will not be filmed in order to provide privacy to residents and visitors. No equipment will be placed in a manner that interferes with any of the daily activities of the Willow dementia unit.

The filmed data will be stored on computer hard drives, and transferred every 3-4 days to the Informedia Digital Video Library at CMU where it will be stored on password-protected computers. Only authorized research team members will have access to data. The computers will keep a running log of all research team members who access the data, and the date and time at which they did so.

What are the possible risks, side effects and discomforts of this research study?

The primary risk of participation in this study stems from the fact that digital images (including faces) and speech will be captured. Moreover, the filming will record all those who enter the unit irrespective of whether they are study subjects. At the present time, we have technologies to render images irreversibly unidentifiable and speech irreversibly unintelligible for those who do not wish to be study subjects after the filming is complete. However, we do not currently have technologies to prevent in real-time the recording of those who do not wish to be filmed at all. One of our longer-term research objectives is to develop mechanisms to block the recording in real-time of non-consenting persons.

Procedures for protecting against or minimizing any potential risks:

A large sign, of poster dimensions, will be posted on the main entrance of the locked dementia unit two weeks prior to and during the study period alerting individuals to the title of the study, the fact that there will be video and audio recording, exact dates of the filming, location of the room that is NOT being filmed (so as to provide added privacy to those who seek it) and contact information should concerns or questions arise. The legally authorized representatives of the dementia unit residents will be notified of study initiation two weeks prior to the onset of the study via a letter from the nursing home administration.

The PI or research associate will be available to all those who have access to the dementia unit on a continuing basis to address any issues pertaining to the study.

The basic protection against risk in this study is the standardization of assessment and follow-up that will be provided by the study. All those who have access to the locked
dementia unit will have continuing access to the research staff for information, education, grievance and reassurance. The study investigators, project staff and data manager(s) will meet weekly to review accrued data, data confidentiality, adherence to study design, recruitment and concerns/complaints that may be raised. During these discussions, any possible changes to the study protocol or risk/benefit ratio level will be discussed. Adverse events, assessment of changes to the risk/benefit ratio, acceptability of study continuation, and concerns/complaints will be reviewed by the principal investigator and reported to the Carnegie Mellon University Institutional Review Board in accordance with their reporting guidelines.

Strict confidentiality will be maintained at all times. Assessments completed in the nursing home will be stored in locked cabinets. Filmed data will be stored on password-protected computers in the Informedia Digital Video Library. Only those staff members who have been authorized by the PI to enter data into the data management system will be permitted to do so. They will be obligated to abide by the confidentiality regulations of the IRB. Nursing home administration will not have access to the video/audio recordings. Faces of staff will be rendered irreversibly unidentifiable and speech irreversibly unintelligible after the filming has been completed.

We will report to the nursing home administrator any physical or sexual abuse of a resident by a staff member as soon as we discover it. There will be a time lag in this process since we do not currently have the capability to analyze the data in real-time. In other words, it may be weeks or months before we review the recordings and discover the abuse.

What are the possible benefits from taking part in this study?

Although we do not anticipate any direct potential benefits to study subjects, your participation in this study will contribute to knowledge regarding the prevalence, characteristics and context of aggressive behaviors in nursing homes that may benefit future nursing home residents. This study will also advance technology development that automates detection and measurement of behaviors, and creates electronic technologies that will record only consenting subjects in future studies.

The medical consultant will meet with the dementia unit staff monthly in a behavior recognition and management training exercise in which actual clinical scenarios captured during this filming will be reviewed without using any data that would personally identify a study subject. In this manner, ongoing staff training will contribute to their skills in proactively recognizing and competently managing problematic behaviors.

The research team, with the approval of the nursing home administration, will provide an opportunity for families to meet on the dementia unit and learn the findings of our ongoing research. At these meetings, we will provide computer demos, with subjects’
faces and speech rendered unidentifiable, to demonstrate to you the knowledge that is being acquired from this study.

**What treatments or procedures are available if I decide not to take part in this research study? (Not Applicable to Staff Participation)**

We are not proposing any treatment in this study.

**If I agree to take part in this research study, will I be told of any new risks that may be found during the course of the study?**

You will be promptly notified if, during the conduct of this research study, any new information becomes available that may cause you to change your mind about continuing to participate.

**Will my insurance provider or I be charged for the costs of any procedures performed as part of this research study? (Not Applicable to Staff Participation)**

There will be no procedures performed that will incur costs to the study participant.

**Will I be paid if I take part in this research study?**

Those staff members who are directly involved in the patient assessment process will be paid $10.00 weekly for their time.

**Who will pay if I am injured as a result of taking part in this study?**

If you believe that you are injured as a result of the research procedures being performed, please contact immediately the Principal Investigator or one of the co-investigators listed on the first page of this form. Researchers at Carnegie Mellon University and their associates recognize the importance of your voluntary participation in their research studies. These individuals and their staff will make reasonable efforts to minimize any injuries that may arise as a result of this research. There will be no monetary compensation made by Carnegie Mellon University in the event of a physical injury or illness resulting from the research procedures.

**Who will know about my participation in this research study?**

Any information about you obtained from this research will be kept as confidential (private) as possible. All records related to your involvement in this research study will be stored in a locked file cabinet. All filmed recordings will be stored on password-protected computers, with data access available only to authorized research team members. Your identity on these records will be indicated by a randomly assigned case number rather than by your name, and the information linking these case numbers with your identity will be kept separate from the research records. Neither you nor the nursing home will be identified by name in any publication of the research results.
Likewise, all subjects' faces as well as staff will be rendered irreversibly unidentifiable and speech irreversibly unintelligible in any public presentations of the research results.

**Will this research study involve the use or disclosure of my identifiable medical information?**

This research study will not involve the use or disclosure of any identifiable medical information since you are not a study subject.

**Who will have access to identifiable information related to my participation in this research study? (Not Applicable to Staff Participation)**

In addition to the investigators listed on the first page of this authorization (consent) form and their research staff, the following individuals will or may have access to identifiable information (which may include your identifiable medical information) related to your participation in this research study:

- Authorized representatives of the Carnegie Mellon University Research Conduct and Compliance Office may review your identifiable research information (which may include your identifiable medical information) for the purpose of monitoring the appropriate conduct of this research study.

- In unusual cases, the investigators may be required to release identifiable information (which may include your identifiable medical information) related to your participation in this research study in response to an order from a court of law. If the investigators learn that you or someone with whom you are involved is in serious danger or potential harm, they will need to inform, as required by Pennsylvania law, the appropriate agencies.

- Authorized representatives of the sponsor of this research study, the National Science Foundation, will review an/or obtain identifiable information (which may include identifiable medical information) related to your participation in this research study for the purpose of monitoring the accuracy and completeness of the research data and for performing required scientific analyses of the research data. Authorized representatives of the study sponsor may also be present during your participation in study procedures performed as part of this research study. While the study sponsor understands the importance of maintaining the confidentiality of your identifiable research and medical information, Carnegie Mellon University cannot guarantee the confidentiality of this information after it has been obtained by the study sponsor. The investigators involved in the conduct of this research study may receive funding from the sponsor to perform the research procedures and to provide the sponsor with identifiable research and medical information related to your participation in the study.
For how long will the investigators be permitted to use and disclose identifiable information related to my participation in this research study? (Not Applicable to Staff Participation)
The investigators may continue to use and disclose, for the purposes described above, identifiable information (which may include your identifiable medical information) related to your participation in this research study for a minimum of 5 years and for as long (indefinite) as it may take to complete this research study.

May I have access to my medical information that results from my participation in this research study? (Not Applicable to Staff Participation)

In accordance with the HIPAA Privacy Practices document that you have been provided, you are permitted access to information (including information resulting from your participation in this research study) about you derived from the filming, however, you will not have access to the actual films themselves since the privacy of other residents who are on those recordings would be violated.

Is my participation in this research study voluntary?

Your participation in this research study is completely voluntary. Whether or not you provide consent for participation will have no effect on your current or future relationship with Carnegie Mellon University or the Asbury Heights Nursing Home.

You are under no obligation to participate in this research study.

May I withdraw, at a future date, my consent for participation in this research study?

You may withdraw, at any time, your consent for participation in this research study. (Note, however, that if you withdraw your consent for the use and disclosure of your identifiable medical record information for the purposes described above, you will also be withdrawn, in general, from further participation in this research study.) Any identifiable research or medical information recorded for, or resulting from, your participation in this research study prior to the date that you formally withdrew your consent may continue to be used and disclosed by the investigators for the purposes described above. (Not Applicable to Staff Participation)

To formally withdraw your consent for participation in this research study you should provide a written and dated notice of this decision to the principal investigator of this research study at the address listed on the first page of this form.
Your decision to withdraw your consent for participation in this research study will have no affect on your current or future relationship with the Carnegie Mellon University or with the Asbury Heights Nursing Home.

If I agree to take part in this research study, can I be removed from the study without my consent?
We do not anticipate any circumstances under which we would need to remove you from the study without your consent. However, if such circumstances arise, we will inform you promptly of our decision to remove you from the study.
VOLUNTARY CONSENT

All of the above has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions about any aspect of this research study during the course of this study, and that such future questions will be answered by the researchers listed on the first page of this form. Any questions which I have about my rights as a research participant will be answered by the Human Subject Protection Advocate of the IRB Office, Carnegie Mellon University (412-268-4727).

By signing this form, I agree to participate in this research study. A copy of this consent form will be given to me.

___________________________________   ___________________
Participant’s Signature     Date

CERTIFICATION OF INFORMED CONSENT

I certify that I have explained the nature and purpose of this research study to the above-named individual(s), and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) has about this study have been answered, and we will always be available to address future questions as they arise.

___________________________________   ___________________
Signature of Person Obtaining Consent   Role in Research Study

___________________________________   ___________________
Investigator’s Signature                          Date
PROXY CONSENT

Participant’s Name (Print)

The above-named individual is unable to provide direct consent for study participation due to:______________________________

Therefore, by signing this form as a legal guardian of the participant I give my consent for his/her participation in this research study.

Representative’s Name (Print)  Representative’s Relationship to Participant

Representative’s Signature  Date

Witness Signature  Date

VERIFICATION OF EXPLANATION: I certify that I have carefully explained the purpose and nature of this research study to the above-named participant in appropriate language. He/she has had an opportunity to discuss it with me in detail. I have answered all his/her questions and he/she has provided affirmative agreement (i.e. assent) to participate in this study.

Investigator’s Signature  Date
CONSENT FOR CONTINUED RESEARCH PARTICIPATION: I understand that I am currently participating in a research study. I further understand that consent for my participation in this research study was initially obtained from my authorized representative as a result of my inability to provide direct consent at the time that this initial consent was requested. I have now recovered to the point where it is felt that I am able to provide direct consent for continued participation in this research study.

All of the above has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions about any aspect of this research study during the continuation of this study and that such future questions will be answered by researchers listed on the first page of this form. I also understand that any questions that I have about my rights as a research participant will be answered by the Human Subject Protection Advocate of the IRB Office, Carnegie Mellon University (412-268-4727).

Participant’s Signature _____________________________ Date _____________________________

Printed Name of Person Obtaining Consent _____________________________ Role in Research Study _____________________________

Signature of Person Obtaining Consent _____________________________ Date _____________________________