CONSENT TO ACT AS A PARTICIPANT IN A RESEARCH STUDY

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

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SOURCE OF SUPPORT: This study is funded by the National Science Foundation, a public agency, which is supporting the costs of conducting the research. Neither Carnegie Mellon University, nor Howard D. Wactlar, will receive any financial benefit based on the results of the study.

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 residents of the Asbury Heights Willow Dementia Unit with a chart diagnosis of dementia and who are not completely bedridden and are out of view of our cameras and microphones will be invited to participate. No restrictions will be placed with regards to the patient’s age, gender, race or ethnicity.

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:

Your age, level of education, current medications, medical and psychiatric conditions will be recorded from your medical record by a clinical research associate who has experience working with the elderly. She will update the information at weekly visits to the nursing home (for example, changes in medications or medical or psychiatric condition(s) since last visit.) The only assessment scale that will require your direct participation will be the Severe Impairment Battery to determine the severity of the dementia. This assessment will be completed at the beginning and end of the study period.

The clinical research associate will also complete assessment instruments by interviewing members of the nursing staff who are most closely involved with your care. 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. In addition, nurses or certified nursing assistants who are caring for you will complete the Ryden Aggression Scale twice a day at 1pm and 8pm. This scale will be necessary to record aggressive behaviors in non-private and private spaces (bedrooms, bathrooms).
Your identity on these assessments will be indicated by a randomly assigned identification number. All private information will be recorded using code numbers. Neither you nor the nursing home will be identified by name in any publication of the research results.

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 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 the 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 voices will be captured, thus potentially compromising subject confidentiality. 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 digitally erase all those who are not study participants 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 long-term research objectives is to develop mechanisms to block the recording in real-time of non-consenting persons. In addition to this risk, the subjects may also experience transient emotional discomfort while being interviewed by the research associate when completing the manual rating instruments. Only one instrument, the Severe Impairment Battery, will require the direct participation of the subject. We will terminate the interview at any time that you so indicate.
Procedures for Protecting Against or Minimizing any Potential Risks:

A large sign, of poster dimensions, will be posted on the main entrance of the 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 activity 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 ongoing 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 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 IRB in accordance with IRB reporting guidelines.

Strict confidentiality will be maintained at all times. Assessment instruments completed in the nursing home will be stored in locked cabinets. Filmed data will be stored in 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. No patient or nursing home will be identified by any published report. Nursing home administration will not have access to the video/audio recordings. Subjects’ faces will be rendered irreversibly unidentifiable and speech irreversibly unintelligible in any public presentation of the research results.

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. Given this, 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?

We do not anticipate any direct potential benefits to the study subjects. However, 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 will automate detection and measurement of behaviors and create electronic technologies that can record only consenting subjects in future studies.

The medical consultant will meet with the dementia unit staff monthly in a behavioral 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 demonstrations, with subjects’ faces and speech rendered unidentifiable, to demonstrate to you the knowledge that is being acquired in the study.

What treatments or procedures are available if I decide not to take part in this research study?

We are not proposing any treatment in this study. Any and all residents of the dementia unit are free to choose not to participate 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 which 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?

There will be no procedures performed that will incur cost to the study participant.
Will I be paid if I take part in this research study?

There will be no payment for participating in this study.

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 staffs 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 identification number 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 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 involve the recording of current and/or future identifiable medical information from your nursing home medical records. The information that will be recorded will be limited to information concerning your age, level of education, current medications, medical and psychiatric conditions, and length of stay on the dementia unit. At each weekly visit, the clinical research associate will update your medication list and changes in your medical or psychiatric condition(s), as well as deaths or discharges (of study subjects) from the unit.
Who will have access to identifiable information related to my participation in this research study?

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, National Science Foundation, will review and/or obtain identifiable information (which may include your 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?

The investigators may continue to use and disclose, for the purposes described above, identifiable information (which may include your identifiable medical information) related to

Participant’s Initials ___

CMU CareMedia Study-Consent Form for Subject
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?**

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) and any that has been derived from the filming. 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, to include the use and disclosure of your identifiable information for the purposes described above, is completely voluntary. (Note, however, that if you do not provide your consent for the use and disclosure of your identifiable information for the purposes described above, you will not be allowed, in general, to participate in the research study.) Whether or not you provide your consent for participation in this research study will have no affect on your current or future relationship with Carnegie Mellon University. Whether or not you provide your consent for participation in this research study will have no affect on your current or future medical care at the Asbury Heights Nursing Home or affiliated health care provider or your current or future relationship with a health care insurance provider.

**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, to include the use and disclosure of your identifiable information for the purposes described above. (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.

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. Your decision to withdraw your consent for participation in this research study will have no affect on your current or future medical care at the Asbury Heights Nursing Home or an affiliated health care provider or your current or future relationship with a health care insurance provider.

**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.

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**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) have about this study have been answered, and we will always be available to address future questions as they arise.

_________________________________  ____________
Signature of Person Obtaining Consent                         Date

_______________________________
Investigator’s Signature

________________________________
Participant’s Initials ___
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

Participant’s Initials ___
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 the 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 __________________________

Participant’s Initials ___