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RUTGERS
Institute for Health, Health Care Policy, and Aging Research

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CONSENT TO TAKE PART IN A RESEARCH STUDY

TITLE OF STUDY: Leveraging Surveillance Technology to Improve Safety in Community Aging Populations
Principal Investigator: XinQi Dong, MD, MPH

STUDY SUMMARY: This consent form is part of an informed consent process for a research study. It will provide information that will help you decide whether you want to take part in this study. It is your choice to take part or not. The purpose of the research is to: 1) understand if cameras protect older adults from harm; 2) study negative outcomes of using the cameras; 3) find out whether older adults think this camera is useful, acceptable, and/or practical. This is an experimental study. If you take part in the research, you will be assigned at random to 1 of 3 study groups. We don't know which group will have a better health and safety outcomes. Additionally, we will ask you questions related to your general characteristics, mental wellbeing, physical wellbeing, and social wellbeing. We will repeat these questions at the 10th, 12th, 14th, 16th, 20th, 24th week follow up interviews. Your participation in the study will take 6 months in total. Some of the questions and the presence of a camera in this study may have unknown potential harm. It is also possible that camera use could worsen safety. There is no direct benefits for participating in this study but we may learn information that could benefit older adults' health and safety. Your alternative to taking part in the research study is not to take part in it.

The information in this consent form will provide more details about the research study and what we will ask you to do if you choose to take part in it. If you have any questions now or during the study, if you choose to take part, you should feel free to ask them and should expect to be given answers that you completely understand. After all of your questions have been answered and you wish to take part in the research study, we will ask you to sign this consent form. You are not giving up any of your legal rights by agreeing to take part in this research or by signing this consent form.

Who is conducting this research study?
Dr. XinQi Dong is the Principal Investigator of this research study. A Principal Investigator has the overall responsibility for the conduct of the research. However, there are often other individuals who are part of the research team.

Dr. XinQi Dong may be reached at +1-848-932-8413 or xinqi.dong@rutgers.edu

The Principal investigator or another member of the study team will also sign this informed consent. We will give you a copy of the signed consent form to keep.

The study is sponsored by the Administration for Community Living and Administration on Aging (ACL/AoA).

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Why is this study being done?
The purpose of this study is to: 1) understand if different technologies protect older adults from harm; 2) study negative outcomes of using the technologies; 3) find out whether older adults find the technology useful, acceptable, and/or practical.

Who may take part in this study and who may not?
People who can participate the study must meet the following: 1) 60 years and older; 2) someone whose safety is currently at risk. People who cannot participate this study if they 1) have plans to move for the next 3 months and 2) have significant thinking or memory impairment and 3) have impairment in eating, dressing, bathing, walking, transferring, grooming, bladder control, or toileting.

Why have I been asked to take part in this study?
We ask you to take part in this study because you are 60 years and older and someone whose safety is currently at risk.

How long will the study take and how many subjects will take part?
About 10 eligible adults will take part in this study. Duration of participation in the study is 6 months.

What will I be asked to do if I take part in this study?
Before you can start the study, the study staff will talk with you about the study. During the initial contact, study staff will describe the purposes of the research project and its general content. With permission, we will also gather information using long screening questions to confirm eligibility. If you are interested in learning more about the project or agree to participate in our research, we will set up a private in-person interview with you, and we will explain the consent form.

If you agree to participate, after signing this consent, we will ask questions about whether you are married, who lives with you, and where you were born. In addition, we will ask about general characteristics, mental wellbeing, physical wellbeing, and social wellbeing. We will repeat these questions at the 10^{th}, 12^{th} 14^{th}, 16^{th}, 20^{th}, 24^{th} week follow up interviews.

Then, we will assign you (by chance, like drawing one out of three balls from a box) to 1 of 3 study groups. Neither you nor the study staff can choose the group you will be in. You will have an equal chance of being placed in any group. Your study group assignment will determine the instructions you will receive.

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Time Chart			
Initial contact	Confirm eligibility and informed consent		
	In-person interview		
	Random assignment to 1 of 3 groups		
	Group 1	**Group 2**	**Group 3**
1st week	• Camera(s) • Weekly assessments • Possible daily check-in • Interview at 8th week		• Weekly assessments
2nd week			
3rd week			
4th week			
5th week			
6th week			
7th week			
8th week			
10th week	Follow-up interview		
12th week (3rd month)	Follow-up interview		
16th week (4th month	Follow-up interview		
20th week (5th month)	Follow-up interview		
24th week (6th month)	Follow-up interview		

Group 1 and 2: with permission, a camera (and Wi-Fi if needed) will be installed in your home.

This device will be installed:

- by a study technician
- in a common area of your home on the ceiling
- remaining for the next 8 weeks

Cameras in group 1 will record audio and video, whereas cameras in group 2 will not. All cameras in group 1 and 2 look exactly the same. Neither you nor the study staff will know whether the camera will record. You will be informed which cameras you received after complete the 6-month participation. If video or audio is recorded, you will not have access to this data. Additionally, we will place a sign outside the home to notify individuals about potential recording, reading, "NOTICE Audio and/or video may be recorded on these premises".

At the end of each week, staff will conduct face-to-face visits in your home and/or telephone follow-up (weekly assessment). The weekly meeting will focus on the use of the camera and its influence on your health and well-being. All participants will get weekly assessments and some participants will receive a daily check-in. After 8 weeks, the camera will be removed. At this time, participants will be asked open-ended questions to better understand the impact of the cameras and signs. Participants in Group 1 and 2 will also participate in follow-up interviews administered by study staff at the 10th, 12th 14th, 16th, 20th, 24th week from enrollment.

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Group 3: study staff will administer assessments and follow-up interviews to during the 8th, 10th, 12th 14th, 16th, 20th, 24th week after enrollment. These interviews will focus on your health and wellbeing, as well as any issues regarding safety since your last interview.

What are the risks and/or discomforts I might experience if I take part in this study?
The project attempts to improve safety outcomes of older adults through the use of cameras. The participants may be bothered by some of the questions on the questionnaire or by the presence of the cameras. Additionally, it is possible that camera placement could worsen safety conditions.

You should <u>not</u> rely on the camera or recordings in emergency situations.

There may also be risk associated with loss of confidentiality of information through data storage or being part of the group with the internet connected recording device. The study staff will take measures to assure that you are comfortable and address any concerns or questions you may have. In the event of any adverse outcomes, you will be encouraged to report the case to a New Jersey APS caseworker and study staff.

Are there any benefits to me if I choose to take part in this study?
There may be no direct benefit to you for participating in this study. By participating, Rutgers may learn information that could prevent older adults from future harm.

What are my alternatives if I do not want to take part in this study?
The alternative to participating in this study is not to participate. You have the right to withdraw from the study at any time. If you choose to withdraw, your information, links, and recorded interviews will also be discarded. The information from the transcribed (copied) interviews will be discarded. If you choose to withdraw, please contact Dr. XinQi Dong at +1-848-932-8413 or xinqi.dong@rutgers.edu

How will I know if new information is learned that may affect whether I am willing to stay in the study?
During the course of the study, you will be updated about any new information that may affect whether you are willing to continue taking part in the study. If new information is learned that may affect you after the study or your follow-up is completed, you will be contacted.

Will I receive the results of the research?
We will not give you any individual results from the study.

Will there be any cost to me to take part in this study?
There will be no cost for you to take part in this study.

Will I be paid to take part in this study?
You will receive $100 upon completion of the 6-month participation.

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How will information about me be kept private or confidential?
All efforts will be made to keep your personal information in your research record confidential, but total confidentiality cannot be guaranteed. An identification number will be assigned to the information you provide, and the link between this number and your identifying information will be maintained in a separated password-protected file. Data will be entered by research assistants directly to a web-based form using tablets. Video information collected by the cameras will be concealed by converting into secret codes and stored in a secure cloud (https://store.google.com/product/nest_aware?hl=en-US). A study technician will download videos daily and upload to our secure database at Rutgers. All data files will be password protected and stored as "read only" files on password and firewall protected computers. The computers will be placed in locked offices at Rutgers Institute for Health.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require, such as laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

What will happen to my information or biospecimens collected for this research after the study is over?
The information collected about you for this research will not be used by or distributed to investigators for other research.

What will happen if I am injured during this study?

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Subjects in this study may be exposed to certain risks of personal injury in addition to those associated with standard forms of treatment. In addition, it is possible that during the course of this study, new adverse effects that result in personal injury may be discovered.

If you get ill or are injured as the direct result of being in this study inform your study doctor as soon as possible. The Institution will make appropriate referrals for treatment. The Study Sponsor shall reimburse all the reasonable and necessary costs of diagnosis and treatment of any Study subject injury, including hospitalization, if it:

a. Is not a medical condition that you had before you started the study;
b. Is not the result of the natural progression of your disease or condition;
c. Is not caused by your failure to follow the study plan; and
d. Is not proved to be directly caused by the Institution's negligence or misconduct.

There are no other plans for the University to provide other forms of compensation (such as lost wages) to you for research related illnesses or injuries. However, by signing this form, you are not giving up any legal rights to seek further compensation.

What will happen if I do not wish to take part in the study or if I later decide not to stay in the study?
It is your choice whether to take part in the research. You may choose to take part, not to take part or you may change your mind and withdraw from the study at any time.

If you do not want to enter the study or decide to stop taking part, your relationship with the study staff will not change, and you may do so without penalty and without loss of benefits to which you are otherwise entitled.

You may also withdraw your consent for the use of data already collected about you, but you must do this in writing to Dr. XinQi Dong at Institute for Health, Health Care Policy, & Aging Research 112 Paterson Street, New Brunswick, NJ 08901.

If you decide to withdraw from the study for any reason, you may be asked to return for at least one additional visit for safety reasons.

Who can I call if I have questions?
If you have questions about taking part in this study or if you feel you may have suffered a research related injury, you can call the study doctor: Dr. XinQi Dong at +1-848-932-8413.

If you have questions about your rights as a research subject, you can call the IRB Director at: New Brunswick/Piscataway ArtSci IRB (732)235-2866 or the Rutgers Human Subjects Protection Program at (973) 972-1149.

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AGREEMENT TO PARTICIPATE

1. Subject consent:

I have read this entire consent form, or it has been read to me. I believe that I understand what has been discussed. All of my questions about this form and this study have been answered. I agree to take part in this study.

Subject Name:_____

Subject Signature:_____ Date:_____

2. Signature of Investigator/Individual Obtaining Consent:

To the best of my ability, I have explained and discussed all the important details about the study including all of the information contained in this consent form.

Investigator/Person Obtaining Consent (printed name):_____

Signature:_____ Date: _____

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CONSENT TO AUDIO-/VISUALLY RECORD OR PHOTOGRAPH SUBJECTS ADDENDUM

You have already agreed to take part in a research study entitled: Leveraging Surveillance Technology to Improve Safety in Community Aging Populations conducted by Dr. XinQi Dong. We are asking your consent to allow us to audiotape (sound) and videotape you as part of the research. You have to consent to be recorded in order to take part in the main research.

The will be used for analysis by the research team to use de-identifiable data to understand occurrences of situations that may be unsafe to the participation.

The recording(s) may include the following information that can identify you: full face photographic images and voice.

The recording(s) will be encrypted (converted into a code to prevent access) and stored in a secure cloud. A study technician will download videos daily and upload to out secure database at Rutgers. All data files will be password protected and stored as “read only” files on password and firewall protected computers in locked offices at Rutgers Institute for Health. All recording(s) will be destroyed at the end of the study.

Your signature on this form permits the investigator named above to record you as described above during participation in the above-referenced study. The investigator will not use the recording(s) for any other reason than that/those stated in the consent form without your written consent.

Subject Name _____

Subject Signature _____ Date _____

Investigator/Person Obtaining Consent Signature _____

Date _____