PLEASE NOTE: The current *reading* level of this form is estimated to be at the 6.0 grade level based on the Flesch-Kincaid index. **Its contents will be read to potential participants** who will be given a copy of the form with which to read along. After each section of the consent form has been read, one or more questions will be asked to ensure that the person has understood the information provided. If this is not the case, the person obtaining informed consent will re-read that section of the form, further simplifying the language used. These questions will not be included in versions of the consent form participants are asked to sign.

**“Goal setting intervention among older adults using Nao, a socially assistive robot (SAR)”**

**CONSENT FORM**

**PHASE 2: experimental Study**

We would like you to help us with a study about how robots can help people like yourself be more active both physically and socially.

Before you say “YES,” we want to make sure you know what we will ask you to do. We also want to make sure you know your rights.

The leader of this study is Dr. Renáta Tichá. She works at the University of Minnesota’s Institute on Community Integration.

**What the study is about**

In this study we are going to introduce you to a robot called Nao. We will bring the robot to where you live for 10 meetings with you over 8 weeks. Each meeting will last for about 30 minutes. During these meetings, the robot will help you develop a set of goals for physical and social activities. The robot will also be available to support you to work toward these goals during the meetings you have with it. We are interested in understanding how this program and people working with the robots affects their physical and social activities. We need the help of seniors like you to support our evaluating this program.

We are looking for people to be part of this study who:

* Are at least 70 years old
* Do not have a serious disability
* Can communicate with the research team
* Can make an informed choice about whether they want to be in the study
* Are interested in and can interact with the robot
* Are willing to take part in 10 meetings with the robot that will last for 5 hours over a 8-week period of time; and
* Two times goal setting conversation that takes 90 min each times. Two times during intervention and one time in two months after intervention
* Two times filling three self-report surveys that takes 45 min each times. Two times during intervention and one time in two months after intervention

**What we will ask you to do.**

As part of the study, we will have a goal setting conversation with you three times and ask you to take part in weekly meetings with the Nao robot. During these meetings, you will interact with the robot, develop a set of physical activity goals with its support, and do activities with it.

If you take part in this research project, we will ask you to do the following things

***You will be asked to fill three surveys at the start of the project and at two additional times. During interviews, we will ask you questions about your background, physical activities, and social relationships.***

* These will include questions about your age, race, and education.
* It will also include questions about the different types of physical activities you do, how often you do them, and who you do them with
* A third type of question will be about your social relationships. We will ask you questions about whether these relationships meet your needs, if you are able to spend time with the people you want to, if you are lonely, and if you would like to make new friends.
* Together these surveys will take about 45 minutes
* You do not have to finish the surveys we are asking you to complete all at once.  We can come back if you need us to.

***We will ask you to take part in 10 meetings with the Nao robot.***

* You will interact with the robot and have a conversation about your goals. During the first meeting you have with the Nao robot, a project staff person from the University will talk with you about your goals. These will be goals you want to set for yourself about your physical activity. This meeting will take about 60-90 minutes depending on the number of goals you want to work on.

You will then meet with the Nao robot for 10-meetings. Each meeting will last about 30 minutes.

* During the meetings the robot will talk with you about your hobbies, interests, family members, friends, and memories that you are willing to share.
* The robot will also talk with you and help you work toward the goals that you have set for yourself for physical activities.
* The robot will be used to check in with you and see what kind of progress you are making toward reaching your goals and problem solve if you are not making the progress you desire.

***After you have completed 10 meetings with the robot, we will talk to you again about your goals, physical activities, and social relationship. This will take about 45-60 minutes***

* + During this second, interview, we will ask you questions similar to those we asked you the first time. These questions will also ask you about whether you believe you have met the goals that you set

***After two months we will reach out to you for a third conversation and filling surveys.***

* During the conversation we will again talk to you about your physical activity goals. This will last about 45-60 minutes
* You will fill the surveys about physical activities and social relationships. These will last about 30 minutes

During conversations and meetings with the Nao robot you can stop the meeting and leave if you feel tired or bored

For some participants, we may record conversation and meetings with the Nao robot. We are doing this to make sure we heard your answers correctly.

**How this could help you or hurt you**

We do not think anything bad will happen to people in this study.  However, a few things could happen.

* You may not remember some information needed to answer the questions we ask you.You might feel embarrassed by this.
* We may ask you some questions that you think are personal. You may not want to answer some of these questions. If we ask a question that you do not want to answer, you can say so. All you need to say is “pass.” It is not a problem.
* Helping us with this study will take about 10 hours and 50 minutes. You could use this time to do other things. You might find these more enjoyable than helping us.

**You can stop being in the study at any time. All you need to do is tell us. This is okay. If you do not want to tell us that you want to stop being in the study, you can tell a family member or some other person that you trust (such as a support person).**

**Volunteering to be in the Study**

We will not offer any reward or payment for taking part in this study. Being in this study is something that you decide to do as a volunteer.

**Your Privacy**

We will try to keep everything we talk about private. That means:

* We will not tell anyone who isn’t a researcher for the project the things you tell us.
* We will not share your name in any reports we write.
* If we record the interview, the recording will be kept private.
* We will keep your information in a locked office on a computer with a secure password.
* If the University of Minnesota which funds this study or the University Humans Subjects Review office asks to see records for the study, we may need to share that information with them.

There is one time when we cannot keep things private.  If we think someone is not getting enough food or their medicine, or if we think someone is being bullied, threatened, or hurt, we need to tell someone. If something like this happens, we will first talk with you in private. We will make sure we understand. If you are not safe, we will tell a person who can help.

**You can say NO**

* You do not have to say YES and be in the study.
* You do not need to answer any question you don’t want to answer.
* You can say “NO” right now.  No one will be upset. We will not ask you again.
* You can decide to be in the study now but change your mind later.  Just tell us and we will leave you alone.
* No one at the University or the people who provide you with support will mind if you say “NO” and decide not to be in the study.
* The people that provide you with support will still help you, whether you say “YES” or “NO.”

If you have any questions that you would like to ask someone who is not working on the study, you can call the **Research Subjects’ Advocate Line** **at (612) 625-1650.**

***\*You will be given a copy of this information for your records.***

**Statement of Consent**

I have read or heard the above information. I understand what I will be asked to do.  I have asked questions and have been given answers to all my questions. I want to take part in the study.

Printed name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of person obtaining consent: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_

Signature of Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_

**WITNESS STATEMENT:**

The participant was unable to read or sign this consent form because of the following reason:

The participant is illiterate

The participant is visually impaired

The participant is physically unable to sign the consent form. Please describe:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Other *(please specify)*:

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My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the participant, and that consent was freely given by the participant.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Witness to Consent Process Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed Name of Person Witnessing Consent Process

|  |  |  |
| --- | --- | --- |
| **Assessment of Capacity to Consent\*** | | |
| **Instructions:** Read aloud each section of the consent form and ask the italicized question(s) below each section. A question can be rephrased if the person has trouble understanding it. Then, rate the demonstrated level of understanding in the person’s response using the following scale**:**  **0-demonstrates no or little understanding;**  **1-demonstrates partial understanding;**  **2-demonstrates clear/complete understanding**.  If the person’s initial response does not demonstrate complete understanding (rating of 0 or 1), the person obtaining consent can review the section again and re-ask the question. Then, circle the final demonstrated level of understanding below the question before moving on to the next section of the consent form. Record scores for each question below and use the total score to determine if the person can consent to being in the study. | | |
| **Question** | | **Score** |
| *1. Can you tell me in your own words what the study is about?* | | 0  1  2 |
| *2. What makes you want to consider taking part in this study?* | | 0  1  2 |
| *3. Can you tell me how long interviews will take?* | | 0  1  2 |
| *4. Can you tell me some of the areas we will talk with you about?* | | 0  1  2 |
| *5. Can you tell me some potential risks or negative things that might happen to you if you take part in this study?* | | 0  1  2 |
| *6. Can you tell me what you can say if you do not want to answer a question?* | | 0  1  2 |
| *7. If you take part in this study, will you be paid for participation?* | | 0  1  2 |
| *8. Can you tell me some ways we will try to keep what we talk about private?* | | 0  1  2 |
| *9. If you say “yes” you want to be a part of the study, but change your mind, what can you do?* | | 0  1  2 |
| *10. If you do not want to take part in this study or decide to stop, what will happen?* | | 0  1  2 |
| Score of **[15]** or higher is needed for inclusion in study. | **Total Score:** |  |

\*Adapted from University of Minnesota IRB Form HRP-227 (UBACC Interview Form)