**INSTRUCTIONS:**

* Use “SOCIAL TEMPLATE PROTOCOL (HRP-580)” to prepare a social-behavioral study (see [InvestigatorManual(HRP-103)](https://drive.google.com/file/d/0B7644h9N2vLcOWtzU2FmSU5oS0U/edit)for a definition of social-behavioral research).
* For social-behavioral research involving biomedical activities, refer to the [InvestigatorManual(HRP-103)](https://drive.google.com/file/d/0B7644h9N2vLcOWtzU2FmSU5oS0U/edit) for further instructions as to whether the “MEDICAL TEMPLATE PROTOCOL (HRP-590)” is required.
* Depending on the nature of what you are doing, some sections may not be applicable to your research. If so mark as “NA”. For example, research involving a retrospective chart review may have many sections with N/A.
* Please do not delete sections if they do not apply to the study.
* We suggest that you use the word “participant” or “volunteer” rather than “subject” throughout your protocol. The reason is that “subject” has the sense of someone under the authority of the investigator while “participant” or “volunteer” has the sense of a person who understands and is an important contributor to the research.
* After you submit your protocol for review in ETHOS, your protocol will be saved there. You should use that saved version as your starting point for edits to the next version. You may choose to track protocol versions for yourself outside of ETHOS; however, you should ensure that any version you edit is the same as the most recently approved version in ETHOS.
* As you are writing the protocol, remove all instructions in red so that they are not contained in the final version of your protocol.
* To update page numbers in the Table of Contents, right click on the table and select “Update Field” and “page numbers only.”

**ANCILLARY REVIEWS**

**DO NOT DELETE. Submit the completed checklist below with your protocol.**

|  |  |  |  |
| --- | --- | --- | --- |
| **Which ancillary reviews do I need and when do I need them?**  Refer to [HRP-309](https://drive.google.com/file/d/0B7644h9N2vLcMTl0ZE9yQkhLd3c/view) for more information about these ancillary reviews. | | | |
| **Select yes or no** | **Does your study…** | *If yes…* | **Impact on IRB Review** |
| **☐ Yes**  **☐ X No** | Include Gillette resources, staff or locations | *Gillette Scientific review and Gillette Research Administration approval is required. Contact:*  [*research@gillettechildrens.com*](mailto:research@gillettechildrens.com) | **Required prior to IRB submission** |
| **☐ Yes**  **☐ X No** | Involve Epic, or Fairview patients, staff, locations, or resources? | *The Fairview ancillary review will be assigned to your study by IRB staff*  *Contact:* [ancillaryreview@Fairview.org](mailto:ancillaryreview@Fairview.org) | **Approval must be received prior to IRB committee/ designated review.**  **Consider seeking approval prior to IRB submission.** |
| **☐ Yes**  **☐ X No** | Include evaluation of drugs, devices, biologics, tobacco, or dietary supplements or data subject to FDA inspection? | *STOP – Complete* [*the Medical Template Protocol (HRP-590)*](https://drive.google.com/open?id=0Bw3yHuGQzD8CaExVUkZEWjBVSU0)  *The regulatory ancillary review will be assigned to your study by IRB staff*  *Contact:* [*medreg@umn.edu*](mailto:medreg@umn.edu)  *See* [*https://policy.umn.edu/research/indide*](https://policy.umn.edu/research/indide) |
|  | Require Scientific Review? Not sure? See guidance in the [Investigator Manual (HRP-103)](https://drive.google.com/uc?export=download&id=0B7644h9N2vLcOWtzU2FmSU5oS0U). | *ONLY REQUIRED*  *BIOMEDICAL RESEARCH REVIEWED BY FULL COMMITTEE* |
| **☐ Yes**  **☐ X No** | Relate to cancer patients, cancer treatments, cancer screening/prevention, or tobacco? | *Complete the* [*CPRC application process*](https://www.cancer.umn.edu/for-researchers/investigator-resources/cancer-protocol-review-committee)*.*  *Contact:* [*ccprc@umn.edu*](mailto:ccprc@umn.edu) |
| **☐ Yes**  **☐ X No** | Include the use of radiation?  (x-ray imaging, radiopharmaceuticals, external beam or brachytherapy) | *Complete the* [*AURPC Human Use Application*](https://radsafety.umn.edu/human-use-application-and-resources) *and follow instructions on the form for submission to the AURPC committee.*  *Contact:* [*barmstro@umn.edu*](mailto:barmstro@umn.edu) | **Approval from these committees must be received prior to IRB approval;**  **These groups each have their own application process.** |
| **☐ Yes**  **☐ X No** | Use the Center for Magnetic Resonance Research (CMRR) as a study location? | *Complete the* [*CMRR pre-IRB ancillary review*](https://www.cmrr.umn.edu/preirb/user/user.php)  *Contact:* [*ande2445@umn.edu*](mailto:ande2445@umn.edu) |
| **☐ Yes**  **☐ X No** | Include the use of recombinant or synthetic nucleic acids, toxins, or infectious agents? | *STOP – Complete* [*the Medical Template Protocol (HRP-590)*](https://drive.google.com/open?id=0Bw3yHuGQzD8CaExVUkZEWjBVSU0) |
| **☐ Yes**  **☐ X No** | Include the use of human fetal tissue, human embryos, or embryonic stem cells? | *STOP – Complete* [*the Medical Template Protocol (HRP-590)*](https://drive.google.com/open?id=0Bw3yHuGQzD8CaExVUkZEWjBVSU0) |
| **☐ Yes**  **☐ X No** | Include PHI or are you requesting a HIPAA waiver? | *If yes, HIPCO will conduct a review of this protocol.*  *Contact:* [*privacy@umn.edu*](mailto:privacy@umn.edu) |
| **☐ Yes**  **☐ X No** | Use data from CTSI Best Practices Integrated Informatics Core (BPIC)  Formerly the AHC Information Exchange (AHC-IE)? | *The Information Exchange ancillary review will be assigned to your study by IRB staff*  *Contact:* [*bpic@umn.edu*](mailto:ics@umn.edu) | **Approval must be received prior to IRB approval.**  **These groups do not have a separate application process but additional information from the study team may be required.** |
| **☐ Yes**  **☐ X No** | Use the Biorepository and Laboratory Services to collect tissue for research? | *STOP – Complete* [*the Medical Template Protocol (HRP-590)*](https://drive.google.com/open?id=0Bw3yHuGQzD8CaExVUkZEWjBVSU0)  *The BLS ancillary review will be assigned to your study by IRB staff.*  *Contact: Jenny Pham Pham0435@umn.edu* |
| **☐ Yes**  **☐ X No** | Have a PI or study team member with a conflict of interest? | *The CoI ancillary review will be assigned to your study by IRB staff*  *Contact:* [*becca002@umn.edu*](mailto:becca002@umn.edu) |
| **☐ Yes**  **☐ X No** | Need to be registered on clinicaltrials.gov? | *If you select “No” in ETHOS, the clinicaltrials.gov ancillary review will be assigned to your study by IRB staff*  *Contact:* [*kmmccorm@umn.edu*](mailto:kmmccorm@umn.edu) |
| **☐ Yes**  **☐ X No** | Require registration in OnCore? | *If you select “No” or “I Don’t Know” in ETHOS, the OnCore ancillary review will be assigned to your study by IRB staff*  *Contact:* [*oncore@umn.edu*](mailto:oncore@umn.edu) | **Does not affect IRB approval.** |

**PROTOCOL COVER PAGE**

|  |  |
| --- | --- |
| **Protocol Title** | “Enhancing physical activity among older adults using Nao, a socially assistive robot (SAR)” |
| **Principal Investigator/Faculty Advisor** | Name: Renáta Tichá |
| Department: Institute on Community Integration (ICI) |
| Telephone Number: (612) 624-5776 |
| Email Address: [tich0018@umn.edu](mailto:tich0018@umn.edu) |
| **Student Investigator** | Name: |
| Current Academic Status (Student, Fellow, Resident): |
| Department: |
| Telephone Number: |
| Institutional Email Address: |
| **Scientific Assessment** | I believe Scientific Assessment is not required. |
| **Version Number/Date:** | Version 1; 4/17/2022 |

**REVISION HISTORY**

|  |  |  |  |
| --- | --- | --- | --- |
| **Revision #** | **Version Date** | **Summary of Changes** | **Consent Change?** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

NOTE: Leave this section blank for the initial submission. The revision history should be documented for modifications to approved studies.

Table of Contents

[1.0 Objectives 8](#_Toc68115614)

[2.0 Background 8](#_Toc68115615)

[3.0 Study Endpoints/Events/Outcomes 8](#_Toc68115616)

[4.0 Study Intervention(s)/Interaction(s) 8](#_Toc68115617)

[5.0 Procedures Involved 8](#_Toc68115618)

[6.0 Data Banking 9](#_Toc68115619)

[7.0 Sharing of Results with Participants 9](#_Toc68115620)

[8.0 Study Duration 9](#_Toc68115621)

[9.0 Study Population 9](#_Toc68115622)

[10.0 Vulnerable Populations 10](#_Toc68115623)

[11.0 Number of Participants 12](#_Toc68115624)

[12.0 Recruitment Methods 13](#_Toc68115625)

[13.0 Withdrawal of Participants 14](#_Toc68115626)

[14.0 Risks to Participants 14](#_Toc68115627)

[15.0 Incomplete Disclosure or Deception 14](#_Toc68115628)

[16.0 Potential Benefits to Participants 15](#_Toc68115629)

[17.0 Statistical Considerations 15](#_Toc68115630)

[18.0 Health Information and Privacy Compliance 15](#_Toc68115631)

[19.0 Confidentiality 19](#_Toc68115632)

[20.0 Provisions to Monitor the Data to Ensure the Safety of Participants 19](#_Toc68115633)

[21.0 Compensation for Research-Related Injury 20](#_Toc68115634)

[22.0 Consent Process 20](#_Toc68115635)

[23.0 Setting 24](#_Toc68115636)

[24.0 Multi-Site Research 25](#_Toc68115637)

[25.0 Coordinating Center Research 26](#_Toc68115638)

[26.0 Resources Available 26](#_Toc68115639)

[27.0 References 27](#_Toc68115640)

**ABBREVIATIONS/DEFINITIONS**

Include any abbreviations or definitions for key or technical terms you use in your protocol.

* ICI/ Institute on Community Integration
* DECE/ Department of Electrics and Computer Engineering
* SAR/socially assistive robot
* BGSI/ the Bangor Goal-Setting Interview
* UNRAQ/ Users’ Needs, Requirements, and Abilities Questionnaire
* PASE/Physical Activity Scale for the Elderly
* CONSORT /the Consolidated Standards of Reporting Trials

# Objectives

* 1. Purpose: Describe the purpose, specific aims, or objectives. If this protocol involves the treatment or prevention of cancer complete required notification and/or application processes for the [Cancer Protocol Review Committee](https://www.cancer.umn.edu/for-researchers/investigator-resources/cancer-protocol-review-committee)*.*

The **aim** of this project is to utilize technology to help older adults experience healthier ageing, providing them with a social assistive robot (SAR) to implement a goal setting program along with mentoring, with the intent to decrease the risk and effects of age-related disabilities.

The project’s **specific objectives** are:

* Exploring likeability and acceptability of Nao by older adults.
* Enhancing the physical activities of older adults;
* Decreasing the feeling of loneliness among older adults.

# Background

* 1. Significance of Research Question/Purpose: Describe the relevant prior research and gaps in current knowledge for your research question.

Using SARs in the health field has started several decades ago for assisting with care activities and rehabilitation for ageing adults 29,30. Regardless of physical and cognitive disabilities, older adults enjoy interacting with SARs 31, expressing more positive emotions and displaying less disruptive behaviours, 32 and having positive attitudes towards the usefulness of SAR for assisting them in performing daily activities 31–33.

Overall, older adults benefit from the physiological (e.g., stress reduction), psychological (e.g., improvement in mood) and social effects (less loneliness) 29,34–36 as well as the motivating effect as a consequence of their interactions with SARs. For instance, SARs can be encouraging for older adults to communicate further with people 37 and to do exercise 38 for a longer time in comparison with when they are alone 39. Older adults can maintain their interest in the SARs (through being active by talking and interacting with the robot) for a month 37.

Based on the studies cited, SARs as intelligent agents can serve as promising assistants for meeting the needs of older adults by promoting their health by optimizing their functioning 28,30,32. However, there is still a need for further research on SARs’ approaches as solutions for health setting 40 and ageing in place 41 as current evidence lacks clear, efficient methodology, intervention, sample size, data and health related outcome measurement 35,41,42. Therefore, it is still not clear the extent to which SARs could be acceptable40 as well as beneficial with respect to quality of life, health and physical functions of older adults 41. Considering the current methodology gaps and the potential of SARs, we aim to work with older adults to investigate their interaction with the SAR for them to feel less lonely as well as to follow their goals in doing physical activities in a fun, meaningful, interactive, and collaborative way.

* 1. Preliminary Data: Describe any relevant preliminary data.

N/A

* 1. Existing Literature: Provide the scientific or scholarly background for, rationale for, and significance of the research based on the existing literature and how will it add to existing knowledge.

The number of older adults has been inevitably increasing due to the reduction in fertility and mortality worldwide and consequently, we are witnessing a shortage of human resources that will likely continue into future. The United States has a high percentage of ageing population, where adults age 65 and over were 54.1 million in 2019, demonstrating 16 percent of the US population. In 2019, the 65-74 age group was about 14 times larger than in 1900, the 75-84 group was 20 times larger, and 85 and older group was around 53 times bigger. It is projected that we will have 80.8 million of aging adults by 2040, constituting 21.6 % of the US population2–4.

As age increases, people are more likely to experience disabilities and decline in their functioning 5. Around 22% of adults ages 65 to 74 rated their health condition as fair or poor, and 19% of those at 65 and older reported reduced ability in all or at least one area (mobility, cognition, communication, self-care, hearing, seeing)4. It is projected that by 2025, 25% of adults aged 65 and over will experience disabilities 6. In addition to disabilities, some medications prescribed to ageing adults impact negatively their daily functioning 7. It is also common for older adults to experience depression, feelings uselessness, and disruptions in their routine activities8,9. Feeling lonely, especially in those age 60 and older (43%), leads to lower quality of life and health issues10.

The effects of age-related disabilities can be decreased with appropriate practices modulating modifiable risk factors, such as physical inactivity, loneliness and depression, smoking, unhealthy diet and excessive alcohol consumption 11–17,17,18. Thus, researchers strongly recommend using interventions to manage potential risks15 and emphasize the significance of policies and plans encouraging older adults to engage in more social communications, cognitively stimulating activities, and further exercise19.

Therefore, it is important to provide health and wellness programs that could be easily and equally accessible for engaging ageing adults from different socioeconomic backgrounds and diverse ethnicities 20–22. Such practices can also prevent older persons from being socially isolated and feeling lonely 9. Researchers 23 identified the most important needs of older adults as engaging in meaningful activities and being independent. In this regard, the goal setting program with regular mentoring 24,25 for improving the life style of older adults could be highly beneficial to engage the ageing population. The proposed program is based on social cognitive theory of behavioural change to promote health26,27 where perceived self-efficacy (the perception that it is possible to achieve desired goals through own actions) impacts directly the health habits, and indirectly outcome expectations (physical, social, self-evaluation) and sociostractural factors (facilitators, barriers). In fact, goal setting creates intentions to determine behaviour 27.

Such programs, however, require great amount of time and frequent sessions, which can lead to an unequal, limited access for people, considering the ever-increasing growth of the ageing population 28. Furthermore, if there is the possibility of delivering this program in a cost-effective way, this can be an integral part of care pathways for helping ageing adults to cope with challenges or as part of home care services 24. Therefore, an innovative way of assisting and managing health and wellbeing of older adults is highly desirable 28. To achieve this, we propose to use a socially assistive robot (SAR; Nao) to improve the health and wellbeing in ageing adults.

# Study Endpoints/Events/Outcomes

* 1. Primary Endpoint/Event/Outcome: Describe the primary study endpoint, event, or outcome you will be evaluating or observing.

The results of the first phase of the study will provide us with information about the experiences of aging adults with SARs that will help the next phases of the project. The outcomes of the second phase of the study include an increase in physical activities and decrease in the feeling of loneliness among participants.

* 1. Secondary Endpoint(s)/Event(s)/Outcome(s): Describe any secondary study endpoints, events, or outcomes you will be evaluating or observing.

A tailored goal-setting intervention along with mentoring will complement the SAR component.

# Study Intervention(s)/Interaction(s)

* 1. Description: Describe the study intervention(s) and/or interaction(s). Interventions may include staging scenarios or manipulating the environment to evaluate behavior. Interactions may include surveys, interviews, or focus groups. If the study does not involve intervention or interactions, describe any observations of public behavior.

The study will be conducted in two phases. The first phase includes a study to explore likeability and acceptability of the SAR by older adults. This phase is conducted in 10 interaction sessions between the SAR and older adult participant and following that, a focus group session. The second phase includes a pilot study using a quasi-experimental design to explore the effectiveness of using Nao robot to enhance physical activity and decrease feelings of loneliness.

**Phase 1.**

***Interaction sessions with Nao & Focus groups***. Recruitment of participants for the 10 interaction sessions with Nao and focus groups will take place through local service providers and community centres in Minnesota. Study participants will be invited to take part in 10 30-minute interaction sessions with Nao, followed by a completion of the *Users’ Needs, Requirements, and Abilities Questionnaire* (*UNRAQ*) 51 and a focus group session. During the interaction sessions, participants will be guided to become familiar with Nao and engage in a verbal and non-verbal interaction with the SAR about their interests, hobbies, and goals. Meanwhile, Nao will record/learn about each participant and their interests to provide adaptive feedback for the next sessions, refer to them via their first names and recognize their faces. Nao will be able to interact with each participant based on their programming. The interaction sessions will be monitored by two project staff (one from ICI and one from engineering) in a separate room to control Nao via the internet. We aim to complete each group session (10 interaction sessions, assessment, and a focus group) in one month per participant.

All sessions will be recorded for further analysing and coding. All data from recordings will be confidentially both stored and coded for key ideas and themes.

Based on the first phase of the study, programming for Nao will be modified/improved and prepared for the next phase of intervention (goal setting and mentoring).

**Phase 2.**

***Intervention****.* Goal setting interventions 19,24,25,46 have previously been used with aging populations with and without disabilities with a human mentor to set cognitive, social, diet and physical goals. This approach has shown promising results supporting improvements in social, physical and cognitive activity, improved memory and executive functions resulting in participants experiencing higher levels of empowerment, motivation, achievement, personal satisfaction and self-confidence. 19,24,25,46 Through the intervention, participants are encouraged to start new cognitive, physical and social activities and raise their levels of current ones. This process is guided using Bangor Goal-Setting Interview (BGSI)26 and prompted by a mentor through phone calls to discuss participant progress and barriers to goal achievement.25 BGSI is guided on social cognitive theory of behavioural change to promote health26,27 through which the users rate the perceived significance of the goal and readiness to start working toward it on a 10-point scale. They are subsequently assisted to revise the goals based on SMART criteria (specific, measurable, achievable, realistic/relevant and time-bound). After setting goals, the difficulties and supports needed to make progress toward them is discussed. Goal attainment indicators (25, 50, 75, 100%) with clear descriptors is set and following participation participants are asked to rate their goal achievement and satisfaction on a 10-point scale.

The proposed project will employ a physically present SAR-Nao programmed to administer the goal setting assessment and intervention. A project staff will oversee each aspect of this intervention to assure each participant feels comfortable with the interaction and the interaction is meaningful to the participants. Each participant will be supported by Nao to set individualized goals focused on enhancing their preferred physical activities (such as, doing exercise, going for a walk, housework, and gardening) as well as to plan on how to achieve them. Participants will receive daily activities plan through the SAR and a visual real-time feedback at the end of each session focused on the progress they have made toward their goals. Further, physical activities and goal attainment rate will be measured immediately before and after the intervention using validated scales to determine the impact of the intervention on participant physical activities. The proposed intervention program will be conducted across 20 daily 20-minute individual sessions for one month followed by a bi-monthly one-hour-follow-up session.

Nao will be programmed to engage participants through daily reminders and interactions, modelling exercises, and providing verbal feedback. In situations in which participants skip two consecutive days of physical activities, Nao will encourage them to continue to work toward their personal goals. Depending on the participant’s physical condition, Nao will prompt the users to walk with it (e.g., this is a programmed function by which Nao can ask the user to hold its hand and walk).

Furthermore, Nao can be a present, tangible agent and as a companion so the older adults may experience less loneliness and more positive interactions. As robotics studies report, compared to avatars of the same robot, the users experienced more positive social interactions, higher likeness, respect and trust (choosing advice from a robot than avatar under risk conditions even when the appearance of avatar and robot is similar) when the robot is physically present 47–49. Besides, the participants are influenced and anthropomorphize more with a present robot 49 and function better in tasks 50. Physical presence is suggested as a crucial factor in developing human robot interaction 47,48.

Along with the presence of Nao, we will use the principles of an empathetic, therapeutic relationship from psychology to provide a meaningful, influential interaction between the participants and Nao. Nao’s functions, such as recognizing participants, calling their names, recognizing their non-verbal communication, listening to their interests, hobbies and memories and providing adaptive feedback, are considered during the intervention sessions. When a participant is sad or bored for example, Nao will offer fun activities, including jokes, playing music, dancing, displaying pictures or clips based on each person’s interest. Further, Nao will randomly talk about the user’s memories/interests (shared previously by the user) with the individual to ensure a more meaningful interaction and draw their attention. Refer to the section about scripts above on programming these functions. Using the robot’s connectivity to the internet, the participants could request any information from Nao to access the news by reading or listening, etc., historical information or other items of interest they want via an iPad (e.g., for entertainment).

# Procedures Involved

* 1. Study Design:

During the first phase of the proposed study, there will be 10 interaction sessions conducted in five groups between Nao and the participants (N=30-40), followed by focus groups (N = 6-8 participants/ group; overall 30-40 participants) to explore the likeability and acceptability of Nao.

In the second phase, a pre/post quasi-experimental design without a control group will be implemented to examine the effectiveness of the intervention with 40-50 participants who will be recruited from the MN local communities.

* 1. Study Procedures: Provide a description of all research procedures being performed and when they are performed, including procedures being performed to monitor participants for safety or to minimize risks.

Describe:

* + - Procedures to be performed for research purposes and, if relevant, which procedures would be performed regardless of whether the research was conducted, e.g., procedures performed for diagnostic or treatment purposes.

[Study procedure was described in section 4.0]

* + - The data to be collected about participants and the source records that will be used to collect those data. (Attach all surveys, scripts, and participant-facing data collection forms in ETHOS.)

***Script preparation for phases 1 and 2.*** First, the required scripts for Nao for the first phase of the project (to interact with the participants) and for the intervention sessions (including interviews with the users using the *Bangor Goal-Setting Interview (BGSI)*26 followed by the provision of a reciprocal interaction and daily conversations leading to physical activities goal setting) will be developed. These scripts will be written by the project psychology and education researchers involved and subsequently shared with the engineering project partners to program Nao based on these scripts. Preparing scripts is a dynamic process because it depends on the users’ responses. For both phases of study, we will use the following process. The scripts for reciprocal interactions are developed for *greeting*, *fixed questions* for all users (e.g., hobbies, friends, family members, memories, routines), *conditional questions/person focused items* that are based on each person stated responses to the fixed questions (e.g., if a person says they are interested in art, the next question is about the type of art, favourite artist and so on). Once the information from both questions types are collected, more tailored scripts about each response is provided, such as information about a specific interest or possible talk about shared memories. The same format will be done for Bangor interview questions that includes fixed and conditional questions/items. Meanwhile, the SAR is programmed for different modules, including motion detection, face and emotion recognition as well as speech interaction so that it can recognize the users’ faces, voices and speech.

**Measures**

*Data from phase 1:*

* Demographic information assessed by demographic survey we developed for this project
* Human robot interaction (collected via the Users’ Needs, Requirements, and Abilities Questionnaire – UNRAQ - and video recordings during interaction sessions)
* Likeability of the robot, opinions of ageing adults about SARs and specifically Nao (recorded from focus groups)
* Human robot interaction recorded by camera

During Phase 1 of the project, immediately following the last “exposure” session, all participants will be individually administered the *Users’ Needs, Requirements, and Abilities Questionnaire* (*UNRAQ*) 51 to independently assess their opinions with respect to the Nao robot within four domains: (a) overall interaction with robot and technical issues; (b) assistive role of robot; (c) social aspects associated with interactions with the robot, and (d) potential ethical issues associated with utilization of the robot to support physical and social engagement. Previous research indicates that the UNRAQ has high internal consistency (0.88).

***Data from phase 2:***

*Questionnaires and Other materials****.*** In the second phase, the participants will be provided with a fitbit to record their movements. They will receive the fitbit a week before starting the intervention to gather baseline data. They will be trained to wear the fitbit for a period of 6-weeks. In addition, the *Physical Activity Scale for the Elderly (PASE)* 52*,* a validated 12-item questionnaire for assessing the frequency, duration, and intensity level of physical activities for ageing adults will be administered via an interview mode both immediately prior to and following the intervention to measure potential changes in physical activities. The *UCLA Loneliness Scale* 53, is a 20-item scale, that will be administered both pre- and post-intervention to evaluate the effect of Nao on the feelings of loneliness. The *Bangor Goal-Setting Interview (BGSI)*26, a structured interview, will be conducted during the intervention and in a two-month follow up. Human robot interaction will be recorded by camera in the second phase, as well. In addition, we will use the Consolidated Standards of Reporting Trials (CONSORT) fidelity checklist to monitor the intervention implementation.

*SAR for both phases of the study*. The Nao robot (Figure 1) is the SAR for our project. Nao was created by Softbank robotics and is an advanced, programmable, human-like robot with 22.8 inches in height and 25 degree of freedom to move, turn his head, hands, sit, and walk. Nao can dance, speak, and recognize faces, objects and speech in 20 languages. We will obtain the robot from the UMN’s engineering department and afford one using equipment budget. Programming will also be conducted by them. In case during the study we experience lack of robot capacity to fully carry out the study, the PI will purchase an additional robot via her ICR account.

|  |  |  |  |
| --- | --- | --- | --- |
| NAO Robot V6 |  |  |  |

Figure 1. Nao robot

**Data analysis**. Data collection and management process both will be conducted securely and the information will be stored in a confidential manner.

*First phase of study.* All interactions between the participants and Nao as well as focus group information will be analysed qualitatively for themes (e.g., grounded theory) using Nvivo software, frequency of codes, themes and sentences are computed using axial coding (assigning numbers to themes)44. Further, a reliability check will be done by an independent researcher to match the sentences with codes. An 80% agreement is considered as a high reliability44. In addition, the data from *Users’ Needs, Requirements, and Abilities Questionnaire* (*UNRAQ*) will be analyzed descriptively.

*Second phase of study*. The outcome variables for the second phase of study are goal attainment, physical activities, and feeling of loneliness. The data from BGSI are both qualitative and quantitative. Descriptive content analysis is performed for qualitative data of BGSI. The quantitative variables, goal attainment (gained from BGSI), physical activities (from PASE) and loneliness (fromUCLA loneliness scale) will be analysed quantitatively, comparing means using a paired t-test before and after intervention using R.

* 1. Follow-Up: The data to be collected, including long-term follow-up data.

We will conduct one bi-monthly follow-up session with the same measures of phase 2.

* 1. Individually Identifiable Health Information: If this research will involve the use of individually identifiable health information, either collecting or having access to, and including Protected Health Information complete and submit the [University’s Privacy Office](https://www.healthprivacy.umn.edu/) [online application](http://z.umn.edu/compliancerequest) for data privacy and security review. Print and upload the application with this protocol in Supporting Documents in the ETHOS SmartForm. Complete and submit a HIPAA authorization form if applicable in Supporting Documents in ETHOS: [UMN Privacy Office Policies](https://policy.umn.edu/operations/phi) and/or [Fairview Health Services Privacy Policies](https://www.fairview.org/Research/Forresearchers/Researchcompliance/Researchpolicies/index.htm), and [UMN HIPAA Agreement Templates](https://policy.umn.edu/contracts/categories/OT/240/253). For research conducted at Gillette Children’s Specialty Healthcare refer to [Gillette Research Administration](https://www.gillettechildrens.org/for-medical-professionals/research/research-administration) for guidance.

# Data Banking

* 1. Storage and Access:

The data will be stored on Box subscribed by the University of Minnesota. Once the data are collected after each session, the sensitive information that could be identifying of people’s identity, such as name of the participants, will be replaced with ID numbers. The ID numbers and rest of the data will stored in separate file from the data identifiers. Only the research coordinator and PIs will have access to demographic information.

All data will be encrypted and stored on secure UMN servers (i.e., Box) that can be accessed only by the Project PI, Co-PI, and project coordinator through use of a secure passcode.

* 1. Data:

**Phase 1**

* Human robot interaction and opinion of participants regarding the robot assessed by the *Users’ Needs, Requirements, and Abilities Questionnaire* (*UNRAQ*)
* Human robot interaction recorded by camera

**Phase 2**

* Demographic information assessed by our demographic survey
* Physical activities assessed by *Physical Activity Scale for the Elderly (PASE)*
* Loneliness feeling assessed by UCLA Loneliness Scale
* The quantity of movements/steps assessed by Fitbit
* Goal attainment and satisfaction assessed by The *Bangor Goal-Setting Interview (BGSI) during intervention* 
  1. Release/Sharing: Describe the procedures to release data, including: the process to request a release, approvals required for release, who can obtain data, and the data elements to be provided.

Data will be released only in a de-identified format to project collaborators following a written request for access to this data. All staff working on the project have completed the CITI training and will follow the guidelines for data release provided in this training. A request for de-identified data will be guided by responses to questions regarding: (a) the intended use of the data; (b) assurances the data will be stored only in an encrypted fashion on secure computers and/or servers; and (c) agreement that the data will not be shared with other parties without prior approval from the Project PI and UMN.

# Sharing of Results with Participants

* 1. Describe whether results (study results or individual participant results, such as survey results) will be shared with participants or others (e.g., participants’ parent or school administrators) and, if so, describe how the results will be shared.

Please see the [Investigator Manual (HRP-103)](https://drive.google.com/file/d/0B7644h9N2vLcOWtzU2FmSU5oS0U/edit) for additional information about language that should be included in the consent form related to sharing of results.

For the first phase of study, after the focus group, summarized notes gathered from focus group will be shared with the participants to add notes or corrections if there are any. For the second phase of study, we will not share the results with the participants until the termination of the follow up, because sharing the results with the participants may interfere with the effect of the intervention. For both phases, results will be shared as a summary with no identifying information via mail or email dependent to the preference of the participants with a simple language free of jargon and technical words. The results will shared with participants at the end of the study in several forms:

* A brief 3-5 Executive Summary Report using non-technical language and easy to read graphics will be prepared and distributed to all organizations that assisted with the project.
* Based on this report, a presentation will be prepared for participants from all partner organizations by project staff.
* Results will be submitted and presented at statewide and nationwide conferences.

# Study Duration

* 1. Describe:
     + The duration anticipated for an individual participant’s participation in the study.

*First phase:*

* Every participant will attend 2 30-minute interaction sessions that will be held over one week (1 hour).
* Every participant’s a close person/family member/friend will fill *Users’ Needs, Requirements, and Abilities Questionnaire* (*UNRAQ*) that could take up to 20 minutes.
* Every participant will a demographic survey that could take up to 20 minutes.
* Every participant will attend a 90-min focus group (two 45 minute sessions with a 15 minute break between two sessions).

*Second phase:*

* Every participant will a demographic survey that could take up to 30 minutes.
* Every participant will fill the physical activity scale for the elderly (PASE) that could take up to 15 minutes (overall: 45 minutes for pre-test measures and a follow up).
* Every participant will fill the UCLA that could take up to 15 minutes (overall: 45 minutes for pre-test measure and a follow up).
* Every participant will be interviewed via the Bangor Goal-Setting Interview that could take up to 60-90 minutes (overall: maximum 270 minutes for pre-test measure and a follow up).
* Daily intervention: 30 minutes per day, overall: 300 minutes for total 10 sessions.
  + - The duration anticipated to enroll all study participants.

*First phase:*

* All participants enrollment (N~30) will be done up to 30 hours overall for all of them (each participant read and if they agree they fill the consent form, which it takes about one hour for each participant).

*Second phase*:

* All participants enrollment (N~30) will be done up to 30 hours overall for all of them (conducting PASE and UCLA).

* + - The duration anticipated to complete all study procedures and data analysis.

*First phase:*

Overall, the recruitment and study duration for each participant will take 3 hours and 50 minutes (around 4 hours). We will need additional time for recruiting participants, replacing missing participants and contacting organizations.

*Second phase:*

Overall, recruitment and the intervention for each participant will take 11 hours and 50 minutes hours (270 hours for 30 participants). We will need additional time for recruiting participants, replacing missing participants and contacting organizations.

# Study Population

* 1. Inclusion Criteria: Describe the criteria that define who will be included in your final study sample.

Please reference Section: Vulnerable Populations. Please note that you may not include vulnerable populations as participants in your research unless you indicate this in your inclusion criteria.

*Inclusion criteria*: The participants will include healthy ageing adults 70 years and older living in Minnesota. They need to be fluent English speaker because the project is delivered in English. Participants need to be able to give informed consent. Further, they need to be able to perform daily physical activities to be able to benefit from the program.

* 1. Exclusion Criteria: Describe the criteria that define who will be excluded in your final study sample.

*Exclusion criteria*: Those with identified physical and cognitive disabilities will be excluded from the study. Participants who have a history of a stroke, brain injury or any other conditions that have a significant effect on their cognitive, behavioural and emotional functioning will be excluded. Those who are unable to speak English fluently will be excluded.

* 1. Screening: Describe how individuals will be screened or assessed for eligibility.

Participants will be screened based on their abilities to speak in English and being physically independent, which means they should be able to walk by themselves we do not use any instrument for screening. ..

# Vulnerable Populations

University requirements for inclusion of vulnerable populations may be stricter than what may be acceptable for sponsors or for lead investigators at other institutions.

* 1. Vulnerable Populations: Identify which of the following populations will be allowed to participate in this study. You may not include members of the populations below as participants in your research unless you indicate this in your inclusion criteria above. Inclusion of an individual from one of these groups will require the investigator to develop additional safeguards (Section 10 .2) proportional to the degree of vulnerability and proportional to the degree of risk and benefit.

We do not work with any of the following vulnerable population. Ageing adults in the proposed study need to be able to consent by themselves in order for them to benefit from the intervention. We will recruit older adults living in assisted living settings in Minnesota based the inclusionary criterial listed above.

|  |  |
| --- | --- |
| Population / Group | Identify whether any of the following populations will be primary focus of the research (targeted), included but not the focus of the research or excluded from participation in the study. |
| Children | Excluded |
| Pregnant women/fetuses/neonates | Excluded |
| Prisoners | Excluded |
| Adults lacking capacity to consent and/or adults with diminished capacity to consent, including, but not limited to, those with acute medical conditions, psychiatric disorders, neurologic disorders, developmental disorders, and behavioral disorders | Excluded |
| Non-English speakers | Excluded |
| Those unable to read (illiterate) | Excluded |
| Employees of the researcher | Excluded |
| Students of the researcher | Excluded |
| Undervalued or disenfranchised social group | Excluded |
| Active members of the military (service members), DoD personnel (including civilian employees) | Excluded |
| Individual or group that is approached for participation in research during a stressful situation such as emergency room setting, childbirth (labor), etc. | Excluded |
| Individual or group that is disadvantaged in the distribution of social goods and services such as income, housing, or healthcare. | Excluded |
| Individual or group with a serious health condition for which there are no satisfactory standard treatments. | Excluded |
| Individual or group with a fear of negative consequences for not participating in the research (e.g. institutionalization, deportation, disclosure of stigmatizing behavior). | Excluded |
| Any other circumstance/dynamic that could increase vulnerability to coercion or exploitation that might influence consent to research or decision to continue in research. | Excluded |

* 1. Additional Safeguards:

If individuals or groups are identified as vulnerable, specific safeguards to protect the population should be implemented, such as consent monitoring or independent capacity to consent assessment, independent clinical monitoring, ensuring confidentiality, and ensuring that potential research participants are free to decline joining the study (Emanuel, Wendler, and Grady, 2008). If the research involves individuals Checked in Section 10 .1 above, provide justification for their inclusion and describe additional safeguards included to protect their rights and welfare. Investigators should tailor protections to the nature and extent of vulnerability, the magnitude of risk, and the assessment of benefit.

* + - If the research involves pregnant women, review “[CHECKLIST: Pregnant Women (HRP-412)](https://research.umn.edu/units/irb/toolkit-library/checklists)” to ensure that you have provided sufficient information.
    - If the research involves neonates of uncertain viability or non-viable neonates, review “[CHECKLIST: Non-Viable Neonates (HRP-413)](https://research.umn.edu/units/irb/toolkit-library/checklists)” or “[CHECKLIST: Neonates of Uncertain Viability (HRP-414)](https://research.umn.edu/units/irb/toolkit-library/checklists)” to ensure that you have provided sufficient information.
    - If the research involves prisoners, review “[CHECKLIST: Prisoners (HRP-415)](https://research.umn.edu/units/irb/toolkit-library/checklists)” to ensure that you have provided sufficient information.
    - If the research involves persons who have not attained the legal age for consent to treatments or procedures involves in the research, review “[CHECKLIST: Children (HRP-416)](https://research.umn.edu/units/irb/toolkit-library/checklists)” to ensure that you have provided sufficient information.
    - If the research involves cognitively impaired adults, or adults with fluctuating, diminished, or lacking capacity to consent, review “[CHECKLIST: Cognitively Impaired Adults (HRP-417)](https://research.umn.edu/units/irb/toolkit-library/checklists)” to ensure that you have provided sufficient information.
    - Provide justification for the inclusion of this population and describe the importance of the knowledge to be gained.
    - Explain how including this population represents the least degree of impairment compatible with the aims of this study.
    - Specify how risks are minimized and/or whether the risks or discomforts are greater for this population.
  1. If research includes potential for direct benefit to participant, provide rationale for any exclusions indicated in the table above:

Explain why excluding certain populations from participation is appropriate (e.g., disease or condition under study does not occur in children). It is particularly important to explain why exclusion is appropriate If there is the possibility of direct benefit to the participant.

N/A

# Number of Participants

* 1. Number of Participants to be Consented: State the approximate number of participants you plan to enroll locally (e.g., the university, Fairview, or Gillette). Give the lowest number that will allow data analysis and the maximum that might agree to participate. If the research involves secondary analysis of existing data, give the estimated number of records that will be used.

*Sample size.* For thefirst phase of the study, we will recruit 30-40 participants to engage in the usability study and focus groups. We propose to work with 30-40 participants in the second phase. Participants from Phase 1 who want to continue will also be enrolled in Phase 2.

# Recruitment Methods

* 1. Recruitment Process: Describe when, where, and how potential participants will be recruited. For example, will recruitment advertisements be sent to potential participants? Will advertisements be posted publicly?

We will recruit participants through service providers for this population and the Council on Ageing in MN. At the Institute on Community Integration, we have developed a network of partner organization that include providers of services to older adults. We will contact the leadership of these organization (via Email or phone), share a flyer with them and provide details of the study in person or via Zoom. Once leadership of each contacted organization agrees that we can recruit participants from their clients, we will conduct an information session for those interested in participant on site or via Zoom.

* 1. Source of Participants: Describe the source of potential participants, e.g., Research Experience Program.

The Council on Ageing in MN, Lutheran Social Services (LSS), Ecumen and similar organizations in MN that serve the ageing population.

* 1. Identification of Potential Participants: Describe the methods that will be used to identify potential participants. Describe whether participants will self-identify in response to posters, mailings, emails, etc., or whether they will be recruited based on information contained in private/protected records (e.g., medical records, student records; note that this also includes participants who will be recruited from the PI’s or Co-PI’s patient or student population.)
     + For information contained in private/protected records, explain how the researcher has legitimate access to these records.
     + Identify who will make initial contact with potential participants.
     + Identify whether the private/protected records will include **MEDICAL** records and the mechanism the PI will use to confirm that patients have agreed to release their PHI contained in their medical records for research purposes; for example, a particular patient has documented consent to research on their treatment, intake, or hospital admitting form. (MN Statute 144.334 Subd. 3; Access to Medical Records for Research), e.g., Academic Health Center Information Exchange (AHC-IE).

Once the leadership of a service provider organization agrees that their clients can participate in the study, potential participants will be invited to take part in information in person or online sessions using Zoom describing the project and its purposes, the voluntary nature of the participation and the responsibilities of project staff from the UMN and project staff.

* 1. Recruitment Materials: Describe materials that will be used to recruit participants. (Attach copies of these materials in ETHOS in the Recruitment section. For advertisements, attach the final copy of printed advertisements. When advertisements are recorded for broadcast, attach the final audio/video recording in ETHOS. You may instead submit the wording or script for any recorded advertisements in ETHOS prior to recording them. This will preclude re-recording because of inappropriate wording, provided the IRB reviews the final audio/video recording after approving the initial wording or script. You would likely include any recording with a modification in ETHOS.)

Recruitment information flyer was developed to share with interested organizations and participants. The flyer briefly describes stud activities, duration of the study, and the study purpose.

* 1. Payment: Describe the amount, timing, and type of any payments to participants.
     + Indicate whether gifts, payments, compensation, reimbursement, services without charge, or extra credit will be provided to the participants for participating in the research.
     + Describe the type of compensation and the maximum value participants may receive during the course of participation.
     + Describe when compensation will be provided, including a schedule, and whether payments will be prorated for multiple visits/sessions.
     + Describe who will receive payments, if not the participants themselves.
     + Describe whether Research Experience Points will be awarded*.*
     + Indicate whether the Greenphire ClinCard will be used for compensation. If used, include the template language in the consent document (see [Consent Template (HRP-592)](https://drive.google.com/open?id=0B7644h9N2vLcVmwxR2dOZFRGSDg)).
     + Investigators planning to use MTurk for recruitment purposes are expected to outline an equivalent hourly rate for participants in the study. If offering less than an hourly rate per the current definition of a living wage (see <https://livingwage.mit.edu/counties/27053>), the investigator must provide a justification to the IRB for review.

There is no payments or any other types of reward to offer to participants who want to enroll this study.

# Withdrawal of Participants

* 1. Withdrawal Circumstances: Describe anticipated circumstances under which participants will be withdrawn from the research without their consent.

We do not anticipate participants withdrawing from the study as the study demand is not high and the use of the SAR may be particularly engaging. We also do not anticipate to withdraw participants from the study ourselves. In case the participants do not attend the interaction sessions in the first phase and intervention sessions for three sessions or more, they will be discarded from the analysis but still can attend the interaction group and intervention.

* 1. Withdrawal Procedures: Describe procedures that will be followed when participants withdraw from procedures, including partial withdrawal, with continued data collection (e.g., participants withdraw, but you wish to continue collecting data from a private/protected record).

According to the consent form, participants have a right to withdraw from the study at any time. They will be encouraged to inform the project staff that they no longer wish to participate in the study. Participants will be informed that their withdrawal will have no negative impact on their relationship with their service provider or UMN.

* 1. Termination Procedures: Describe any procedures for orderly termination and describe whether data will be used after termination.

If any participant desires to withdraw from the project, they will be asked to directly contact the Project PI or Co-PI at the University of Minnesota. Staff at UMN will assume responsibility for communicating that person’s withdrawal to the participating organization. This approach is being followed to minimize the chance that persons associated with the project would attempt to convince an individual who desires to withdraw to not do so. Given that UMN project staff are serving in a role in which they are least likely to profit from having persons who wish to withdraw reverse his/her decision this was determined to be the most prudent course of action when handling such situations. No data from individuals who withdraw from the study will be used in any analyses undertaken as part of this research effort.

# Risks to Participants

For each risk or set of risks below, include the procedures to be performed to lessen the probability, magnitude, duration, or reversibility of those risks.

* 1. Foreseeable Risks: List the reasonably foreseeable risks, discomforts, hazards, or inconveniences related to participants’ participation in the research. Include, as may be useful for the IRB’s consideration, a description of the probability, magnitude, duration, and reversibility of the risks. Depending on the type of research, this description may or may not include statistical information. Categories such as common, rare, etc., may be acceptable. Consider physical, psychological, social, legal, and economic risks.
* Some questions on the pre/post assessments may be hard to answer or to remember. A participant may not know what to say and as a result feel uncomfortable. However, the researchers will remind participants, that we all forget things and we can let them have a paper version of questionnaire to have and answer it whenever they remember well.
* Participation in this study will take up some of the time participants could be engaged in other activities. Although we believe the intervention may prove beneficial to ageing adults, they may not all be of the same opinion and think that they could be spending this time doing other things. We will remind participants that the results of this study will help improve a future, more effective intervention of this nature and help them to set their own healthy lifestyle goals.
* Participants may not feel comfortable interacting with a SAR and it may take them some time to get used to these interactions. The project team will provide an orientation and training for the participants to become familiar with its physical appearance and interaction possibilities and style.
  1. Reproduction Risks: If applicable, indicate which procedures may have risks to an embryo or fetus should the participants or participants’ partners be or become pregnant. (Note that if reproductive risks are a factor, then you are likely conducting procedures that would require use of “MEDICAL PROTOCOL TEMPLATE (HRP-590).” Please review the instruction at the beginning of this protocol template.)

N/A

* 1. Risks to Others: If applicable, describe risks to others who are not participants.

N/A

# Incomplete Disclosure or Deception

* 1. Incomplete Disclosure or Deception:
     + If the research will use incomplete disclosure or deception, please provide a rationale.
     + Indicate if participants will be informed that the study involves deception and given the opportunity to authorize the deception through a prospective agreement.
     + Please also provide a description and documentation of the debriefing process, if appropriate, that will be used to make participants aware of the incomplete disclosure or deception and their right to withdraw any record of their participation.

N/A

# Potential Benefits to Participants

* 1. Potential Benefits: Describe the potential benefits that individual participants may experience from taking part in the research. Include, as may be useful for the IRB’s consideration, the probability, magnitude, and duration of the potential benefits.

Indicate if there is no direct benefit to individual participants. Do not include benefits to society or others.

The goal setting intervention using SAR can be beneficial for the ageing adults’ health and wellbeing because it can encourage them to set their own goals to raise the level of physical activities. Further, we assume that the interaction between Nao robot and the participants may decrease the feeling of loneliness.

# Statistical Considerations

* 1. Data Analysis Plan: Describe the data analysis plan, including any statistical procedures.

*Phase 1.*

All interactions between the participants and Nao as well as focus group information will be analyzed qualitatively for themes (e.g., grounded theory) using Nvivo software, frequency of codes, themes and sentences will be computed using axial coding (assigning numbers to themes). Further, a reliability check will be done by an independent researcher to match the sentences with codes. An 80% agreement is considered as a high reliability. In addition, the data from *Users’ Needs, Requirements, and Abilities Questionnaire* (*UNRAQ*) will be analyzed descriptively.

*Phase 2.*

The outcome variables for the second phase of study are goal attainment, physical activities, and feeling of loneliness. The data from Bangor goal setting interview (BGSI) are both qualitative and quantitative. Descriptive content analysis will be performed for qualitative data of BGSI. The quantitative variables, goal attainment (gained from BGSI), physical activities (from PASE) and loneliness (fromUCLA loneliness scale) will be analysed quantitatively, comparing means using a paired t-test before and after intervention using R.

* 1. Power Analysis: Provide a power analysis, if applicable.

We will recruit 30-40 participants to engage in the usability study and focus groups. Data will be analysed qualitatively and descriptively – no power analysis needed.

If we work with 30 participants in the second phase of the study, we will be able to perform a paired sample t-test with Alpha .05, Power .80, and large effect size of .45. Participants from Phase 1 who want to continue will also be enrolled in Phase 2. We will oversample by 10 participants to assure a sufficient sample size for planned analysis.

* 1. Statistical Analysis: Describe statistical analysis plans.

Already mentioned in data analysis plan.

* 1. Data Integrity: Describe any procedures that will be used for quality control of collected data.

Data integrity will be assured starting from base-line data collection by: 1. Data collectors completing necessary human subject and data integrity IRB training; 2. Training data collectors on data collection and data entry procedures specific to the study; and 3. Conducting inter-rater reliability checks on 20% of data collected. The study PIs will oversee all activities related to data collection, data entry and analysis.

Usual data cleaning procedures will be implemented (e.g., removal of outliers, unreliable data due to poor fidelity). Given our use of paired t-test, special attention will be paid to the following assumptions: (1) The dependent variables should be continuous (interval/ratio); (2) The observations are independent; (3) The dependent variable should have a normal distribution; (4) The dependent variables are free of any outliers.

All data will be secured on encrypted, password protected computers to assure integrity and confidentiality.

# Health Information and Privacy Compliance

Individually Identifiable Health Information: for guidance regarding the use, collection, storage and sharing outside of the covered entity of identifiable health information please see: [UMN Privacy Office Policies](https://policy.umn.edu/operations/phi) and/or [Fairview Health Services Privacy Policies](https://www.fairview.org/Research/Forresearchers/Researchcompliance/Researchpolicies/index.htm), and [UMN HIPAA Agreement Templates](https://policy.umn.edu/contracts/categories/OT/240/253)*.* For research conducted at Gillette Children’s Specialty Healthcare refer to [Gillette Research Administration](https://www.gillettechildrens.org/for-medical-professionals/research/research-administration) for guidance.

Under the HIPAA Privacy Rule, research studies at the University are permitted to use and disclose protected health information with the authorization of the research participants, or without individual authorization in limited circumstances.

* 1. Select which of the following is applicable to your research:

☐ X My research does not require access to individual health information and therefore assert HIPAA does not apply.

☐ I am requesting that all research participants sign a HIPCO approved HIPAA

Disclosure Authorization to participate in the research (either the standalone form or the combined consent and HIPAA Authorization).

☐ I am requesting the IRB to approve a Waiver or an alteration of research participant authorization to participate in the research.

Appropriate Use for Research: Explain how you will ensure that only records of patients who have agreed to have their information used for research will be reviewed.

☐ An external IRB (e.g. Advarra) is reviewing and we are requesting use of the authorization language embedded in the template consent form in lieu of the U of M stand-alone HIPAA Authorization. Note: External IRB must be serving as the privacy board for this option.

* 1. Identify the source of Private Health Information you will be using for your research (Check all that apply)

☐ I will use the Informatics Consulting Services (ICS) available through CTSI (also referred to as the University's Information Exchange (IE) or data shelter) to pull records for me

☐ I will collect information directly from research participants.

☐ I will use University services to access and retrieve records from the Bone Marrow Transplant (BMPT) database, also known as the HSCT (Hematopoietic Stem Cell Transplant) database.

☐ I will pull records directly from EPIC.

☐ I will retrieve record directly from axiUm / MiPACS

☐ I will receive data from the Center for Medicare/Medicaid Services

☐ I will receive a limited data set from another institution

If the limited data set used will contain information from somewhere other than the University of Minnesota or MHealth, then you must enter into a Data Use Agreement with the data source. You may use the University’s standard Data Use Agreement or another form approved by the health information Privacy & Compliance Office. Please upload in ETHOS the Data Use Agreement you will use for this transfer of information.

If you do not have a Data Use Agreement in place, you may submit your protocol for review however, you must complete a Data Use Agreement before you can receive the Limited Data Set. If you have questions about Limited Data Sets, please refer to http://www.healthprivacy.umn.edu/policies-procedures/creating-limited-data-set, or contact the privacy office at (612)-624-7447, or by e-mail at privacy@umn.edu.

☐ Other. Describe: Describe in detail the source of the information.

* 1. Explain how you will ensure that only records of patients who have agreed to have their information used for research will be reviewed.

N/A

* 1. Approximate number of records required for review:

If not applicable, enter N/A. UMN/Fairview researchers: If indicated you will retrieve records directly from EPIC and response is greater than or equal to 200, please explain below why you cannot use Informatics Consulting Service to retrieve data from the Information Exchange.

N/A

* 1. Please describe how you will communicate with research participants during the course of this research. Check all applicable boxes

☐ This research involves record review only. There will be no communication with research participants.

☐ Communication with research participants will take place in the course of treatment, through MyChart, or other similar forms of communication used with patients receiving treatment.

☐ Communication with research participants will take place outside of treatment settings. If this box is selected, please describe the type of communication and how it will be received by participants. If you anticipate using e-mail, please read the University’s Policy on E-Mail and PHI at http://policy.umn.edu/operations/phi-appa, which requires encryption of out-going emails. More information on the University’s encryption tool is available at <http://it.umn.edu/technology/proofpoint-secure-email-center>.

We will not communicate with participants directly in a remote way. We will direct our communication through the service providers. On site, we will communicate in person with the participants.

* 1. Access to participants

Explain why the research team is permitted to access medical records or any other sources of private information about the participants. (Note that you were asked a similar question above about access to information about potential participants. This item refers to information about participants who have consented to participate and about whom you are collecting research data.)

N/A

* 1. Location(s) of storage, sharing and analysis of research data, including any links to research data (check all that apply).

☐ In the data shelter of the [Information Exchange (IE)](https://www.ctsi.umn.edu/consultations-and-services/data-access-and-informatics-consulting/bpic)

☐ Store ☐ Analyze ☐ Share

☐ In the Bone Marrow Transplant (BMT) database, also known as the HSCT (Hematopoietic Stem Cell Transplant) Database

☐ Store ☐ Analyze ☐ Share

☐ In REDCap (recap.ahc.umn.edu)

☐ Store ☐ Analyze ☐ Share

☐X In Qualtrics (qualtrics.umn.edu)

X☐ Store X☐ Analyze ☐ Share

☐ In OnCore (oncore.umn.edu)

☐ Store ☐ Analyze ☐ Share

☐X In the University’s Box Secure Storage (box.umn.edu)

☐X Store ☐ Analyze ☐ Share

☐ In an AHC-IS supported server. Provide folder path, location of server and IT Support Contact:

The path should be in the form of “\\vp.ahc.umn.edu\vp\Research\Study0004” HIPCO requires this information to verify the data are in a properly encrypted server.

☐ Store ☐ Analyze ☐ Share

☐ In an AHC-IS supported desktop or laptop.

Provide UMN device numbers of all devices:

HIPCO requires and will confirm that devices used in this manner are properly encrypted.

☐ Store ☐ Analyze ☐ Share

☐ Other. Describe in detail the location and whether the data / specimens will be stored, analyzed, or shared, and in what ways.

Indicate if data will be collected, downloaded, accessed, shared or stored using a server, desktop, laptop, external drive or mobile device (including a tablet computer such as an iPad or a smartform (iPhone or Android devices) that you have not already identified in the preceding questions

☐I will use a server not previously listed to collect/download research data

☐I will use a desktop or laptop not previously listed

☐I will use an external hard drive or USB drive (“flash” or “thumb” drives) not previously listed

☐I will use a mobile device such as an tablet or smartphone not previously listed

N/A

* 1. Consultants. Vendors. Third Parties. Describe whether you will collect, store, analyze or share any information using a consultant, vendor, or third party software application, system, device or technology (other than REDCap or OnCore).
  2. Links to identifiable data: indicate how you will generate the links, how you will store these links, and how and when you will destroy these links
  3. Sharing of Data with Research Team Members. Indicate how you will share research data among research team members.

Data will be shared with team members via Box.

* 1. Storage of Documents: Describe how you will store any paper or electronic documents generated as a result of this research project.

Data will be stored on Box.

* 1. Disposal of Documents: Describe if, when, and how you will dispose of research documents. Reminder: research regulations and policies require each investigator to retain research data not only while the research is being conducted but also after the research is completed. Retention requirements vary depending on whether federal funding was provided for the project, whether there is funding from industry with contractual provisions governing data retention, or whether the study was conducted under FDA regulations. It is recommended that researchers comply with the longest applicable standard.

We will retain data collection for a minimum of 5 years after the study has ended.

# Confidentiality

* 1. Data Security: Describe the steps that will be taken to secure the data (e.g., training, authorization of access, password protection, encryption, physical controls, certificates of confidentiality, and separation of identifiers and data) for storage, use, and transmission of data. **Include also whether a copy of the consent form or other research study information will be placed in the participants’ medical, employment, or educational records, and why that is appropriate (if so, this information must be included in the confidentiality section of the consent form).** [Review the University’s Privacy Office guidance on securing and de-identification of data](https://www.healthprivacy.umn.edu/research).

All of the project researchers either have already undergone CITI and related IRB trainings (PI & Co-PI) or will be required to complete this training (data collectors) prior to any contact with participants. In addition, all data collectors will be personally trained by the PI/Co-PI in procedures necessary to ensure the confidentiality of survey and interview data recorded in an electronic format (Qualtrics).

A web-based data collection (i.e., Qualtrics) or paper-based (in case of technology malfunction) will be used to record responses. All data will be both encrypted and stored on UMN certified secure servers. The only individuals having access to these servers will be the Project PI, Co-PI and project coordinator who will only be able to retrieve data through use of a UMN compliant passcode. All data will be stored on Box.

Data collectors will be provided with tablets or use their work computer to run Qualtrics questionnaires. These tablets will be used exclusively by data collectors associated with this project. All data will be coded with the participant’s ID #.

All identifying information will be stored on Box. Only the Project PI, Co-PI and project coordinator will have access to these files*.* The electronic data will be stored on Box in separate folders for participants’ identifying information and participant data.

Only data that has previously been de-identified will be shared with other project personnel. Authorized project staff will have access to the de-identified project data with an authorization of the Project PI or co-PI. Provider organizations will only have access to de-identified, aggregated data across individuals within their organization presented by project staff.

# Provisions to Monitor the Data to Ensure the Safety of Participants

All studies should have a data safety monitoring plan. This plan should be commensurate with the risks and complexities of the study. Refer to “[WORKSHEET: Data and Safety Monitoring Plan (HRP-335)](https://research.umn.edu/units/irb/toolkit-library/worksheets)” for additional information. All greater than minimal risk research must have a plan for independent ongoing evaluation of the study. Greater than minimal risk research will not be approved by the IRB without an adequate plan for independent monitoring.

* 1. Data Integrity Monitoring. Describe the following:
     + The plan to oversee the progress of the study and to ensure that it is conducted, recorded, and reported in accordance with the protocol, standard operating procedures, and applicable regulatory requirements.
     + Describe the selection of and qualification of the monitor(s).
     + Describe the extent and nature of monitoring based on the study characteristics, objective(s), purpose, design, complexity, blinding, size, and endpoint(s), event(s), or outcome(s).
     + Describe the monitor’s responsibilities.
     + Define monitoring procedures.
     + List the expected elements of the monitoring reports, the distribution plan, and expected follow-up.

Data collectors will have undergone all necessary IRB training necessary for keeping data safe and uncompromized. The project PI and co-PI will observe data collectors on site at the beginning of the study to assure that data collectors are following IRB procedures.

* 1. Data Safety Monitoring. Describe:
     + The plan to periodically evaluate the data collected regarding both harms and benefits to determine whether participants remain safe. The plan might include establishing a data monitoring committee and a plan for reporting data monitoring committee findings to the IRB and the sponsor.
     + What data are reviewed, including safety data, untoward events, and efficacy data.
     + How the safety information will be collected (e.g., with case report forms, at study visits, by telephone calls with participants).
     + The frequency of data collection, including when safety data collection starts.
     + The stopping rules (i.e. study wide and individual participants, as appropriate).
     + Who will review the data.
     + The frequency or periodicity of review of cumulative data.
     + The statistical tests for analyzing the safety data to determine whether harm is occurring.
     + Any conditions that trigger an immediate suspension of the research.

Oversight of the data collection and intervention is provided by the PI, Dr. Tichá, and co PI, Dr. Abery. The PI and co-PI of study staff will review all data collection forms and procedures on an ongoing basis for data completeness and accuracy as well as protocol compliance. Since the probability and magnitude of harm or discomfort anticipated in the study are not greater than those ordinarily encountered in daily life, the data safety monitoring will follow standard procedures. Study progress and safety will be reviewed quarterly (and more frequently if needed, e.g. during bi-weekly project meetings).

# Compensation for Research-Related Injury

* 1. Compensation for Research-Related Injury: If the research involves greater than Minimal Risk to participants, describe the available compensation in the event of research-related injury.
  2. Contract Language: Provide a copy of the contract language, if any, relevant to compensation for research-related injury*.*

N/A

# Consent Process

Note: The process and documentation plan must follow “[SOP: Informed Consent Process for Research (HRP-090)](https://research.umn.edu/units/irb/toolkit-library/standard-operating-procedures)” and “[SOP: Written Documentation of Consent (HRP-091)](https://research.umn.edu/units/irb/toolkit-library/standard-operating-procedures).”

* 1. Consent Process (when consent will be obtained): Describe the consent process, including:
     + Where the consent process will take place.
     + Any waiting period available between informing the prospective participants and obtaining the consent.
     + Any process to ensure ongoing consent.

Informed consent for participation in this project will take place in two stages and on an organization-by-organization basis.

Leadership of service provider organizations

In the first stage of the study, managers, who are interested in assisting with this project, will be invited to attend an in-person or online informational meeting about the study. At this meeting, UMN (PI & Co-PI) and other project staff persons will describe the overall project, participant and project responsibilities, consent process, assessment procedures, focus group, and the intervention (different study conditions) in detail. Any questions that arise will be answered and interested managers then provided with the opportunity to meet with a project staff person trained to have any additional questions answered, express potential concerns, and take part in the formal consent process.

After this, then information about the project (flyer) will be shared with managers to hand out among the potential participants when they describe the study to them. The participants will be encouraged to tell their managers if they are interested in taking part in this project. Those who show interest to participate will receive information about the project, its duration, activities, etc. At the end of session, those who are still interested they will be enrolled into a consent process.

The same process will be conducted for both phase of study.

Both the study consent forms and recruitment protocols are included in ETHOS and are designed to complement each other.

Waiver or Alteration of Consent Process (when consent will not be obtained, required information will not be disclosed, or the research involves deception): If you are not requesting a consent alteration or waiver, type “N/A” and delete the bullets below. Otherwise, provide rationale for the waiver or alteration:

* + - Review “[CHECKLIST: Waiver or Alteration of Consent Process (HRP-410)](https://research.umn.edu/units/irb/toolkit-library/checklists) to ensure that you have provided sufficient information in this protocol for the IRB to make these determinations. Do not fill out the checklist.
    - Describe how your protocol meets the requirements noted in HRP-410.
    - If the research involves a waiver of the consent process for planned emergency research, please review “[CHECKLIST: Waiver of Consent for Emergency Research (HRP-419)](https://research.umn.edu/units/irb/toolkit-library/checklists)” to ensure that you have provided sufficient information for the IRB to make these determinations.
  1. Waiver of Written/Signed Documentation of Consent (when written/signed consent will not be obtained): If you are not requesting a waiver of documentation of consent, type “N/A” and delete the bullets below. Otherwise, provide rationale for the waiver.
     + Review “[CHECKLIST: Waiver of Written Documentation of Consent (HRP-411)](https://research.umn.edu/units/irb/toolkit-library/checklists)” and provide rationale as to why a waiver of written documentation of consent is appropriate for this research study.
     + If you will obtain consent, but not document consent in writing, submit a consent script in ETHOS.

N/A

* 1. Non-English Speaking Participants: Indicate what language(s) other than English is/are understood by prospective participants or their representatives.
  + If participants who do not speak English will be enrolled, describe the process to ensure that the oral or written information provided to those participants will be in their own language. Indicate the language that will be used by those obtaining consent.
  + If you will be using an interpreter during recruitment, consent, data collection, or data analysis, specify how you will identify an appropriate interpreter and what the provisions will be for protecting the confidentiality of participants.
* If the protocol will allow for unexpected enrollment of non-English speakers, this should be included in this section. The IRB must approve the use of the Short Form process before it can be utilized in a study.
* Effective July 1, 2019, for studies that are greater than minimal risk and participation in the study is planned to last 30 days or more, investigators must translate the full study consent document. In addition, the investigator is responsible for ensuring that:
  + - The translation be certified and from a reputable translation service (See “What translation or certification services are acceptable or required?”) within 30 days of the initial consent obtained via the short-form method.
    - Once certified, the translated study consent document and the certification must be submitted to the IRB for review and approval, via a Modification in ETHOS.
    - Translated short forms are available on the UMN IRB website: <https://research.umn.edu/units/irb/toolkit-library/templates>.

N/A

* 1. Participants Who Are Not Yet Adults (infants, children, teenagers under 18 years of age):
     + Describe the criteria that will be used to determine whether a prospective participant has not attained the legal age for consent to treatments or procedures involved in the research under the applicable law of the jurisdiction in which the research will be conducted. (E.g., in Minnesota, individuals under the age of 18 years.)
       - For research conducted in Minnesota, review “[SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)](https://research.umn.edu/units/irb/toolkit-library/standard-operating-procedures)” to be aware of which individuals in the state meet the definition of “children.”
       - For research conducted outside of Minnesota, provide information that describes which persons have not attained the legal age for consent to treatments or procedures involved the research, under the applicable law of the jurisdiction in which research will be conducted. One method of obtaining this information is to have a legal counsel or authority review your protocol along with the definition of “children” in “[SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)](https://research.umn.edu/units/irb/toolkit-library/standard-operating-procedures).”
     + Describe whether parental permission will be obtained from:
       - Both parents, unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.
       - One parent, even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child.
     + Describe whether permission will be obtained from individuals other than parents, and if so, who will be allowed to provide permission. Describe the process used to determine these individuals’ authority to consent to each child’s general medical care.
     + Indicate whether assent will be obtained from all, some, or none of the children. If assent will be obtained from some children, indicate which children will be required to assent.
     + When assent of children is obtained describe whether and how it will be documented.

N/A

* 1. Cognitively Impaired Adults, or adults with fluctuating or diminished capacity to consent:
     + Describe the process to determine whether an individual is capable of consent. Review “[POLICY: Capacity to Consent (HRP-110)](https://drive.google.com/open?id=0B7644h9N2vLcR2hQaXlzbnNsUWc)” and “[POLICY: Research Involving Adults Under Court Jurisdiction (HRP-111)](https://drive.google.com/open?id=0B7644h9N2vLcTTF3dEhlMFJtQUU)” for additional information. Reference “[CHECKLIST: Cognitively Impaired Adults (HRP-417)](https://research.umn.edu/units/irb/toolkit-library/checklists).”
     + Indicate who will be responsible for assessing capacity to consent for this protocol. Review training requirements to ensure those responsible for assessing capacity to consent have completed the required training ([SOP: Education and Training (HRP-066)](https://research.umn.edu/units/irb/toolkit-library/standard-operating-procedures)).
     + Confirm use of one of the approved validated instruments to assess capacity to consent appropriate for the level of risk associated with the research (i.e., the MacArthur Competence Assessment Tool for Clinical Research for greater than Minimal Risk research or the UCSD Brief Assessment of Capacity to Consent for Minimal Risk research). If you will not be using one of these tools, describe the alternative validated tool(s) you propose to use instead. If available in electronic format, submit the alternative tool(s) for review by the IRB in ETHOS.
     + Document plans, if any, to avoid seeking consent during periods of greater than normal impairment.

N/A

* 1. Adults Unable to Consent:
     + Permission: List the individuals from whom permission will be obtained in order of priority (e.g., durable power of attorney for health care, court appointed guardian for health care decisions, spouse, and adult child.)
       - For research conducted in Minnesota, review “[SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)](https://research.umn.edu/units/irb/toolkit-library/standard-operating-procedures)” to be aware of which individuals in the state meet the definition of “legally authorized representative.” Additionally, be aware of special restrictions regarding recruiting or enrolling persons under a stay of commitment.
       - For research conducted outside of Minnesota, provide information that describes which individuals are authorized under applicable law to consent on behalf of a prospective participant to their participation in the procedure(s) involved in this research. One method of obtaining this information is to have a legal counsel or authority review your protocol along with the definition of “legally authorized representative” in “[SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)](https://research.umn.edu/units/irb/toolkit-library/standard-operating-procedures).”
     + Assent: Describe the process for assent of the participants. Indicate whether:
       - Assent will be required of all, some, or none of the participants. If some, indicate which participants will be required to assent and which will not.
       - If assent will not be obtained from some or all participants, an explanation of why not.
       - Describe whether assent of the participants will be documented and the process to document assent.
       - Dissent: Describe the process of identifying the dissent of the participants. Reference the [Legally Authorized Representative Brochure](https://research.umn.edu/units/hrpp/education-training/order-print-participant-materials) and [Investigator Manual (HRP-103)](https://drive.google.com/open?id=0B7644h9N2vLcMGhpekhzTnZ3ODQ) for additional guidance.

N/A

# Setting

* 1. Research Sites: Describe the sites or locations where your research team will conduct the research.
     + Identify where your research team will identify and recruit potential participants.
     + Identify where research procedures will be performed.
     + Describe the composition and involvement of any community advisory board, school board, school principals or teachers, etc.
     + For research conducted outside of your organization and its affiliates, describe:
       - Site-specific regulations or customs affecting the research.
       - Local scientific and ethical review structure.

This research will be conducted in assisted living facilities and nursing homes managed by service providers that agreed to assist with this study. The actual study activities may also take place in community centers if that is the participants’ preference.

Potential participants will be invited for initial informational meetings organized for organizations that have expressed an interest in this study on their premises where their trainings and cross-facility meetings are typically held. Recruitment of all participants will take place online or in-person in separate meetings at each interested organization (community room, meeting room, etc.). The data collection and intervention activities will take place in available meeting/community spaces of these provider organizations or other community spaces (e.g., meeting room at the library).

Although there may be some variation depending on the size of the organization and its services, it is expected that both phases of study will take place in person.

For this study, the PI and co-PI will rely upon the input of the Institute on Community Integration’s Community Advisory Group for additional organization recruitment. This group is composed of persons with a variety of seniority and disabilities, representatives from provider organizations.

There are no explicit site-specific regulations or customs in place at participating organizations that we believe have the potential to have a significant impact on the proposed research.

The boards of the collaborating organizations are responsible for determining the scientific merit and review structure for research going on within the organization. These boards are designated to reviewed the proposal prior to its submission to the funding agency and approve the organization’s involvement at that time.

* 1. International Research: If the research will take place in an international location or if the participants may be located in a General Data Protection Regulation compliant country, include information below for each location.
     + Indicate whether the [General Data Protection Regulation (GDPR)](https://privacy.umn.edu/general-data-protection-regulation-gdpr) applies to your research study. Research does not physically have to take place in the GDPR country for GDPR to apply. See the [Consent Template](https://drive.google.com/open?id=0B7644h9N2vLcVmwxR2dOZFRGSDg) for instructions on what must be included for GDPR compliance.
     + Review “[WORKSHEET: International Research (HRP-336)](https://research.umn.edu/units/irb/toolkit-library/worksheets)” when developing an international research protocol.
     + Describe where the research will take place and how culturally appropriate access to the community will be obtained.
     + Note if there are any aspects of the cultural, political, or economic climate that might increase risks for participants. Detail strategies to mitigate or minimize these risks.
     + Describe relevant ways in which the cultural norms and/or laws differ between the host site and the United States.
     + Indicate whether a local participant advocate will be available for participants.
     + To minimize health and safety risks, University policy requires special permission from the University’s International Travel Risk Assessment and Advisory Committee (ITRAAC) prior to travel in specific circumstances, and applies as follows to both students participating in, and faculty/staff leading the education experience. For more information, visit the [ITRAAC website](http://global.umn.edu/travel/approval/index.html#who-tab).

N/A

* 1. Community Based Participatory Research: If the research will be based in or in partnership with more than one community, include information below for each community.
     + Describe how community partners will participate in various stages of the research.
     + Describe the plan for educating community partners about human research protections.
     + Describe the agreement with the community partner organization. If appropriate, provide a letter, memorandum of understanding, or contract in the “Supporting Documents” section in ETHOS.

This study will be conducted in collaboration with multiple community-based service provider organizations that support older adults. A support letter has been attached. More letters will be added as they are received.

# Multi-Site Research

If this is not a multi-site study where you are the lead investigator, type “N/A” and delete the sub-headings below. Otherwise, complete all items below. Note, if this is a federally funded research study, sIRB requirements may apply. Please review [information on sIRB](https://research.umn.edu/units/irb/how-submit/single-irb-sirb-external-irb-requests-process) prior to submitting to the IRB.

* 1. Study-Wide Number of Participants: Indicate the total number of participants to be accrued across all sites.
  2. Study-Wide Recruitment Methods: If participants will be recruited by methods not under control of the local site (e.g., call centers, national advertisements), describe those methods. Local recruitment methods are described earlier in the protocol.
  3. Study-Wide Recruitment Materials: Describe any template materials that will be used to recruit participants across all sites. (Attach copies of these materials in ETHOS if you will serve as the lead investigator and the University’s IRB will serve as the IRB of record for all sites.)
  4. Communication Among Sites: If this is a multi-site study where you are the lead investigator, describe the processes to ensure communication among sites, such as:
     + All sites have the most current version of the protocol, consent document(s), and, when applicable, HIPAA authorization.
     + All required approvals (initial, continuing review, and modifications) have been obtained at each site (including by the site’s IRB of record).
     + All modifications have been communicated to sites, and approved (including approval by the site’s IRB of record) before the modification is implemented.
     + All engaged participating sites will safeguard data, including secure transmission of data, as required by local information security policies.
     + All local site investigators conduct the study in accordance with applicable federal regulations and local laws.
     + All non-compliance with the study protocol or applicable requirements will be reported in accordance with university or local policy.
     + All other reportable events in accordance with university or local policy.
  5. Communication to Sites: Describe the method for communicating to engaged participating sites:
     + Problems (inclusive of reportable events).
     + Interim results.
     + The closure of the study.

N/A

# Coordinating Center Research

If the University of Minnesota is serving only as the Coordinating Center for this research study, describe the Coordinating Center functions and responsibilities. Include the center’s SOPs in your ETHOS submission.

* 1. Role: Describe the role of the Coordinating Center.
  2. Responsibilities: Describe the responsibilities of the Coordinating Center. Indicate how you will assuring that all centers have the most current version of the protocol and that amendments to the protocol will be communicated to all centers.
  3. Oversight: Provide each participating center FWA number with OHRP (if the research is federally funded). Provide a process for reporting and evaluating protocol events and deviations from participating centers (if applicable).
  4. Collection and Management of Data: Provide your plan for collection and management of data from all centers.

N/A

# Resources Available

* 1. Resources Available: Describe other resources available to conduct the research. For example, as appropriate:
     + If the study is being conducted by a student investigator, include a description of how the faculty advisor will support the student. Note that interventions or uses of investigational drugs or devices involving greater than Minimal Risk should include detailed information regarding faculty oversight and participation in the research.
     + Justify the feasibility of recruiting the required number of suitable participants with the agreed upon recruitment period. For example, to how many potential participants do you have access? What percentage of those potential participants do you need to recruit?
     + Describe the time that you will devote to conducting and completing the research.
     + Describe your facilities.
     + Describe the availability of medical or psychological resources that participants might need as a result of an anticipated or unanticipated consequences of the research.
     + Describe your process to ensure that all persons assisting with the research are adequately informed about the protocol, the research procedures, and their duties and functions.

This project has been funded by the College of Education and Human Development (CEHD) Jump Start program.

**Departments**

**University of Minnesota – Institute on Community Integration (ICI)**

The Institute on Community Integration (ICI) is a nationally recognized center of training, technical assistance, and education and a University Center for Excellence in Disabilities (UCED). Located within one of the nation's largest research universities, it has access to a rich set of resources to assist in this project. The University of Minnesota, a major center of education, research, and service, is one of the largest universities in the U.S. with an enrollment of 75,000 students. The University’s ICI serves as an organizational structure for the Minnesota University Center of Excellence for Developmental Disabilities (UCEDD) providing training, exemplary services, information, and conducting research for persons with disabilities, their families, and communities. The Institute manages an $18 million annual budget and is one of the largest research and training centers in the Midwest. The ICI has over 30-years of experience supporting and evaluating the development of services for persons with disabilities, their families and the people who provide support to them. A major component of these activities has been the development and evaluation of innovative programs designed to enhance the educational, employment, and community outcomes of individuals with IDD and other types of disabilities.

ICI houses the Research and Training Center on Community Living (RTC/CL) as well as the Research and Training Center on Outcome Measurement (RTC/OM) and other federal and foundation grants to fulfill its mission. ICI collaborates with many national, state and local partners, including Administration for Community Living (ACL), National Association of State Directors of Developmental Disabilities Services (NASDDDS), Minnesota DHS, etc.

Additional organizational capacities at ICI include: The Research and Technology Consulting Group (RTCG) which provides expertise in statistics, data analysis and computer technology, and the Institute Publications Office which furnishes assistance in the development and distribution of all ICI publications.

Support Services. Among resources available at the University are information retrieval services, computer centers, and a statistical center. In addition, editing, printing and graphic arts services are available through the Institute’s publications office. Administrative support for this project will be provided through ICI administrative staff which includes individuals with financial/budgetary, secretarial, technology, and human resources skills.

Accessibility. The University of Minnesota’s ICI and the collaborating employment agencies are fully accessible to persons with disabilities including those of a physical nature (e.g., furniture to accommodate the needs of staff members who use wheelchairs; work locations; computer technology, etc.). When selecting employment sites for people with disabilities, they assure that the person can access the site. All products produced as part of this development effort will be available in alternative formats upon request such that consumers, family members, policy-makers and human service professionals who are individuals with disabilities will have full access. Organization web designers work closely with stakeholders with disabilities to ensure that electronically available products and web sites can be fully accessed.

**University of Minnesota - Department of Electrical and Computer Engineering**

The Department of Electrical and Computer Engineering consistently ranks among the top 20 of all electrical and computer engineering programs in the country. Our faculty engage in research that is spearheading developments in technology that impact our world and the lives we lead. There are 7 key areas of research in ECE: biomedical and biological computational methods, devices, and systems; communications, signal processing, and networking; computer engineering, VLSI, and circuits; energy systems, and power electronics; fields, photonics, and magnetics; micro and nano structures; systems and control.

The interdisciplinary nature of these areas encourages our faculty and students to collaborate across subjects and departments in ways that are significant and meaningful to solving problems that affect our lives and the world around us. Such research and design experience also benefits our students as they learn about the intertwined nature of research and problem solving that promotes advancements at the scientific, and technological levels.

**Key Project Staff**

***PERSONNEL***

***PERSONNEL – Institute on Community Integration (ICI)***

**Renáta Tichá**, Ph.D., Principal Investigator, Project Director (4% FTE). Dr. Renata Tichá is a Research Associate at the Institute on Community Integration and an adjunct faculty member within the Special Education Program at the University of Minnesota with extensive experience in services to children with disabilities as a program evaluator and researcher. She holds a doctorate in Special Education and has worked at the ICI for 12-years, coordinating and directing projects involving survey, assessment, and intervention research for children and youth with a variety of disabilities. Dr. Tichá will oversee implementation & administration of project. She will take the lead in developing project products including the intervention content, training and supervision of data collectors. She will oversee budgetary and contract matters, data collection and analysis, and content development. In addition, she will work together with Dr. Abery to supervise day-to-day efforts of the Project staff, other research staff, and GRAs as well as serve as the liaison between collaborating University departments and community organizations.

**Brian Abery**, Ph.D., Co-Principal Investigator (3% FTE). Brian Abery is the Director of the Research and Training Center on HCBS Outcome Measurement and Co-Director of the Educational Assessment and Intervention Program and International Institute on Progress Monitoring at the Institute on Community Integration (ICI). He has been Principal Investigator of numerous projects designed to enhance the self-determination of students with disabilities, better understand the impact of care coordination on the health outcomes experiences by these vulnerable population. His most recent related projects have focused on robotic in workforce for people with disabilities in collaboration with Japan, understanding the impact of smart home technology on the self-determination and social inclusion of adults with IDD. Dr. Abery holds a doctorate in educational psychology and has an extensive background in research, program development, and evaluation. He is currently or in the recent past has been the PI or Co-PI on NIDILRR (smart home technology, HCBS Outcome Measurement; self-determination); U.S. Department of State (self-determination, Response to Intervention and inclusive service learning), UNICEF, UKAID. In addition to contributing heavily to the content development, Dr. Abery will oversee evaluation/assessment activities taking place as part of the project data collection and analysis and assume responsibility for overseeing the work of the Project Coordinator related to data management. He will also work with Dr. Tichá in overseeing budgetary and contract matters and in supervising staff.

**Maryam Mahmoudi**, Ph.D., Co-PI and Project Coordinator (25% FTE). Maryam Mahmoudi has a Ph.D. in psychology and currently is an ARRT postdoctoral associate at the ICI and is working on a variety of projects including smart home technologies for people with disabilities and robotic in workforce for people with disabilities in collaboration with Japan. She has about a decade of experiences in interdisciplinary research area. For her master degree, she developed an online expert system for screening autism accessible free for through whole country. Then, she start her collaboration with the Advanced Robotics and Intelligent Systems on projects applying a parrot-like robot to screen autism in children and teach basic social skills to those with autism. She also was a postdoctoral fellow at the social robot lab at the NTNU, Norway. During her fellowship, she gained experience of working with Nao robot, developed projects for using Nao and Pepper robot to teach advanced social problem solving skills to children with autism and provide cognitive stimuli interventions for ageing adults. For the current project, she will work on developing content for the program and preparing the scripts for coding Nao in collaboration with engineering department. She will apply for IRB for both phases and contact communities to recruit participants, she conducts the studies, and prepare reports under supervision of PI and in working with other project partners.

**Roger Stancliffe**, Ph.D. is a Senior Research Associate at the University of Minnesota's Institute on Community Integration. He holds a conjoint appointment as Professor Emeritus of Intellectual Disability at the University of Sydney in Australia. Previously, he was a Senior Research Fellow at the Centre for Disability Studies (1997-2007) in Sydney. He has maintained an ongoing collaboration with disability researchers at the University of Minnesota since 1994. Stancliffe's research focuses on making a difference in the everyday lives of people with intellectual and developmental disability (IDD). His current work is on aging with IDD and focuses on retirement and end-of-life issues as well of factors associated with aging, including physical activity. He is the recipient of the 2011 AAIDD Research Award and the 2019 Centre for Disability Studies Lifetime Achievement Award. Dr. Stancliffe current provides mentoring to early researchers at ICI related to their research ideas, methodology and research implications. In this project, he will provide expertise on aging and physical activity as related to aging adults.

**PERSONNEL – Department of Electrical and Computer Engineering**

***Vassilis Morellas, Ph.D. - CS & E.*** Dr. Vassilios Morellas serves as the Research professor at the University of Minnesota, the *Department of Electrical and Computer Engineering (DECE)*. His research interests include geometric image processing, machine learning, robotics and sensor integration. He is Executive Director of the NSF Center for Safety Security and Rescue. Prior to his current position he was a Senior Principle Research Scientist at Honeywell Laboratories where he developed technologies in the general areas of access control, security and surveillance and biometrics with emphasis on the problem of tracking of people and vehicles across non-overlapping cameras. Past research experience also includes work on Intelligent Transformation Systems where he developed innovative technologies to reduce run off the road accidents. Dr. Morellas obtained his B.S. in Mechanical Engineering from the National Technical University of Athens, Greece, his MSME from Columbia University, NY and his PhD from the Department of Mechanical Engineering at the University of Minnesota. He publishes regularly in peer review conference proceedings and journals and has coauthored a book on camera programming. Dr. Morellas will direct the technical aspects of programming the robot for speech, face, and emotion recognition. In this position, he will work with ICI and project GRA to convert the content scripts and scenarios developed into an integrated system for Nao. Dr. Morellas will directly supervise the work of the GRA in programming and other developmental work necessary for running the robot successfully.

***TBH Graduate Research Assistant.*** The DECE under the direction of Dr. Morellas at the Department of Engineering will recruit and hire a Graduate Research Assistant with a background in robotic and NLP programming to work with the project staff to program Nao for the content scripts of the project. The GRA is attending in meetings to work on scripts and coding Nao and project conductions when is required.

# References

Include references to any scholarly articles or other materials used to discuss the background for the study or to justify any proposed procedures.

1. Feil-Seifer, D. & Mataric, M. J. Defining socially assistive robotics. in *9th International Conference on Rehabilitation Robotics, 2005. ICORR 2005.* 465–468 (2005). doi:10.1109/ICORR.2005.1501143.

2. United Nations, Department of Economic and Social Affairs, & Population Division. *World population ageing, 2017 highlights*. (2017).

3. United Nations, Department of Economic and Social Affairs, & Population Division. *World population ageing 2020 Highlights: living arrangements of older persons.* (2020).

4. 2020 Profile of Older Americans. 21.

5. Ferrucci, L., Giallauria, F. & Guralnik, J. M. Epidemiology of Aging. *Radiol. Clin. North Am.* **46**, 643–v (2008).

6. Guzman-Castillo, M. *et al.* Forecasted trends in disability and life expectancy in England and Wales up to 2025: a modelling study. *Lancet Public Health* **2**, e307–e313 (2017).

7. Kose, E., Hirai, T. & Seki, T. Psychotropic drug use and cognitive rehabilitation practice for elderly patients. *Int. J. Clin. Pharm.* **40**, 1292–1299 (2018).

8. Gu, D., Brown, B. L. & Qiu, L. Self-perceived uselessness is associated with lower likelihood of successful aging among older adults in China. *BMC Geriatr.* **16**, 172 (2016).

9. McCrae, N. *et al.* ‘They’re all depressed, aren’t they?’ A qualitative study of social care workers and depression in older adults. *Aging Ment. Health* **9**, 508–516 (2005).

10. Committee on the Health and Medical Dimensions of Social Isolation and Loneliness in Older Adults *et al.* *Social Isolation and Loneliness in Older Adults: Opportunities for the Health Care System*. 25663 (National Academies Press, 2020). doi:10.17226/25663.

11. Lo Coco, D., Lopez, G. & Corrao, S. Cognitive impairment and stroke in elderly patients. *Vasc. Health Risk Manag.* **12**, 105–116 (2016).

12. Ritchie, K. *et al.* Designing prevention programmes to reduce incidence of dementia: prospective cohort study of modifiable risk factors. *BMJ* **341**, c3885 (2010).

13. Rosenberg, A., Mangialasche, F., Ngandu, T., Solomon, A. & Kivipelto, M. Multidomain Interventions to Prevent Cognitive Impairment, Alzheimer’s Disease, and Dementia: From FINGER to World-Wide FINGERS. *J. Prev. Alzheimers Dis.* **7**, 29–36 (2020).

14. Kivipelto, M., Mangialasche, F. & Ngandu, T. Lifestyle interventions to prevent cognitive impairment, dementia and Alzheimer disease. *Nat. Rev. Neurol.* **14**, 653–666 (2018).

15. Edwards III, G. A., Gamez, N., Escobedo Jr., G., Calderon, O. & Moreno-Gonzalez, I. Modifiable Risk Factors for Alzheimer’s Disease. *Front. Aging Neurosci.* **11**, 146 (2019).

16. Barnes, D. E. & Yaffe, K. The Projected Impact of Risk Factor Reduction on Alzheimer’s Disease Prevalence. *Lancet Neurol.* **10**, 819–828 (2011).

17. E, R. *et al.* Estimating the potential for dementia prevention through modifiable risk factors elimination in the real-world setting: a population-based study. *Alzheimers Res. Ther.* **12**, (2020).

18. Livingston, G. *et al.* Dementia prevention, intervention, and care: 2020 report of the Lancet Commission. *Lancet Lond. Engl.* **396**, 413 (2020).

19. Clare, L. *et al.* Potentially modifiable lifestyle factors, cognitive reserve, and cognitive function in later life: A cross-sectional study. *PLoS Med.* **14**, e1002259 (2017).

20. Kim, K.-S. & Cho, Y.-S. The effects of an occupation-centered cognitive rehabilitation program on elderly individuals with mild cognitive impairment. *J. Phys. Ther. Sci.* **30**, 332–334 (2018).

21. Kim, S. Cognitive rehabilitation for elderly people with early-stage Alzheimer’s disease. *J. Phys. Ther. Sci.* **27**, 543–546 (2015).

22. Sugano, K. *et al.* Effect of Cognitive and Aerobic Training Intervention on Older Adults with Mild or No Cognitive Impairment: A Derivative Study of the Nakajima Project. *Dement. Geriatr. Cogn. Disord. Extra* **2**, 69–80 (2012).

23. Jennings, L. A. *et al.* Patient and caregiver goals for dementia care. *Qual. Life Res. Int. J. Qual. Life Asp. Treat. Care Rehabil.* **26**, 685–693 (2017).

24. Clare, L. *et al.* Individual goal-oriented cognitive rehabilitation to improve everyday functioning for people with early-stage dementia: A multicentre randomised controlled trial (the GREAT trial). *Int. J. Geriatr. Psychiatry* **34**, 709–721 (2019).

25. Nelis, S. M., Thom, J. M., Jones, I. R., Hindle, J. V. & Clare, L. Goal-setting to promote a healthier lifestyle in later life: Qualitative evaluation of the agewell trial. *Clin. Gerontol. J. Aging Ment. Health* **41**, 335–345 (2018).

26. Clare, L. *et al.* The AgeWell study of behavior change to promote health and wellbeing in later life: study protocol for a randomized controlled trial. *Trials* **13**, 115 (2012).

27. Bandura, A. Health promotion by social cognitive means. *Health Educ. Behav. Off. Publ. Soc. Public Health Educ.* **31**, 143–164 (2004).

28. Mordoch, E., Osterreicher, A., Guse, L., Roger, K. & Thompson, G. Use of social commitment robots in the care of elderly people with dementia: a literature review. *Maturitas* **74**, 14–20 (2013).

29. Bemelmans, R., Gelderblom, G., Jonker, P. & Witte, L. D. de. Socially assistive robots in elderly care: a systematic review into effects and effectiveness. *J. Am. Med. Dir. Assoc.* (2012) doi:10.1016/j.jamda.2010.10.002.

30. Tiberio, L., Cesta, A., Cortellessa, G., Padua, L. & Pellegrino, A. R. Assessing affective response of older users to a telepresence robot using a combination of psychophysiological measures. in *Proceedings - IEEE International Workshop on Robot and Human Interactive Communication* 833–838 (2012). doi:10.1109/ROMAN.2012.6343855.

31. Louie, W., McColl, D. & Nejat, G. Playing a memory game with a socially assistive robot: A case study at a long-term care facility. *2012 IEEE RO-MAN 21st IEEE Int. Symp. Robot Hum. Interact. Commun.* (2012) doi:10.1109/ROMAN.2012.6343777.

32. Libin, A. V. & Libin, E. V. Person-robot interactions from the robopsychologists’ point of view: the robotic psychology and robotherapy approach. *Proc. IEEE* **92**, 1789–1803 (2004).

33. Kazuyoshi, W., Shibata, T., Saito, T. & Tanie, K. Robot assisted activity to elderly at a health service facility for the aged. *First Int. IEEE EMBS Conf. Neural Eng. 2003 Conf. Proc.* (2003) doi:10.1109/CNE.2003.1196863.

34. Wada, K. & Shibata, T. Robot therapy in a care house - its sociopsychological and physiological effects on the residents. *Proc. 2006 IEEE Int. Conf. Robot. Autom. 2006 ICRA 2006* (2006) doi:10.1109/ROBOT.2006.1642310.

35. Pu, L., Moyle, W., Jones, C. & Todorovic, M. The Effectiveness of Social Robots for Older Adults: A Systematic Review and Meta-Analysis of Randomized Controlled Studies. *The Gerontologist* **59**, e37–e51 (2019).

36. AlonsoSusel, G. *et al.* Social Robots for People with Aging and Dementia: A Systematic Review of Literature. *Telemed. E-Health* (2019) doi:10.1089/tmj.2018.0051.

37. Wada, K., Shibata, T., Saito, T. & Tanie, K. Analysis of factors that bring mental effects to elderly people in robot assisted activity. *IEEERSJ Int. Conf. Intell. Robots Syst.* (2002) doi:10.1109/IRDS.2002.1043887.

38. Fasola, J., Matarić, M. J. & Ieee, F. INVITED PAPER Using Socially Assistive Human–Robot Interaction to Motivate Physical Exercise for Older Adults. (2011).

39. Shibano, T., Ho, Y., Kono, Y., Fujimoto, Y. & Yamaguchi, T. Daily support system for care prevention by using interaction monitoring robot. in *2010 IEEE/RSJ International Conference on Intelligent Robots and Systems* 3477–3482 (IEEE, 2010). doi:10.1109/IROS.2010.5653582.

40. Cooper, S., Di Fava, A., Vivas, C., Marchionni, L. & Ferro, F. ARI: the Social Assistive Robot and Companion. in *2020 29th IEEE International Conference on Robot and Human Interactive Communication (RO-MAN)* 745–751 (2020). doi:10.1109/RO-MAN47096.2020.9223470.

41. Sumner, J., Chong, L. S., Bundele, A. & Wei Lim, Y. Co-Designing Technology for Aging in Place: A Systematic Review. *The Gerontologist* **61**, e395–e409 (2021).

42. Mahmoudi, M. & Hameed, I. COGNITIVE REHABILITATION FOR THE ELDERLY USING SOCIAL ROBOTS: A BRIEF REVIEW. *ICERI2019 Proc.* 7029–7034 (2019).

43. Valenzuela, M. J. & Sachdev, P. Assessment of complex mental activity across the lifespan: development of the Lifetime of Experiences Questionnaire (LIFETIME OF EXPERIENCES QUESTIONNAIRE (LEQ)). *Psychol. Med.* **37**, 1015–1025 (2007).

44. Breen, R. L. A Practical Guide to Focus-Group Research. *J. Geogr. High. Educ.* **30**, 463–475 (2006).

45. Constructing Grounded Theory: A practical guide through qualitative analysis Kathy Charmaz Constructing Grounded Theory: A practical guide through qualitative analysis Sage 224 £19.99 0761973532 0761973532 [Formula: see text]. *Nurse Res.* **13**, 84 (2006).

46. Clare, L. *et al.* The Agewell trial: a pilot randomised controlled trial of a behaviour change intervention to promote healthy ageing and reduce risk of dementia in later life. *BMC Psychiatry* **15**, 25 (2015).

47. Bainbridge, W. A., Hart, J., Kim, E. S. & Scassellati, B. The effect of presence on human-robot interaction. in *RO-MAN 2008 - The 17th IEEE International Symposium on Robot and Human Interactive Communication* 701–706 (2008). doi:10.1109/ROMAN.2008.4600749.

48. Pan, Y. & Steed, A. A Comparison of Avatar-, Video-, and Robot-Mediated Interaction on Users’ Trust in Expertise. *Front. Robot. AI* **0**, (2016).

49. Kiesler, S., Powers, A., Fussell, S. R. & Torrey, C. Anthropomorphic Interactions with a Robot and Robot–like Agent. *http://dx.doi.org/10.1521/soco.2008.26.2.169* https://guilfordjournals.com/doi/abs/10.1521/soco.2008.26.2.169 (2008) doi:10.1521/soco.2008.26.2.169.

50. Leyzberg, D., Spaulding, S., Toneva, M. & Scassellati, B. The Physical Presence of a Robot Tutor Increases Cognitive Learning Gains. *Proc. Annu. Meet. Cogn. Sci. Soc.* **34**, (2012).

51. Tobis, S., Neumann-Podczaska, A., Kropińska, S. & Suwalska, A. UNRAQ—A Questionnaire for the Use of a Social Robot in Care for Older Persons. A Multi-Stakeholder Study and Psychometric Properties. *Int. J. Environ. Res. Public. Health* (2021) doi:10.3390/ijerph18116157.

52. Logan, S. L., Gottlieb, B. H., Maitland, S. B., Meegan, D. & Spriet, L. L. The Physical Activity Scale for the Elderly (PASE) Questionnaire; Does It Predict Physical Health? *Int. J. Environ. Res. Public. Health* **10**, 3967–3986 (2013).

53. Russell, D., Peplau, L. A. & Cutrona, C. E. Revised UCLA Loneliness Scale. (2011) doi:10.1037/t01011-000.

54. *Improving Sustainability During Hospital Design and Operation: A Multidisciplinary Evaluation Tool*. (Springer International Publishing, 2015). doi:10.1007/978-3-319-14036-0.