UNIVERSITY of ROCHESTER MEDICAL CENTER

Department of Psychiatry
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CONSENT FORM

CAPABLE Transitions: A Home Health Agency-Based Intervention to Optimize the Post-Acute Care-to-Home Transition

Principal Investigator: Adam Simning, MD, PhD

University of Rochester is receiving funding from the National Institute on Aging to support this research study.

This consent form describes a research study, what you may expect if you decide to take part and important information to help you make your decision. Please read this form carefully and ask questions about anything that is not clear before you agree to participate. You may take time to think about and discuss this consent form with family or friends.

Key Information

- Being in this research study is voluntary – it is your choice.
- You are being asked to take part in this study because you were recently discharged from the hospital or post-acute care facility and began receiving services from a home health agency.
- The purpose of this study is to obtain information to allow us to test and improve upon an intervention that we are developing to help individuals return to and remain in their home following discharge from the hospital or post-acute care facilities.
- If you are eligible and agree to participate in the study, you will be randomly assigned to one of two groups. If assigned to the first group, you will receive care as usual, and participating in the study will not affect any of the services you receive. If assigned to the second group, you will receive care as usual AND the in-home intervention described later in this document. Participants in both groups will be asked to complete in-person interviews that will focus on their health and functioning.

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- You will have the option to include a caregiver if they are willing to be your **Study Partner** in the research study.
- Your participation in this study will last for about 6 months.
- You might not benefit from being in this research study. If you are assigned to the group that will receive the intervention, the potential benefit to you might include Occupational Therapy, Registered Nurse, and Handyworker study visits. These study visits will be different from the services you receive from the home health agency as study visits will focus on your functioning and home safety and will be based on your treatment goals rather than focusing on management of specific medical problems.
- One of the most serious risks is that there could be a breach in confidentiality. See the "Risks of Participation" section in this consent form for more information. You should discuss these risks in detail with the study team.
- Procedures and their common risks are shown in the chart below. More detailed information about the study procedures can be found under "*Description of Study Activities*."
- If you do not want to take part in this study, it will not affect the standard treatment you are receiving from the home health agency.

Why are we doing this research study?

Older adults often have trouble in returning home from the hospital or post-acute care facilities, like an inpatient rehabilitation or skilled nursing facility. The purpose of this study is to test and improve upon an intervention that we are developing to help older adults return to and remain in their homes following discharge from the hospital or a post-acute care facility. This intervention includes an Occupational Therapist, Registered Nurse, and a Handyworker who will work with study subjects to improve physical functioning, home safety, and other health-related concerns. We also will examine information from older adults who receive care as usual that is delivered by a home health agency. This information will provide us with data that we need to develop a large-scale study to examine if our intervention is effective. Care as usual is delivered and determined by the home health agency and may include nursing, home health aide, medical social work, and occupational, physical, and speech therapy services. These home health services are completely separate from the research study, and your participation in the study will have no impact on the home health services you receive.

How are the study occupational therapy and nurse visits different from home health agency occupational therapy and nurse visits?

Both the study occupational therapist and study registered nurse will conduct a comprehensive in-home assessment that will examine your health and functioning. The study occupational therapy visits will focus on the functional goals you prioritize (such as dressing or bathing). The study registered nurse visits will target the health issues that may be impairing function (e.g., depression, pain, incontinence) that you prioritize, fall prevention, and communication with your doctor. In contrast, the services delivered by home health agencies are generally directed by a doctor's order and tend to focus on a specific medical problem identified by the doctor (e.g., wound care, diabetes management, and heart failure treatment).

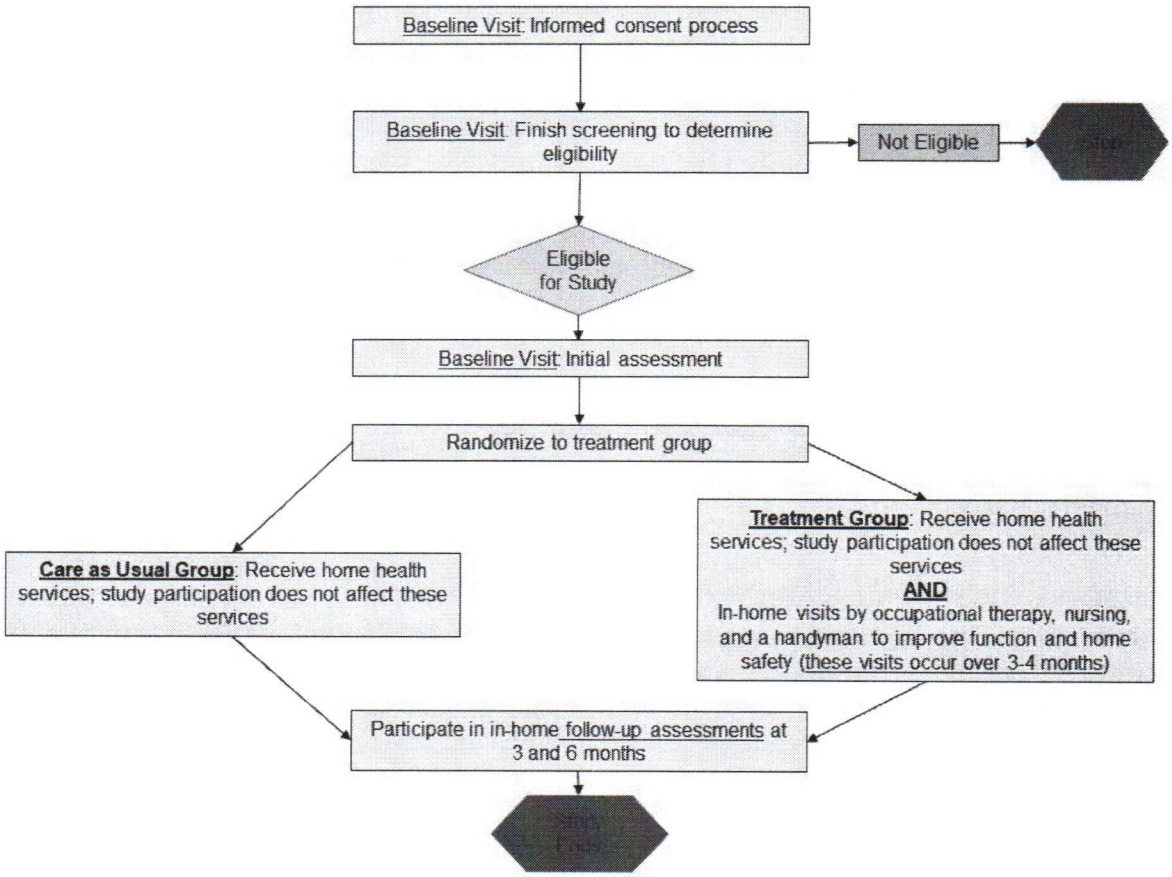
How many people will take part in this study?

About 60 people will take part in this study, all of whom will be recruited from the Rochester region.

What will happen if I take part in this research study?

If you are eligible and agree to participate in this study, you will be asked to complete **Study Screening**, an **Initial Baseline Study Visit**, and two **Follow-Up Study Visits**. Additionally, if you are randomized to the intervention group, you will be asked to participate in up to 11 **Intervention Visits** that will include working with an Occupational Therapist, Registered Nurse, and Handyworker. All of these visits will occur in your home.

Please see Figure below for an overview of the study activities.



ALL PARTICIPANTS RECEIVE THE FOLLOWING:

1) Screening Interview (occurs during 1st in-home visit)

At the beginning of the screening visit, we will explain all of the study procedures and answer any questions that you and, if applicable, your study partner may have. The screening visit will include questions about your eligibility as well as a cognitive performance test, which allows the study team to determine if you meet all the requirements to be in the study, and to make sure it is safe for you to undergo all of the procedures that are required for the study. Regardless of this screening, you will have the option to include a caregiver if they are willing to serve as a **Study Partner**. If you are unable to provide informed consent, you will only be enrolled if you are able to provide a co-signer for the informed consent form. After you sign the consent to participate, we ask that you report all injuries, illness or reactions to study procedures as soon as you are able to either: 1) the study staff (Occupational Therapist, Registered Nurse, Handyworker,

research coordinator), or 2) the study doctor, Adam Simning, at 585-474-9534 during normal hours, evenings, holidays, and weekends so that it can be recorded in your study records. The 1st in-home visit will last approximately 2 hours.

2) Baseline Assessment (occurs during 1st in-home visit)

If you meet the requirements to be in the study, you will be enrolled and will be asked to participate in the baseline assessment. The purpose of the baseline assessment is to obtain information about your demographics, physical and mental health and functioning, home hazards and environment, and use of medical and non-medical services. Demographic information includes information such as your age, education level, health insurance status, and income. The 1st in-home visit will last approximately 2 hours. If need-be, this visit can be split over multiple days. This assessment visit may be audio-recorded for quality control purposes. Access to these audio recordings will be password protected and recorded on encrypted devices. Audio recordings will be destroyed in accordance with local and federal guidelines.

3) Random Assignment to Group (occurs following the 1st in-home visit)

Following the baseline visit, if you are eligible and agree to participate in this study, you will be assigned by chance (like flipping a coin) to one of two groups. Group 1 will receive home health agency care as usual. Group 2 will receive the study intervention as well as home health agency care as usual.

4) Home Health Agency Care as Usual Services (duration and timing of visits vary across people)

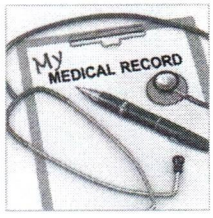
Both the intervention group and the care as usual group will receive services from the home health agency, which participation in the study will not affect. Home health services can consist of nursing, health aide, social work, and physical, occupational, and speech therapists, and the home health services people receive are based on their unique medical needs. Home health services can last for a short period of time, such as a week or two, or may last many months depending on a person's medical needs.

5) Two Follow-Up In-Home Assessments (3 and 6 months following the 1st in-home visit)

The two follow-up in-home visits will be used to measure any changes in your health and functioning over time. These visits will last approximately 90 minutes and study staff will ask about your physical and mental health and functioning, home environment, and use of medical and non-medical services. Study staff also will ask you (and, if applicable, Study Partner) about anything that might have happened during the time between visits, such as changes in your health, any injuries or illnesses, or any reactions to study procedures. If you are in the intervention group, you (and, if applicable, Study Partner) will be asked questions to obtain feedback on the intervention. If need-be, these visits

can be split over multiple days. Your assessment visits may be audio-recorded for quality control purposes. Access to these audio recordings will be password protected and audio recordings will be destroyed in accordance with local and federal guidelines.

6) Medical Chart Review (throughout course of study)



We will review your electronic medical records to examine your use of medical services in the 6 months following the initial in-home visit from the study team and your discharge from the hospital or post-acute care facility. From your medical chart, we will extract information about your medical conditions, medications, dates of services, types of services used, and communications with your providers. Of note, information about your participation in this study will be included in your electronic medical records. If you have concerns about this or to obtain more detail, you should discuss this with the study team.

7) Study Withdrawal Procedures

You may withdraw voluntarily from participation in the study at any time and for any reason.

PARTICIPANTS RANDOMLY ASSIGNED TO THE INTERVENTION GROUP ALSO RECEIVE THE FOLLOWING:

1) Occupational Therapy and Nurse Intervention Sessions (occur in the 3-4 months following the baseline assessment)

Intervention sessions will consist of up to 11 total home visits typically lasting 60-90 minutes by either an Occupational Therapist or Registered Nurse. Initially, these visits may occur within 1 week of one another, but gradually they will be spaced out later in the study and there may be several weeks between visits. At these visits, they will examine daily functioning, your medications, home hazards, and diseases and conditions that may impact functioning. With you, they will develop strategies and activities to help improve your functioning. They also may assist you with connecting with your outpatient medical providers or with non-medical providers. Your interventions visits may be audio-recorded for quality control purposes. Access to these audio recordings will be password protected and occur on encrypted devices. Audio recordings will *not* be transcribed and all recordings will be destroyed in accordance with local and federal guidelines.

Of note, the study occupational therapy services focus on client-prioritized functional goals while study nurse services target client-prioritized conditions and syndromes that may be impairing function (e.g., depression, pain, incontinence) as well as fall prevention and communication with your doctor. In contrast, the services delivered by home health agencies are generally directed by a doctor's order and tend to focus on a specific medical

problem identified by the doctor (e.g., wound care, diabetes management, and heart failure treatment).

2) Handyworker Services (occur within the first 1-2 months following the baseline assessment)

To provide the study Handyworker services, the study has a contract with Lifespan, a local aging services agency. Lifespan has a program called, Home-Safe-Home, that has been available to the community for more than 20 years and consists of a Lifespan-employed Handyworker who makes home modifications such as grab bars, tub grips, shower seats, handheld showers, commodes, railing modifications, and other simple yet helpful modifications that reduce the risk of falling. By agreeing to participate in this study, you will be enrolled in Lifespan's Home-Safe-Home program, which will work closely with the study staff to guide home modifications. More specifically, in coordination with the study's Occupational Therapist, Lifespan's Handyworker will identify possible home repairs and modifications, and may make repairs or modifications to your home over 1 or more visits that may last several hours. No repairs or modifications to your home, however, will be made without your permission. Any repairs or modifications the Handyworker makes will occur at no cost to you and will be paid for by the study.

If home repairs or modifications outside the Handyworker's scope of practice are indicated such as plumbing, carpentry, or electrical work, your compensation may include additional cash payments for home repair and modification services performed through Catholic Family Center's HomeWorks Program, which is a program that provides low-cost home maintenance/repair support to older adults. These additional cash payments of $100 would cover the expense of enrolling in HomeWorks for 3 months and obtaining an initial estimate of the cost of the modifications/repairs and/or the expense of minor home repairs and modifications that are recommended and agreed upon by our study interventionists and performed by Catholic Family Center's HomeWorks contractors. You would receive this compensation in cash prior to paying for these services. No repairs or modifications to your home, however, will be made without your permission.

The recommended home repairs, home modifications, and assistive devices will be determined by the study's Occupational Therapist, Registered Nurse, and Handyworker team. There is an upper limit of a $1,200 budget for home repairs, modifications, and assistive devices per participant, which includes the Handyworker's time as well as other items that may be identified by the study's Occupational Therapist and Registered Nurse. This $1,200 budget also includes a maximum of $500 to compensate for the HomeWorks home modifications and repairs.

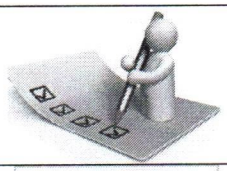
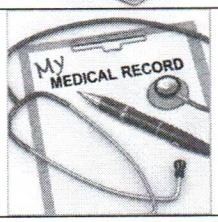
Similar to above, if larger home repairs or modifications outside of both Lifespan and Catholic Family Center's scope of practice are indicated (e.g., masonry, bathroom remodeling), your compensation may include additional cash payments for home repair and modification services performed by another person (e.g., a handy worker or separate contractor) or agency (e.g., bathroom modelers) within our allowed $1,200 total budget. This will allow you to complete indicated home repairs or modifications that are outside the scope of both Lifespan and Catholic Family Center capabilities. We will only reimburse you for agreed upon repairs and modifications that are consistent with the objectives of the CAPABLE Transitions intervention and we will plan to obtain an estimate of the work prior to agreeing to reimburse it. These additional cash payments would cover obtaining an initial estimate of the cost of the modifications/repairs as well as the expense of the home repairs and modifications that are recommended and agreed upon by our study interventionists and performed by these contractors or agencies. No repairs or modifications to your home will be made without your permission and you will be responsible for any costs that are associated with maintaining or replacing these items following the termination of the study. If there are home repairs and modifications and assistance devices identified by the study team that exceed this $1,200 upper limit, it will be up to you to help prioritize which repairs, modifications, and assistive devices you will want to receive through the study. However, once the repairs/modifications/devices have been provided, the study will manage and pay for any extra costs (over the initial $1,200 limit) related to replacement, repairs, or maintenance of these items during the study period. In unusual circumstances, we may also be able to allow for expenses exceeding $1,200 if necessary to improve home safety or function. In these instances, study staff may need to reassess our current expenses and will let you know if this is feasible.

If there are any issues with the Handyworker's home modifications and repairs, you are encouraged to follow-up with Lifespan at 585-244-8400 to resolve these issues. If there are any issues with the Catholic Family Center HomeWork's contractor home modifications and repairs, you are encouraged to follow-up with Catholic Family Center at 585-262-7050 or the contractor who performed the work to resolve these issues. Similarly, if there are any issues with other contractors or handyworkers, you are encouraged to follow-up with these contractors and handyworkers to resolve issues related to the services they performed. You can also call the study team at any time, for any reason (Dr. Simning: 585-474-9534 during normal hours, after hours, and during weekends and holidays). As you will be a participant in Lifespan's Home-Safe-Home program, Lifespan will be aware that you received this program's services. Additionally, Lifespan's Home-Safe-Home Program also will be aware that you are a study participant when you call.

Again, any costs that are associated with maintaining or replacing these items following the termination of the study will be your responsibility.

3) Intervention Withdrawal Procedures

If you are receiving the intervention, you may withdraw voluntarily from participation in the intervention, the study assessments, or both the intervention and study assessments at any time and for any reason. For instance, even if you are satisfied with the intervention, you may decide to stop the intervention because you no longer want to receive study intervention visits from the Occupational Therapist or Registered Nurse. You also may decide to stop the intervention if you not satisfied with the intervention and you no longer want to receive study intervention visits from the Occupational Therapist or Registered Nurse. Our interventionists can terminate the study intervention if your identified and agreed-upon goals are completed (or unable to be completed) and there are no further agreed-upon goals to work on. There are also several reasons that the study staff may discontinue the intervention. These include a long hospital stay (14+ days hospitalized in first month of intervention, 21+ days hospitalized after the first month), changing residences, or death. Even if study staff discontinue the intervention, you can continue to participate in the study assessments if you are willing and able to do so.

	Research Procedures	Potential Risks
	FOR ALL PARTICIPANTS	
	Questionnaires regarding your medical history, physical health and functioning, mental health and functioning, and social support	Frustration or stress during the interview
	Review of your medical records, possibly including Medicare and Medicaid claims and notation of study participation in your electronic medical chart	Chance your information may be seen by someone else (this is unlikely)
	FOR PARTICIPANTS ASSIGNED TO THE INTERVENTION GROUP	
	Home repairs and modifications to improve safety and functioning	Anxiety about having work performed on the house
	Exercises and activities designed to address physical functioning and decrease impairments	Fatigue during the activities
	Audio recordings of the interview and intervention visits	Chance your information may be heard by someone else (this is unlikely)

Will I receive any of my study results?

In general, we will not give you any individual results from your participation in the study. If we find something of urgent medical importance to you, we will inform you, although we expect that this will be a very rare occurrence.

What will happen to my research data?

Your information might be distributed or used for future research studies without additional informed consent. All identifiers will be removed before your information is used or distributed. You will be given the option at the end of this consent form to decide if you would like your information used for future research. Your privacy will be protected. Your data will be labeled with a coded research identifier to protect your identity. During the study, your name and other information which identifies you will be linked to your research data using the coded research identifier.

Your information might be distributed or used for future research studies without additional informed consent. All identifiers will be removed before your information is used or distributed. You will be given the option at the end of this consent form to decide if you would like your information used for future research.

What are the risks of participating in this study?

The risks of participation in this study are minimal. Some of the questions the interviewer will ask may be upsetting or make you feel uncomfortable. Additionally, you may become fatigued during the intervention sessions. You do not have to answer any questions you do not want to answer, and you can stop at any time. Additionally, because this study involves collecting personal identifiable information about you, there is a potential for invasion of privacy or breach in confidentiality. While we will make every effort to maintain confidentiality, it cannot be absolutely guaranteed and may be breached.

As a result of the information collected as part of this study, we may discover that you have a medical condition that you did not previously know about. If we discover something new as a result of this study, you will be told about it. The study staff or doctor will talk with you about the findings and your options. You may be told to follow up with your regular doctor or other specialists for future care. With your permission, we also would be willing to discuss our findings with your doctor or other health care providers.

If there is a medical emergency, study staff may contact emergency services. Additionally, the researchers are required to report information regarding potential child or older adult abuse or neglect reported by you or observed at your home during the research visit.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

The study team may be notified if you receive other health care services at URMC or its Affiliates (e.g., visit to the emergency room). In addition, the following individuals may know you participated in research and may see results of testing conducted for this study:

- Staff at the University of Rochester Medical Center and its Affiliates (e.g., Strong Memorial Hospital, Highland Hospital, URMC primary care, specialist physician offices) who have a reason to access your electronic health record.
- Health care providers who are involved in your care at a facility that is not part of the University of Rochester Medical Center and its Affiliates and who have reason to access your electronic health record.
- Individuals who request a copy of information from your health record for activities such as treatment or payment (e.g., medical insurance companies, worker's compensation).

Will my medical information be kept private/confidential?

The University of Rochester makes every effort to keep the information collected from you private. To protect your confidentiality and minimize this risk, we will assign you a study number instead of labeling the information we collect from you with your name (or medical record number). All of the information we collect will be stored in a secure manner and only study team members will have access your data. Sometimes, however, researchers need to share information that may identify you with people that work for the University, regulators or the study sponsor.

Our study records will be kept confidential as required by law. In order to conduct the study, the study doctor will use and share personal health information (PHI) and research records about you. Your PHI is information about you that could be used to find out who you are. This includes information already in your medical record, as well as information created or collected during the study. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. The results of this research study will be presented at meetings and in publications. These results are presented in summary form and will not include any information that could directly identify you.

What information may be used and given to others?

The study doctor will obtain your personal and medical information. For example:

- Research records
- Records about phone calls made as part of this research
- Records about your study visits and research participation

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- Past and present University of Rochester medical records, including records of external providers that are available via your electronic health records at University of Rochester Medical Center & Affiliates
- Past and present medical records from non-University of Rochester providers, which may be obtained ffrom the Centers for Medicare and Medicaid Services

Who may use and give out information about you?

- The study doctor and the study staff
- URMC and Affiliates
- UR Medicine Home Care
- Centers for Medicare and Medicaid Services

Your information may be given to:

- The Department of Health and Human Services
- The University of Rochester
- The National Institute on Aging
- The study's Data and Safety Monitoring Committee and study monitors who oversee the safety of this study
- Government regulatory agencies such as the Office for Human Research Protection

Why will this information be used and/or given to others?

- To do the research
- To study the results
- To see if the research was done correctly

If the results of this study are made public, your privacy will be protected and information that identifies you will not be used.

What if I decide not to give permission to use and give out my health information?

Then you will not be able to be in this research study.

May I review or copy my information?

Yes, but only after the research is over.

How long will this permission be valid?

This permission will last indefinitely.

May I cancel my permission to use and disclose information?

Yes. You may cancel your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. Upon receiving the written

notice, the study team will no longer use or disclose your health information and you will not be able to stay in this study. Information that has already been gathered may need to be used and given to others for the validity of the study.

May I withdraw from the study?

Yes. If you withdraw your permission to be in the study, no new health information identifying you will be gathered after that date. Information that already has been gathered may still be used and given to others.

Is my health information protected after it has been given to others?

No. There is a risk that your information will be given to others without your permission.

Certificate of Confidentiality

To help us further protect your privacy, the investigators have a Certificate of Confidentiality from the Department of Health and Human Services (DHHS).

With this Certificate, the investigators cannot be forced (for example, by court subpoena) to disclose or use research information, documents, or samples that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, other proceedings, or be used as evidence. Disclosure will be necessary, however, upon request of DHHS for audit or program evaluation purposes, or to other government agencies related to communicable diseases.

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your consent to receive research information, then the investigator may not use the Certificate to withhold that information. This means that you and your family must also actively protect your own privacy.

Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others. The Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities of child abuse and neglect or of serious harm to you or others.

What are the benefits of taking part in this study?

You might not benefit from being in this research study. If you are assigned to the group that will receive the intervention, the potential benefit to you might include Occupational Therapy, Registered Nurse, and Handyworker study visits that seek to address safety and functioning. These study visits will be different from the services you receive from the

home health agency as study visits will focus on your functioning and home safety and will be based on your treatment goals rather than focusing on management of specific medical problems.

What are the costs of taking part in this research study?

There will be no cost to you to participate in this study. Study-related home repairs and modifications will be paid for by the study.

Will I be paid for taking part in this research study?

If you do not meet study requirements, we will compensate you $10 for completing screening procedures. If you are eligible and decide to enroll in the study, you will be paid $50 per study interview. If you are enrolled in the intervention group, your compensation also may include additional cash payments to cover the expense of home repairs and modifications that are recommended and agreed upon by our study interventionists and performed by Catholic Family Center's HomeWorks contractors or other contractors and handyworkers. You will not be paid for study intervention visits by the Occupational Therapist, Registered Nurse, and Handyworker. You will be paid up to a total of $150 for your time and up to $500 to reimburse the cost of the HomeWorks Program including the home repairs and modifications performed by its contractors.

Payment received for participation in research is considered taxable income. If you receive payment for your participation in studies at the University of Rochester and its affiliates of $600.00 or more in any one calendar year, the University is required to report this information to the Internal Revenue Service (IRS) in a 1099 (Miscellaneous Income) form. You will be sent a copy of this form and a copy will be sent to the IRS. Depending on the amount you are paid, you may be asked to submit a W-9 form, which includes your Social Security Number.

If I have questions or concerns about this research, whom can I contact?

For more information concerning this research or if you feel that your participation has resulted in any research related injury, emotional or physical discomfort, please contact: **Adam Simning, MD, PhD** (study doctor) at 585-474-9534 during normal hours, after hours, and during weekends and holidays.

Please contact the University of Rochester Research Subjects Review Board at 265 Crittenden Blvd., CU 420628, Rochester, NY 14642, Telephone (585) 276-0005 or (877) 449-4441 for the following reasons:

- You wish to talk to someone other than the research staff about your rights as a research subject;

- To voice concerns about the research;
- To provide input concerning the research process;
- In the event the study staff could not be reached.

You have a research advocate available to you if you or your appointed research proxy have any questions about the study during your participation, and would like to speak to someone that is not a member of the study team. Your research advocate is:

Carol Podgorski, PhD
University of Rochester Medical Center
Box Psychiatry
300 Crittenden Boulevard
Rochester, NY 14642
Telephone: (585) 275-8307

Is participation in this research study voluntary? What if I want to withdraw?

Taking part in this study is voluntary. You are free not to take part or to withdraw at any time, for whatever reason. No matter what decision you make, there will be no penalty or loss of benefit to which you are entitled. In the event that you do withdraw from this study, the information you have already provided will be kept in a confidential manner.

Can I choose a research proxy?

You have the option to choose a substitute decision maker, referred to as a "research proxy," in the event you become unable to make decisions for yourself. If you lose the ability to make decisions and have chosen a research proxy, you may continue in the study if your research proxy agrees. You will fill out a separate form if you choose to identify a research proxy. You will be provided with a copy of the research proxy form.

Do you choose to identify a research proxy?

☐ **Yes** ☐ **No** _____ **Subject Initials**

After reading and discussing the information in this consent form you should understand:

- Why this study is being done;
- What will happen during the study;
- Any possible risks and benefits to you;
- Other options you may have instead of being in the study;
- How your personal information will be protected;
- What to do if you have problems or questions about this study.

STATEMENT OF CONSENT

By signing this page, I am confirming the following:

- I have read (or have had read to me) the contents of this consent form and have been encouraged to ask questions.
- All of my questions have been answered to my satisfaction.
- I agree to participate in this study, to follow study procedures, and to provide necessary information to study staff as requested.
- I allow study staff and the sponsor to use and disclose my personal health information as described in this document.

I have received (or will receive) a signed copy of this consent form to keep.

FUTURE USE OF INFORMATION

Please mark an X in the boxes below to indicate if you are willing to have your de-identified information be used in future research studies.

☐ **Yes**, I agree for my de-identified information to be used in future research studies.

☐ **No**, I do not want my de-identified information to be used in future research studies.

By signing below, I voluntarily agree to participate.

Subject Name (Print)	Signature	Date

OR

Subject Name (Print)

Legally Authorized Representative (LAR) Name (Printed)	Signature	Date

Legally Authorized Representative's Relationship to Subject (if Friend, complete Friend LAR Form)

Assent (to be obtained when consent is provided by a LAR): This research study has been explained to me and I agree to be in this study.

Subject's signature for assent	Date

Person Obtaining Consent and/or Assent:
I have read this form to the subject and LAR (if applicable) and/or the subject (and LAR) has read this form. I will provide the subject/LAR with a signed copy of this consent form. An explanation of the research was given and questions from the subject/LAR were solicited and answered to the subject's satisfaction. In my judgment, the subject (or LAR if applicable) has demonstrated comprehension of the information. I have given the subject/LAR adequate opportunity to read the consent before signing.

Name and Title (Print)	Signature	Date

STUDY PARTNER INFORMATION & CONSENT

In choosing to be the subject's study partner, you will have the option to help us perform important tasks in order for the study to be conducted in the best manner possible. These responsibilities include:

1) It is preferable for you to be a primary caregiver to the study subject.
2) We expect Study Partners to attend home visits and intervention sessions and be available via phone to answer questions from the research assistant. It is preferential, but not required, for your presence for all in home visits (3 visits in total that will last about 90 minutes each) and intervention sessions (up to 11 visits in total that will last between 60-90 minutes). If you are not available, it is helpful to be available via phone to answer questions from study staff.
3) You will be asked general questions about yourself (such as age and gender) as well as about your relationship to the study subject. You also will be asked questions about the study participant's daily functioning, wellbeing, and health services use as well as for feedback about the study intervention.

For any reason, if you become unable to carry out your responsibilities, please tell the study team immediately. You may be asked, if possible, to select a substitute who can take over your duties.

I have read all of the preceding information which describes both the subject's participation in the study and my involvement as the subject's Study Partner. The study has been explained to me in detail. All my question have been answered to my satisfaction.

By signing below, I voluntarily agree to participate as a Study Partner.

_____	_____	_____
Subject Name (Print)	Signature	Date

Person Obtaining Consent

I have read this form to the Study Partner and/or the Study Partner has read this form. I will provide the Study Partner with a signed copy of this consent form. An explanation of the research was given and questions from the subject were solicited and answered to the Study Partner's satisfaction. In my judgment, the Study Partner has demonstrated comprehension of the information. I have given the Study Partner adequate opportunity to read the consent before signing.

_____	_____	_____
Name and Title (Print)	Signature	Date