Consent Form

Official Title: Facilitating Optimal Routines in Aging

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CONSENT TO ACT AS A PARTICIPANT IN A RESEARCH STUDY

Title: Facilitating Optimal Routines in Aging (ForAging)

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KEY INFORMATION

The following is a short summary of this research study. Information that is much more detailed is included later in this form.

- This research study is testing to see if we can improve performance in daily activities using a regular intervention strategy with a rehabilitation specialist. Your participation in this research study is voluntary.
- You are being invited to participate as an older adult who is living in the community who has met the preliminary screening criteria. We will determine inclusion based on Mild Cognitive Impairment after the full screening process.
- During the study it is possible that the Mild Cognitive Impairment may progress. In this situation, the study team will ask if you would like to continue participating in the study. You will also be given the option to assign a proxy decision maker if there is progression.
- The study includes 5 assessment timepoints. The below table provides a summary of the assessments and the timepoints in which they will be provided.

Areas for Assessment	**Timepoints**				
	Screening	**Baseline**	**8 weeks**	**6 months**	**12 months**
Demographics (age, education)	X				
Medical History (co-morbidities)	X				X
Thinking (memory, executive function)	X			X	X
Feeling (mood, anxiety)	X	X	X	X	X
Daily Activities (instrumental activities of daily living, participation)		X	X	X	X

- After the tests, you will be randomized to one of two groups. You will receive either a strategy training intervention or Enhanced Usual Care.
- In the strategy training group, you will be asked to meet with a rehabilitation professional for approximately 10 sessions over 5 weeks for about 1 hour each session. The professional will ask you about everyday activities that are important to you and will have you practice these activities. In the enhanced usual care group, you will be asked to document and monitor all mental health treatment (e.g., medications that you may be taking) and psychotherapy (e.g., counseling or social services).
- There is no direct benefit to you for participation. You may become frustrated, upset, or tired during the assessment procedures, cognitive testing, and the intervention sessions. There is also the risk of a breach of confidentiality. These risks are explained in more detail later in the document.
- You may also be asked to undergo a brain imaging study called a PET scan. You will be asked to sign a separate consent form that details the PET scan procedure and its risks. If you have had a PET scan in another study in the past 18 months, we will review those

images. You will be asked to sign a release of information, in order to complete screening for metal or other MRI contraindications and to review for pertinent eligibility criteria.

Title: Facilitating Optimal Routines in Aging (ForAging)

This informed consent form is designed to help you understand the study as you talk with the study investigator(s). It should help you understand what will happen in the study, why the study is being done, and what the risks or benefits are if you decide to be in the study. Your participation in the study is voluntary. If you decide to participate, you must sign this informed consent form before any study procedures are performed. You are encouraged to discuss your decision with your friends and family. You can also discuss it with your doctors. If you have any questions after reading this informed consent form, you should ask your study investigator(s) for further explanation.

This research study is testing to see if we can improve performance in daily activities using a regular intervention strategy with a rehabilitation specialist. This is being done to identify ways to support older adults and maintain independence in daily activities for as long as possible. We are asking up to 150 older adults age 60 or older who are living in the community to participate.

If you decide to take part in this research study, medical professionals will be identified by you with an appropriate badge with a picture. We will ask you to complete some tests of your thinking and daily activities, and answer questions about your mood, medications, medical history, demographics, well-being, and your everyday activities. Topics that will be covered in these tests include the following: cognitively-challenging activities of daily living, coping with adversity, worry, self-efficacy, sleep quality, social support, physical activity, participation, as well as a variety of areas of thinking and memory. These tests will take approximately 4 hours at screening, 2 hours at baseline and 5 hours at 6 and 12 months including all of the technology set up. The visits will take place virtually in your home or in a location of your choosing at screening, baseline, 6 and 12 months. A shorter assessment will occur at 8 weeks. Any equipment such as laptops and cameras that are provided for use during the study remain the property of the University of Pittsburgh and must be returned following completion of your participation in the study.

If you have <u>not</u> participated in a PET (Positron Emission Tomography) scan under a parent study within the past 18 months, we will ask if you would be willing to complete a onetime PET scan with [C-11 PiB] prior to baseline. If you completed a PET scan greater than 18 months ago, we will review your scan to determine if another PET scan is necessary. Consent for the PiB PET scan will be obtained by a physician, using a separate consent form. We are reviewing PET scan images of the brain to better understand how a buildup of amyloid-beta plaques, a type of protein in the brain, is associated with maintenance of independence in daily activities

After the tests, you will be randomized to one of two groups. Randomization is like flipping a coin. Depending on the group to which you are randomized, you as an individual will receive a strategy training (ST) intervention or Enhanced Usual Care (EUC).

Strategy Training (ST) and Enhanced Usual Care: If you are randomized to ST, a rehabilitation professional will meet with you for approximately 10 sessions over 5 weeks for about 1 hour each session. The rehabilitation professional will ask you about everyday activities that are important to you, and will have you practice these activities. These sessions will be conducted virtually and recorded or videotaped in a location of your choosing. Your participation will end after 1 year. This group will also receive Enhanced Usual Care, which is described below.

Enhanced Usual Care (EUC): If you are randomized to EUC, we will ask you about, document and monitor all mental health treatment (e.g., medications that you may be taking) and psychotherapy (e.g. counseling or social services). We will notify appropriate physicians when required (e.g., participant meets criteria for depression). Furthermore, all participants assigned to EUC will receive the same assessments as other participants. The close monitoring will track potential changes in symptoms (e.g., depressive symptoms), and we'll refer them to services as appropriate. Participants randomized to EUC will not receive ST.

The possible risks and discomforts of this research study include the possibility that you may become frustrated, upset or tired during the assessment procedures, cognitive testing, and the intervention sessions. If this happens, you will be allowed to take a break or stop. You may indicate depression symptoms. If symptoms are noted, you will be referred for services, as appropriate. There is also the risk that information about you may be seen by someone who is not part of the research team. We will make every effort to ensure that your information is protected so only authorized persons can see your information. You may feel uncomfortable with the use of the video camera or have a breach of confidentiality with the videos being taken.

Risks of Cognitive Testing: The only risks identified at this time are possible fatigue and frustration that may occur when someone has trouble performing a task.

You may benefit by participating in the sessions with the rehabilitation professional **but there is no guarantee that this will help you**. We hope to learn whether the program is useful to people like you as an intervention.

If we learn about any new risks that may cause you to change your mind about continuing to participate, we will let you know.

Participating in this research study will not cost you any money. If you complete all the data collection portion of the study, you will receive $200. If you only complete part of the data collection portion of the study, you will be paid for the completed assessment sessions. You will be compensated $50 for the full screening process, $25 for the baseline, $25 for the 8 week follow up assessment, $50 for the 6-month assessment, and $50 for the 12-month assessments. You will receive payment on a reloadable debit card. Since you are being compensated for your participation in this study, your name, address, and social security number will be released to

the Accounting Office. If the total reimbursement for your participation in research is greater than $600 in a year, this will be reported to the Internal Revenue Service (IRS) as income.

If you are completing the PET/MRI scan and are unable to get to the imaging center on your own, the study will provide transportation via Uber Health at no cost to you if you live within 50 miles of UPMC Presbyterian Hospital. If you choose to utilize Uber Health for study transportation the study team will explain in depth how the process will work.

Commercialization

Your data or information obtained in this research study may contribute to a new discovery or treatment. In some instances, these discoveries or treatments may be of commercial value and may be sold, patented, or licensed by the investigators and the University of Pittsburgh for use in other research. You will not retain any property rights, nor will you share in any money that the investigators, the University of Pittsburgh, or outside agencies may receive.

Who will pay if I am injured because of taking part in this research study?

If you believe that the research procedures have resulted in an injury to you, immediately contact the Principal Investigator who is listed on the first page of this form. Emergency medical treatment for injuries solely and directly related to your participation in this research study will be provided to you by the hospitals of UPMC. Your insurance provider may be billed for the costs of this emergency treatment, but none of those costs will be charged directly to you. If your research-related injury requires medical care beyond this emergency treatment, you will be responsible for the costs of this follow-up care. Currently, there is no plan for any additional financial compensation. You waive no legal rights by signing this consent.

Will this research study involve the use or disclosure of my identifiable medical information?

Investigators will collect personal information including general information such as your date of birth, sex, racial or ethnic origins and information about your current and past health. We are requesting your authorization or permission to review information from your medical records by your other doctors (UPMC or externally) or review your medical charts to confirm eligibility. We will obtain the following information: History & Physicals (H&PS), surgical history, operative reports, laboratory reports, physician orders, progress notes, radiology reports, EKG reports, emergency department reports, consults, and discharge summaries. This identifiable medical record information will be made available to members of the research team for an indefinite amount of time. This information is needed to determine whether you meet the conditions for participation in this study.

This authorization is valid for an indefinite period of time. However, you can always withdraw your authorization to allow the research team to review your medical records by contacting the investigator listed on the first page and making the request in writing. If you do so, you will no longer be permitted to participate in this study. Any information obtained from you up to that

point will continue to be used by the research team. If you choose not to sign this authorization, you cannot participate in the study.

Any information about you obtained from this research will be kept as confidential (private) as possible. Research records, including the videotapes, will be stored in a locked file cabinet or in password-protected computer databases, and you will not be identified by name in any publication of the research results unless you sign a separate consent form giving your permission (release).

In addition to the investigators listed on the first page of this consent form and their research staff, authorized representatives of the University of Pittsburgh Office of Research Protections or the National Institutes on Aging may review your identifiable research information for monitoring the appropriate conduct of this research study.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

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 written consent to receive research information, then the researchers may not use the Certificate to withhold that information. Finally, you should also understand that this federal Certificate does not prevent investigators from taking steps, including reporting to appropriate authorities, to prevent serious harm to you or others. If the investigators learn that you or someone with whom you are involved is in serious danger or potential harm, they will need to inform, as required by Pennsylvania law, the appropriate agencies.

We will protect your privacy and the confidentiality of your records, as described in this document, but cannot guarantee the confidentiality of your research records, including information obtained from your medical records, once your personal information is disclosed to others outside UPMC or the University.

Will my de-identified information be shared?

Sharing of Data/Images:
Your images, and data, may be shared with other researchers and with federal repositories for future research. All study data and the images from the PET/MRI scan will be de-identified. Videos and images recorded during the assessments and strategy training will contain your face, but not have your name or data connected in any way. These videos and images may be shared with professionals in the field for educational purposes. **If you do not want the images and videos containing your face to be shared, please alert the study team when you sign this document.**

If you have previously given your consent to participate in one of the following research studies,

- Depression Agency-Based Collaborative (Depression ABC),
- Reducing Pain, Preventing Depression (RAPID)
- Return of Amyloid Imaging Results
- Individualize Everyday Activities (IDEA)
- LATTICE
- IGNITE Pittsburgh
- IDEA+NPR, PRO15090555
- PPG Project 1 and 2 Study
- Retaining Cognition While Avoiding Late-Life Depression (RECALL)
- MYHAT: Mon-Yough Health Aging Team

We are seeking your authorization to combine the information that you provided as part of that study with the information collected in the current study. This would include information that was obtained from your medical record for the previous study, listed above. In providing your authorization, you are agreeing that in addition to the investigators listed on this consent form, the investigators of the above named research study, in which you were previously enrolled, will have access to your research records. This data will be de-identified.

The investigators may continue to use and disclose, for the purposes described above, identifiable information related to your participation in this research study for a minimum of 7 years and for as long as it may take to complete the study. **Your participation in this research study is completely voluntary.** Whether or not you provide your consent for participation in this research study, or if you decide to withdraw your consent after you sign this consent form, will have no effect on your current or future relationship with the University of Pittsburgh. You waive no legal rights by signing this consent form. If you have a change in medical status due to illness or injury, we will evaluate whether it is necessary to discontinue your participation.

You may withdraw your consent for participation in this research study at any time. To formally withdraw your consent for participation in this research study, provide a written and dated notice of this decision to the Principal Investigator of this research study at the address listed on the first page of this form or call the number listed.

If you withdraw your consent, contact with the research group will be completed. The records will be maintained in accordance with the procedures already described. If a participant has a change in medical status due to illness or injury, we will evaluate whether it is necessary to discontinue your participation. You may be removed from the study if it is determined by the research team for any reason that you do not meet criteria for the study.

One of your health care providers may be involved as an investigator in this research study. As both your provider and a research investigator, s/he is interested both in your medical care and the conduct of this research study. Before agreeing to participate in this research study, or at any time during your study participation, you may discuss your care with another provider who is not associated with this research study. You are not under any obligation to participate in any research study offered by a member of your health care team.

A description of this clinical trial will be available on http://www.clinicaltrials.gov, as required by US 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.

VOLUNTARY CONSENT

The above information has been explained to me and all my current questions have been answered. I understand that I am encouraged to ask questions about any aspect of this research study during this study, and that such future questions will be answered by a qualified individual or by the investigator(s) listed on the first page of this consent document at the telephone number(s) given. I understand that I may always request that my questions, concerns, or complaints be addressed by a listed investigator. You may call Dr. Rodakowski at (412) 383-6615.

I understand that I may contact the Human Subjects Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668) to discuss problems, concerns, and questions; obtain information; offer input; or discuss situations that have occurred during my participation.

By signing this form, I agree to participate in this research study and provide my authorization to share my medical records. A copy of this consent form will be given to me.

_____	_____
Participant's Signature	Date
_____	_____
Printed Name of Participant	Time

CERTIFICATION of INFORMED CONSENT

I certify that I have explained the nature and purpose of this research study to the above-named individual(s), and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions as they arise. I further certify that no research component of this protocol was begun until after this consent form was signed.

_____	_____	
Printed Name of Person Obtaining Consent	Role in Research Study	
_____	_____	_____
Signature of Person Obtaining Consent	Date	Time