UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY

NAME OF STUDY AND RESEARCHERS

Title of Project: Unite Assisted Living

Principal Investigator: Lesli E. Skolarus, MD, MS, Department of Neurology, University of Michigan

GENERAL INFORMATION

We're doing a study to learn more about the role of the Hamilton-McFarlan health clinic in improving the health and wellbeing for older adults. To get information, we'd like 30 people to participate in 2 assessments – one now, and one follow-up visit (12-15 months). We expect each visit to take about 30-60 minutes. During each assessment, we will be taking your blood pressure and asking you some survey questions. We will also obtain your housing status transition information from the McFarlan Home Assisted Living Facility building records.

Participating in this study is completely voluntary. Even if you decide to participate now, you may change your mind and stop at any time. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. Answering this survey is voluntary. You don't have to answer it if you'd rather not. You can skip any questions that you don't want to answer, whatever the reason, and you don't have to tell us why. Choosing not to answer our survey won't affect the medical care you might receive at the University of Michigan Health System.

It's possible that some of the questions may make you feel uncomfortable. If a question makes you uncomfortable, you can just skip it and go to the next question.

To keep your information confidential, we will keep research records in a separate research file that does not include your name or other information that is likely to allow someone other than the researchers to link the information to you. Your research information will be stored in a locked cabinet and will not be made a part of your regular medical record.

Answering our survey won't benefit you directly. We hope what we learn will help other people in the future.

Your collected information may be shared with the National Institutes of Health.

With appropriate permissions, your collected information may also be shared with other researchers, here, around the world, and with companies.

Your identifiable private information may be stripped of identifiers and used for future research studies or distributed to another researcher for future research studies without additional informed consent.

Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them.

To thank you for taking part in our study, you will be provided $20 for completing the first assessment today. You will then receive $25 when you have completed the final outcome visit. If an LAR is needed, the LAR will also be provided $10 for completing first assessment and $15 for final outcome proxy survey. The University of Michigan accounting department may need your name, address, Social Security number, payment amount, and related information for tax reporting purposes.

This research will be covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the National Institutes of Health which is funding this project or 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 from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law such as child abuse and neglect, or harm to self or others.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document.

CONTACT INFORMATION

To find out more about the study, to ask a question or express a concern about the study, or to talk about any problems you may have as a study subject, you may contact one of the following:

Principal Investigator: Lesli E. Skolarus, MD, MS Mailing Address: 1500 E. Medical Center Drive, Ann Arbor, MI 48109 Telephone: 734-936-9075 Email: lerushe@med.umich.edu	Study Coordinator: Mackenzie Dinh, MS Mailing Address: 1500 E. Medical Center Drive, Ann Arbor, MI 48019 Telephone: 734-647-0865 Email: mdome@med.umich.edu

You may also express a concern about a study by contacting the Institutional Review Board:

University of Michigan Medical School Institutional Review Board (IRBMED)
2800 Plymouth Road
Building 520, Room 3214
Ann Arbor, MI 48109-2800
734-763-4768
E-mail: irbmed@umich.edu

If you are concerned about a possible violation of your privacy or concerned about a study, you may contact the University of Michigan Health System Compliance Help Line at 1-866-990-0111.

CONSENT RECORD

The following should be completed by the study member conducting the consent process if the subject and/or LAR agrees.

Research Subject:

Date: _____

Name (Print legal name): _____

Legal Representative (if applicable):

Name (Print legal name): _____

Date: _____

Relationship to Subject:

☐Parent ☐Spouse ☐Child ☐Sibling ☐Legal Guardian ☐Other: _____

Reason subject is unable to sign for self:

_____

_____

Principal Investigator or Designee

Legal Name: _____

Date(mm/dd/yy): _____