ORAL CONSENT SCRIPT

Hello. My name is **[name]**, and I am from **Albert Einstein College of Medicine** and would like to talk to you about a research study called the **5-Cog Battery to improve detection of cognitive impairment and dementia. We are hoping to learn whether our cognitive assessment is effective in improving dementia care in primary care settings.**

We ask you to join this study because you **are a 65 and older patient registered at the Montefiore Medical Group Clinics. You were selected from a patient list of adults age 65 and older who are registered at a Montefiore Medical Group Clinic and you have an appointment with your primary care doctor this week.** You do not have to participate, it is your choice. Your decision will not affect your rights or benefits or your access to care.

If you say yes, **we will randomly assign you to receive a 5-minute memory and mobility (the way to walk) assessment or a 5-minute health literacy (knowledge) and strength assessment.** The study interviewer will ask you questions about your education, occupation, medical history and mood. You will also receive tests that measure cognitive functions such as memory and attention. As part of this study we will review your medical records and put the information we collect in our research records.

The interview will be done on the day of your appointment with your primary care doctor. It will take approximately 5-minutes before you see your doctor and 60-minutes after you see your doctor (65 minutes total). You can choose to complete only the 5-minute evaluation before you see your doctor and not do the 60-minute evaluation after you see your doctor.

You can also choose to complete the 60-minute session after you see your doctor over the telephone or via video-conference within 1 week of your appointment. If you chose to complete the 60-minute session via video-conference you will NOT be recorded.

You may be uncomfortable answering some questions. You do not have to answer all the questions and you may stop at any time.

A risk of taking part in this study is the possibility of a loss of confidentiality or privacy. Loss of privacy means having your personal information shared with someone who is not on the study team and was not supposed to see or know about your information. The study team plans to protect your privacy.

You may or may not receive personal, direct benefit from taking part in this study. The possible benefits of taking part in this study include cognitive information that may reveal presence or absence of cognitive impairment. Your primary care physician will be informed of all clinical results that are relevant to patient care.

Some researchers may develop tests, treatments or products that are worth money. You will not receive payment of any kind for your information or for any tests, treatments, products or other things of value that may result from the research.

You will receive a total of $10 for completing the 5-minute assessment before seeing your doctor. If you choose to complete the 60-minute evaluation after seeing your doctor you will receive an additional $10.

We will do our best to keep your information safe by using a special code. We do not plan to share the information from this study with other researchers. Your study information will be kept as long as it is useful for this research.

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

Medical information collected during the research, such as test results, may be entered into your Montefiore electronic medical record and will be available to clinicians and other staff at Montefiore who provide care to you.

To maintain the integrity of this research study, you generally will not have access to your research-related personal health information. If it is necessary for your care, your research-related health information will be provided to you or your physician.

Information Banking (Future Use and Storage)
We will store information about you in a "bank", which is a library of information from many studies. This information cannot be linked to you. In the future, researchers can apply for permission to use the information for new studies to prevent, diagnose or treat disease. Your information may be kept for a long time, perhaps longer than 50 years. If you agree to the future use, some of your de-identified health information (not linked to you) may be placed into one or more scientific databases. These may include databases maintained by the federal government.

You can choose not to participate in the bank and still be part of the main study and this will not affect your treatment at this facility.

Please choose one of the following options:

_____ I consent to have my information used for future research studies.

_____ I do NOT consent to have my information used for future research studies. Information about me will be kept as long as required by regulations and institutional policy, but will not be used for future studies.

Confidentiality
The researchers and study staff follow federal and state laws to protect your privacy. Your information and research records will be kept confidential. Your study information will be kept as long as they are useful for the research described in this form.

The only people who can see your research records are:

- Researchers and other individuals who work with the researchers
- Organizations and institutions involved in this research, including those that fund the research, if applicable

- Groups that review research such as central reviewers, Institutional Review Boards, the Office for Human Research Protections, the US Food and Drug Administration, data coordinating centers, and domestic and foreign agencies that regulate research.

In addition, the researchers wish to review information pertaining to your substance abuse treatment records/psychiatric treatment records. By law, you must specifically authorize access to these records:

☐ Yes, I authorize the use and disclosure of my information pertaining to HIV testing and HIV status.

Initial: _____ Date: _____

☐ Yes, I authorize the use and disclosure of my information pertaining to substance abuse treatment.

Initial: _____ Date: _____

☐ Yes, I authorize the use and disclosure of my information pertaining to psychiatric treatment.

Initial: _____ Date: _____

These people who receive your health information, may not be required by privacy laws to protect it and may share your information with others without your permission, if permitted by laws governing them. All of these groups have been asked to keep your information confidential.

As a way to protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health, which is funding this study. If information from this study were requested or subpoenaed by government agencies or the courts, we would use the Certificate to attempt to legally refuse to provide that information. These requests are rare – in only a few cases did researchers have to use the Certificate, and it was honored most of the time, but not every time. There are several kinds of situations to which the Certificate does not apply. For example, we are still required to report child abuse and some diseases, and we must make data available to the government for review or evaluation of our research. The Certificate does not prevent you or a member of your family from voluntarily sharing information. Similarly, 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.

If you change your mind and don't want your information used for the study anymore, you can call the person in charge of this study. His name is **Dr. Joe Verghese** and he can be reached at **718-430-3808**. Or, you can call Einstein Institutional Review Board at 718-430-2253. They will let you know how to write to the Principal Investigator to let her/him you want to stop participating. Just remember, if we have already used your information for the study, the use of that information cannot be cancelled.

Do you have any questions? You may ask me now or contact **Dr. Joe Verghese** about your questions or problems with this study.

CONSENT TO PARTICIPATE

Printed name of participant		Date
Printed name of the person conducting the consent process	Signature	Date