

Consent Form

The purpose of this form is to provide you with important information about taking part in a research study.

The person in charge of this study is Ioannis Paschalidis, Professor of Electrical & Computer, Systems, and Biomedical Engineering at Boston University. Please find contact information for Professor Paschalidis at the end of this form.

The purpose of this research study is to collect a diverse sample of cognitive test data that will enable the development of better and more reliable Artificial Intelligence (AI) models that assess a person's cognitive status. Participants who take part in this research study will be in this research study for about 15 minutes and will be asked to complete a Clock Drawing Test, the Trail Test, and provide answers to demographic questions.

The AI models tested in this study will characterize the results of the online tests as either normal or consistent with possible cognitive decline that may be associated with Alzheimer's disease and other forms of dementia. The result of this research assessment is **not** a medical diagnosis.

Taking part in this research study is up to you. You may choose not to participate.

Online Tasks

1. You will be asked to provide:
 - a. A drawing of an analogue clock showing ten past eleven. We ask that you scan it or take a picture with a device (e.g., smartphone) and upload it to the website.
 - b. An image of the Trail A test. This test consists of 25 circles distributed over a sheet of paper. The circles are numbered 1 – 25, and you will be asked to draw lines to connect the numbers in ascending order. You should complete the test using a stopwatch, scan it or take a picture with a device (e.g., smartphone), and upload the image to the website along with the time it took to complete the test.
 - c. Answers to a questionnaire that asks for your year of birth, gender, race, height, weight, education level, limited family health history (memory or any neurodegenerative diagnosis), cerebrovascular disease history (Stroke, Transient Ischemic Attack, Parkinson's disease, Seizures, Multiple Sclerosis, Brain tumor, and Cerebral Palsy), partial medical history (cirrhosis of the liver, cancer, heart disease, COPD, kidney disease, and diabetes), and lifestyle questions (physical activity, alcohol consumption, smoking, trouble in recalling things, and trouble in using appliances).

Once the online study tasks are completed, the results of the assessment will be shared with you. There is the risk of receiving an inaccurate assessment which may cause stress. You may also feel emotional distress receiving a result that indicates possible cognitive decline. There is also a risk of receiving an inaccurate assessment. Participants are reminded that the result of this assessment is **not** a medical diagnosis. Participants should follow up with a medical provider should they wish to receive a medical assessment.

As part of this research, you will **not** be asked to provide any identifying information. The results of this research study may be published. We will not include identifiable information on data that are used for these research purposes.

We do not anticipate loss of confidentiality risks because **subject identifiers will not be collected**.

Study personnel will have no way of tracing a submission to a person. Data will be maintained in encrypted storage and will only be available to study personnel for analysis and development of improved AI models. A list of the people or groups who may review the study records for purposes such as quality control or safety may include: the Institutional Review Board at Boston University, the sponsor or funding agency for the study, federal and state agencies that oversee or review research, and Central University Offices.

There are no direct benefits to you. With your participation, this study may help improve automated models for assessing cognitive decline, which can benefit many who do not have easy access to appropriate medical care. You will receive the result of a model assessing your cognitive status. This model has been validated and tested using data from participants in the [Framingham Heart Study](#). In that study, the model has been shown to be fairly accurate and could prompt you with cognitive decline to seek medical attention.

You will not be paid for your participation and there is no cost to you.

The lead investigator of the present study is

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He is available to answer questions regarding this study.

If you have additional questions please contact: Boston University Charles River Campus Institutional Review Board (IRB) at 617-358-6115. The [IRB Office webpage](#) has information where you can learn more about being a participant in research, and you can also complete a Participant Feedback Survey.

Statement of Consent

By clicking on the corresponding box on the study's website (health-ai.bu.edu) I acknowledge that I have read the information in this consent form including risks and possible benefits. I have been given the chance to ask questions by either contacting the lead investigator or the Boston University IRB. My questions (if any) have been answered to my satisfaction, and I agree to participate in the study.