Consent Form

1. This is a research study entitled "Assessment of Dementia from Drawing Tests using AI Methods." The objective is to collect diverse data, which will enable the development of better and more reliable Artificial Intelligence (AI) models that assess the subject's cognitive status and determine whether it can be characterized as normal or whether it is consistent with cognitive decline that may be associated with Alzheimer's disease and other forms of dementia.

2. Participants are asked to provide:
    a. Image of the clock drawing test: draw an analogue clock showing ten past eleven, scan it or take a picture with a device (e.g., smartphone), and upload it to the site.
    b. 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 the participant is asked to draw lines to connect the numbers in ascending order. The participant 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 site along with the time it took to complete the test.
    c. Answers to a questionnaire including: 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).
    d. If a participant submits, at the very minimum, a clock drawing test and year of birth, the AI model published at:
    "**An Artificial Intelligence-Assisted Method for Dementia Detection Using Images from the Clock Drawing Test",** Amini, Samad; Zhang, Lifu; Hao, Boran; Gupta, Aman; Song, Mengting; Karjadi, Cody; Lin, Honghuang; Kolachalama, Vijaya B.; Au, Rhoda; and Paschalidis, Ioannis Ch., Journal of Alzheimer's Disease, vol. 83, no. 2, pp. 581-589, 2021,
    will be used to provide a normal vs. cognitive decline assessment.

3. Eligible participants include adults who understand English. While there is no age restriction, the study would be more useful to those above the age of 50 who are at a higher risk for Alzheimer's disease and dementia. Participation is voluntary.

4. We estimate that it will take on the order of 15 minutes to provide all the information requested.

5. Participants are **not** asked to provide any identifying information. 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.

Study Title: Assessment of Dementia from Drawing Tests using AI Methods
IRB Protocol Number: 6341E
Consent Form Valid Date: January 24, 2022
Study Expiration Date: January 23, 2023

6. Use of Your Study Information/Biospecimens: Data (images and responses to the questionnaire) collected from you during this study may be used for future research studies or shared with other researchers for future research. **However, as stated earlier, none of these data contain identifiable information that could be linked to you.** Future research leveraging the collected data may consider improving existing AI models to detect dementia or developing new models, that is, the use of the data will be limited to disease under study and related disorders. If the researcher distributes your samples and/or information to other researchers or institutions, your samples and/or information will be labeled with a research code without identifiers so that you cannot be identified. No additional consent will be requested for the future use of your samples or information. If you have questions about storing samples or would like to request that samples be removed from storage, please let us know. It is not always possible to remove samples from storage or to retrieve samples from which identifiers have been removed and/or that have already been sent to other investigators.

7. We do not anticipate loss of confidentiality risks because **subject identifiers will not be collected**. There is a risk of the cognitive assessment model returning an inaccurate assessment. In this case, the participants may be alarmed and seek medical help. We emphasize that the assessment of the model does not constitute a medical diagnosis and should not be taken as such.

8. There are no direct benefits to participants. With their participation they help improve automated models for assessing cognitive decline, which can benefit many who do not have easy access to appropriate medical care. Participants will receive the result of a model assessing their cognitive status. This model has been validated and tested using data from participants in the Framingham Heart Study. It that study, the model has been shown to be fairly accurate and could prompt a participant with cognitive decline to seek medical attention.

9. The lead investigator of the present study is

   Ioannis Paschalidis,
   Professor of Electrical & Computer, Systems, and Biomedical Engineering,
   Founding Professor of Computing & Data Sciences,
   Director, Center for Information & Systems Engineering,
   Boston University,
   15 Saint Mary's St.,
   Boston, MA 02215,
   Tel: 617-353-0434
   yannisp@bu.edu
   sites.bu.edu/paschalidis

   He is available to answer questions regarding this study.

10. 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.

11. A list of the people or groups who may review the study records for purposes such as quality control or safety (e.g. the Institutional Review Board at Boston University, the sponsor or funding agency for the study, federal and state agencies that oversee or review research, Central University Offices)

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.