May 10, 2019

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Computer Science & Engineering
The University of Texas at Arlington

EXPEDITED APPROVAL OF FEDERALLY FUNDED HUMAN SUBJECT RESEARCH

IRB No.: 2019-0253
Study Title: *CogBeacon: Towards detecting cognitive fatigue*
Approval Date: May 4, 2019
Federal Funding Source: NSF
Mentis Bluesheet Number: #2019-350

Continuing Review Required? No
Anniversary Date is on: May 4, 2020

The University of Texas Arlington Institutional Review Board (UTA IRB) has made the determination that this research protocol involving human subjects is eligible for expedited review in accordance with the Revised Common Rule at Title 45 CFR 46.110(a)-(b)(1), 63 FR 60364 and 63 FR 60353, categories 4, 6, and 7. The IRB Chairperson (or designee) approved this protocol effective **May 4, 2019.**

The IRB has determined that annual continuing review **is not** required for this protocol per the federal regulations at Title 45 CFR 46.109(f).

As Principal Investigator of this IRB approved study, the following items are your responsibility throughout the life of the study:

UNANTICIPATED ADVERSE EVENTS:
Please be advised that as the Principal Investigator, you are required to report local adverse (unanticipated) events to The UT Arlington Office of Research Administration; Regulatory Services within 24 hours of the occurrence or upon acknowledgement of the occurrence.

INFORMED CONSENT DOCUMENT:
The IRB approved version of the informed consent document (ICD) must be used when prospectively enrolling volunteer participants into the study. Unless otherwise determined by the IRB, all signed consent forms must be securely maintained on the UT Arlington campus for the duration of the study plus a minimum of three years after the completion of all study procedures (including data analysis). The complete study record is subject to inspection and/or audit during this time period by entities including but not limited to the UT Arlington IRB, Regulatory Services staff, OHRP, FDA, and by study sponsors.

MODIFICATIONS TO THE APPROVED PROTOCOL:
All proposed changes must be submitted via the electronic submission system and **approved by the IRB prior to implementation**, except when necessary to eliminate apparent immediate hazards to the subject. Modifications include but are not limited to: Changes in protocol personnel, changes in proposed study procedures, and/or updates to data collection instruments. Failure to obtain prior approval for modifications is considered an issue of non-compliance and will be subject to review and deliberation by the IRB which could result in the suspension/termination of the protocol.

ANNUAL CHECK-IN:
Although this study is not required to submit annual continuing reviews to maintain IRB approval, you will receive an email around the anniversary date of your initial approval date to request an annual check in. Please notify Regulatory Services once your study is completed to begin the required 3-year research record retention period.

HUMAN SUBJECTS TRAINING AND CONFLICTS OF INTEREST DISCLOSURES:
All investigators and personnel identified in the protocol must have documented Human Subjects Protection (HSP) training on file and must have filed a current Conflict of Interest Disclosure (COI) with The UT Arlington Office of Research Administration; Regulatory Services. HSP completion certificates are valid for 3 years from completion date.

COLLABORATION:
If applicable, approval by the appropriate authority at a collaborating facility is required prior to subject enrollment. If the collaborating facility is *engaged in the research*, an OHRP approved Federalwide Assurance (FWA) may be required for the facility (prior to their participation in research-related activities). To determine whether the collaborating facility is engaged in research, go to: https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-engagement-of-institutions/index.html

CONTACT FOR QUESTIONS:
The UT Arlington Office of Research Administration; Regulatory Services appreciates your continuing commitment to the protection of human research subjects. Should you have questions or require further assistance, please contact Regulatory Services at regulatoryservices@uta.edu or 817-272-3723.

Sincerely,

Dr. Deborah Behan

Deborah Behan, PhD
Associate Clinical Professor, Nursing
UT Arlington IRB Chair