SUMMARY STATEMENT

PROGRAM CONTACT: *(Privileged Communication)*
[redacted]
[redacted]

Release Date: 02/18/2026
Revised Date:

Application Number: 1R44AG129874-01

Principal Investigators (Listed Alphabetically):

[redacted] (Contact)
[redacted]
[redacted]
[redacted]

(List continued at end of document)

Applicant Organization: [redacted]

Review Group: ZRG1 BSPH-J (12)
Center for Scientific Review Special Emphasis Panel
Small Business: Biomedical Sciences and Public Health

Meeting Date: 01/15/2026
Council: JAN 2026
Requested Start: 04/01/2026

Opportunity Number: PA-24-246
PCC: NNS -SO

Project Title: Development and Validation of a Rapid Point-of-Care Cognitive Screening Platform for Early Detection of Age-Related Cognitive Decline

SRG Action: Impact Score:23
Next Steps: Visit https://grants.nih.gov/grants/next_steps.htm
Human Subjects: 30-Human subjects involved - Loss to follow-up concerns
Animal Subjects: 10-No live vertebrate animals involved for competing appl.
Participant Sex:
Participant Race and Ethnicity:
Participant Age:
1A-Both sexes, scientifically acceptable
1A-Minority and non-minority, scientifically acceptable
3A-Only Older Adults, scientifically acceptable

Project Year	Direct Costs Requested	Estimated Total Cost
1	245,310	303,784
2	812,445	1,007,432
3	758,920	940,060
TOTAL	**1,816,675**	**2,251,276**

ADMINISTRATIVE BUDGET NOTE: The budget shown is the requested budget and has not been adjusted to reflect any recommendations made by reviewers. If an award is planned, the costs will be calculated by Institute grants management staff based on the recommendations outlined below in the COMMITTEE BUDGET RECOMMENDATIONS section.

1R44AG129874-01 [redacted]

RESUME AND SUMMARY OF DISCUSSION: The committee was uniformly enthusiastic about this application. The technology addresses a well-recognized gap in cognitive health monitoring, and the preliminary data are compelling. The study design is rigorous with appropriate phased milestones and go/no-go criteria. Minor concerns were raised about the recruitment timeline and the need for more detailed attention to participants with varying levels of technological literacy, but these did not significantly dampen enthusiasm.

- The potential for earlier detection of age-related cognitive decline through accessible, repeated screening was considered highly innovative and clinically significant for this Fast Track application.
- The approach was considered rigorous and well-designed, progressing from analytical validation to clinical evaluation of diagnostic accuracy.
- The commercialization plan was assessed as strong with a credible path to market.
- Minor concerns about recruitment timelines were noted but did not significantly affect overall enthusiasm.

DESCRIPTION (provided by applicant): This Fast-Track SBIR project proposes to complete clinical validation and achieve FDA clearance for a tablet-based cognitive screening system enabling daily, self-administered monitoring of cognitive function in adults aged 60 and older. The project addresses the critical detection gap between standard clinical cognitive assessments administered once annually and the gradual onset of age-related cognitive decline that progresses over months. Primary objectives are to: 1) demonstrate through randomized controlled trials that the platform detects cognitive changes earlier than standard clinical assessments; 2) achieve FDA De Novo clearance for this first-in-class diagnostic platform; and 3) establish commercial partnerships for deployment across primary care networks. The innovation integrates validated gamified cognitive tasks calibrated against established neuropsychological measures, adaptive machine learning algorithms that detect subtle longitudinal changes, and a secure cloud-based platform enabling remote physician monitoring. Initial pilot testing with 40 adults demonstrated detection of clinically meaningful cognitive changes an average of 4.2 months earlier than standard annual screening. Phase I (months 1-7) will enroll 80 adults across three clinical sites to validate detection sensitivity. Phase II (months 6-30) expands to 280 participants to evaluate time-to-detection of clinically meaningful cognitive change.

PUBLIC HEALTH RELEVANCE: The proposed platform may enable earlier detection of age-related cognitive decline for the millions of older Americans who currently receive only annual cognitive screening. This tablet-based diagnostic tool provides daily self-administered cognitive monitoring with machine learning-based longitudinal analysis. The proposed clinical trials will demonstrate earlier detection and improved clinical decision-making, potentially reducing the substantial healthcare costs associated with late-stage diagnosis. By transforming cognitive screening from periodic clinical snapshots to continuous monitoring, this innovation may enable earlier therapeutic intervention, reduce caregiver burden, and establish a new standard of care.

CRITIQUE 1

Significance: 2

Investigator(s): 1

Innovation: 2

Approach: 3

Environment: 2

Overall Impact: This is a strong application proposing validation of a tablet-based cognitive screening platform. The technology is innovative and addresses a genuine clinical need. The team is exceptionally qualified with strong preliminary data. The approach is well-designed with appropriate milestones. Minor concerns about technological literacy stratification and recruitment do not significantly diminish enthusiasm.

1. Significance:

Strengths

- Early detection of cognitive decline is a pressing unmet need. Current tools require trained administrators and are insensitive to subtle early changes.
- A self-administered, repeatable tool could enable longitudinal monitoring that single-time-point assessments cannot provide.
- The potential to detect changes months earlier than current standard of care is clinically meaningful.

Weaknesses

- Simpler alternatives exist, though each has recognized limitations in frequency and sensitivity.

2. Investigator(s):

Strengths

- The team brings together exceptional expertise in clinical neurology, digital health, machine learning, and clinical trials.
- Multiple team members have prior experience developing and validating digital health diagnostics.
- The advisory board includes nationally recognized experts in geriatric cognitive assessment.

3. Innovation:

Strengths

- The platform represents a genuinely novel approach to cognitive health monitoring.

- The combination of gamified assessment, adaptive ML algorithms, and longitudinal analysis is first-in-class.
- Preliminary data showing 4.2-month earlier detection is compelling and supports the innovation claim.
- Patent protection strengthens the innovation profile.

Weaknesses

- The extent to which the platform outperforms simpler digital alternatives will need to be confirmed in the proposed trials.

4. Approach:

Strengths

- The approach is rigorous and appropriately staged from validation to clinical evaluation.
- The multicenter design strengthens generalizability.
- Sample size calculations and statistical plans are clearly articulated with appropriate power.
- Go/no-go criteria are well-specified and appropriate.
- Prior pilot data and usability studies support readiness for clinical testing.

Weaknesses

- Stratification should include baseline cognitive function and technological literacy, not just age.
- The recruitment timeline of 280 participants in 18-21 months is ambitious; contingency plans for slower enrollment should be described.

5. Environment:

Strengths

- Clinical trial sites are high-quality academic medical centers with established geriatric research populations.
- Data management and regulatory infrastructure are well-developed.
- The environment is well-matched to the clinical demands of the project.

Study Timeline:

- Well defined and described. Minor concerns about ambitious recruitment targets.

Commercialization Plan (Phase II and Fast-Track Only):

- The commercialization plan is detailed and credible with experienced investors and advisors.
- Pricing, manufacturing, and market assumptions are plausible.

Protections for Human Subjects:

Acceptable Risks and/or Adequate Protections

Budget and Period of Support:

Recommend as Requested

CRITIQUE 2

Significance: 1

Investigator(s): 2

Innovation: 2

Approach: 2

Environment: 2

Overall Impact: This is an excellent application with high potential for clinical impact. The technology is genuinely innovative, the preliminary data are strong, and the study design is rigorous. The team is well-qualified and the commercialization plan is credible. This project could meaningfully advance cognitive health monitoring.

1. Significance:

Strengths

- The application compellingly addresses a critical gap in cognitive health monitoring.
- Earlier detection could enable therapeutic interventions that delay progression and reduce costs.

2. Investigator(s):

Strengths

- Team brings together stellar expertise in digital health and clinical neurology.
- Track record of developing and launching diagnostic platforms is impressive.

Weaknesses

- The company is still early-stage and will need to grow organizational capacity.

3. Innovation:

Strengths

- Pilot data showing 4.2-month earlier detection are compelling.
- The platform is first-in-class for continuous self-administered cognitive monitoring.

4. Approach:

Strengths

- Rigorous randomized design with appropriate staging from validation to efficacy.
- Statistical plans and protocols are clearly described.

Weaknesses

- Recruitment timeline may need adjustment depending on actual enrollment rates.

5. Environment:

Strengths

- Outstanding clinical trial sites with strong geriatric research infrastructure.

Commercialization Plan (Phase II and Fast-Track Only):

- Well-described market opportunity and pathway to market. No major issues.

Budget and Period of Support:

Recommend as Requested

CRITIQUE 3

Significance: 2

Investigator(s): 2

Innovation: 3

Approach: 3

Environment: 1

Overall Impact: This is a well-designed application addressing a clinically important problem. The proposal is supported by strong evidence, relevant clinical rationale, rigorous trial design, and a credible commercialization pathway. The technology will require demonstration of adoption at scale, but the proposed work is well-positioned to generate meaningful evidence. Reviewers viewed the overall impact as high.

1. Significance:

Strengths

- Well-documented clinical problem with clear unmet need for continuous monitoring.
- Commercial and clinical relevance is high across primary care and specialty settings.

Weaknesses

- Simpler alternatives partially address related needs, though with recognized limitations.

2. Investigator(s):

Strengths

- Strong complementary expertise across clinical neurology, digital health, and research methodology.
- Combination of clinical and entrepreneurial expertise is appropriate for this stage.

Weaknesses

- Key personnel are working part-time; organizational capacity will need to grow.

3. Innovation:

Strengths

- Novel solution to a long-standing problem in cognitive health monitoring.
- First to combine clinical-grade accuracy with self-administered daily monitoring.
- Patent protection strengthens innovation profile.

Weaknesses

- Advantage over simpler alternatives will need empirical demonstration.

4. Approach:

Strengths

- Rigorous and appropriately staged design.
- Multicenter design strengthens generalizability.

- Sample size, statistics, and protocols clearly articulated.
- Milestones and go/no-go criteria well specified.

Weaknesses

- Complex and resource-intensive, though appropriate for clinical aims.
- Downstream adoption and scalability remain to be demonstrated.

5. Environment:

Strengths

- Multiple high-quality academic medical centers with strong geriatric research infrastructure.
- Data management, monitoring, and regulatory support well-developed.

Commercialization Plan (Phase II and Fast-Track Only):

- Detailed and credible. Pricing and market assumptions plausible.
- IP protection through patents and trade secrets well-addressed.

Budget and Period of Support:

Recommend as Requested

THE FOLLOWING SECTIONS WERE PREPARED BY THE SCIENTIFIC REVIEW OFFICER TO SUMMARIZE THE OUTCOME OF DISCUSSIONS OF THE REVIEW COMMITTEE, OR REVIEWERS' WRITTEN CRITIQUES, ON THE FOLLOWING ISSUES:

PROTECTION OF HUMAN SUBJECTS: ACCEPTABLE.

PARTICIPANT SEX CODE: ACCEPTABLE

PARTICIPANT RACE AND ETHNICITY CODE: ACCEPTABLE

PARTICIPANT AGE CODE: ACCEPTABLE

COMMITTEE BUDGET RECOMMENDATIONS: The budget was recommended as requested.

Footnotes for 1R44AG129874-01; PI Name: [redacted]
NIH has modified its policy regarding the receipt of resubmissions (amended applications). See Guide Notice NOT-OD-18-197 at https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-197.html. The impact/priority score is calculated after discussion of an application by averaging the overall scores (1-9) given by all voting reviewers on the committee and multiplying by 10. The criterion scores are submitted prior to the meeting by the individual reviewers assigned to an application, and are not discussed specifically at the review meeting or calculated into the overall impact score. Some applications also receive a percentile ranking. For details on the review process, see http://grants.nih.gov/grants/peer_review_process.htm#scoring.

Principal Investigators (continued from first page):

[redacted]

[redacted]

MEETING ROSTER

Center for Scientific Review Special Emphasis Panel

CENTER FOR SCIENTIFIC REVIEW

Small Business: Biomedical Sciences and Public Health

ZRG1 BSPH-J (12)

01/15/2026

Notice of NIH Policy to All Applicants: Meeting rosters are provided for information purposes only. Applicant investigators and institutional officials must not communicate directly with study section members about an application before or after the review. Failure to observe this policy will create a serious breach of integrity in the peer review process, and may lead to actions outlined in NOT-OD-22-044 at https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-044.html, including removal of the application from immediate review.

CHAIRPERSON(S)

[redacted]
PROFESSOR
DEPARTMENT OF NEUROLOGY
MASSACHUSETTS GENERAL HOSPITAL
HARVARD MEDICAL SCHOOL
BOSTON, MA 02114

MEMBERS

[redacted]
ASSOCIATE PROFESSOR
DEPARTMENT OF BIOMEDICAL ENGINEERING
JOHNS HOPKINS UNIVERSITY
BALTIMORE, MD 21205

[redacted]
PROFESSOR
DEPARTMENT OF PSYCHIATRY AND BEHAVIORAL SCIENCES
STANFORD UNIVERSITY
STANFORD, CA 94305

[redacted]
ASSISTANT PROFESSOR
DEPARTMENT OF COMPUTER SCIENCE
CARNEGIE MELLON UNIVERSITY
PITTSBURGH, PA 15213

[redacted]
ASSOCIATE PROFESSOR
DEPARTMENT OF GERIATRIC MEDICINE
UNIVERSITY OF MICHIGAN
ANN ARBOR, MI 48109

[redacted]
PROFESSOR
DEPARTMENT OF EPIDEMIOLOGY
COLUMBIA UNIVERSITY
NEW YORK, NY 10032

[redacted]

ASSISTANT PROFESSOR
DEPARTMENT OF NEUROSCIENCE
UNIVERSITY OF PENNSYLVANIA
PHILADELPHIA, PA 19104

[redacted]
ASSOCIATE PROFESSOR
DEPARTMENT OF HEALTH INFORMATICS
UNIVERSITY OF WASHINGTON
SEATTLE, WA 98195

[redacted]
PROFESSOR
DEPARTMENT OF PSYCHOLOGY
UNIVERSITY OF CALIFORNIA, SAN DIEGO
LA JOLLA, CA 92093

[redacted]
ASSOCIATE PROFESSOR
SCHOOL OF PUBLIC HEALTH
EMORY UNIVERSITY
ATLANTA, GA 30322

[redacted]
ASSISTANT PROFESSOR
DEPARTMENT OF BIOSTATISTICS
UNIVERSITY OF NORTH CAROLINA
CHAPEL HILL, NC 27599

[redacted]
PROFESSOR
DEPARTMENT OF REHABILITATION MEDICINE
UNIVERSITY OF MINNESOTA
MINNEAPOLIS, MN 55455

[redacted]
ASSOCIATE PROFESSOR
DEPARTMENT OF INTERNAL MEDICINE
YALE UNIVERSITY
NEW HAVEN, CT 06510

SCIENTIFIC REVIEW OFFICER

[redacted]
SCIENTIFIC REVIEW OFFICER
CENTER FOR SCIENTIFIC REVIEW
NATIONAL INSTITUTES OF HEALTH
BETHESDA, MD 20892

EXTRAMURAL SUPPORT ASSISTANT

[redacted]
EXTRAMURAL SUPPORT ASSISTANT
THE CENTER FOR SCIENTIFIC REVIEW
THE NATIONAL INSTITUTES OF HEALTH
BETHESDA, MD 20892

Consultants are required to absent themselves from the room during the review of any application if their presence would constitute or appear to constitute a conflict of interest.