

Request for Information (RFI): Clinical study of non-invasive assessment technologies designed for the detection and management of mild traumatic brain injury (mTBI)

Key Dates

Release Date: 24 Apr 2020 (anticipated)

Response Date: 27 Jul 2020

Issued by

The Uniformed Services University of the Health Sciences, Bethesda, Maryland.

This RFI is issued solely for information and planning purposes and does not constitute a solicitation or issuance thereof.

Background

The Uniformed Services University of the Health Sciences (USU) is the leadership academy for military medicine and a research and development institution for the Department of Defense medical research program. As part of its mission, USU is charged to catalyze scientific collaboration among military and civilian investigators that results in the development and translation of knowledge and materiel products aligned with Military Health System (MHS) and Department of Defense (DoD) requirements.

Developing new methods and technologies to improve the diagnosis and management of mild traumatic brain injury (mTBI), otherwise known as concussion, is a high priority for the MHS. The USU TBI Research Consortium (TBIRC) coordinates multiple lines of effort in this clinical area. The USU TBIRC is composed of several leading research groups involved in the conduct of clinical studies on all severities of TBI (mild, moderate and severe). USU is seeking information related to planned or ongoing clinical trial research projects on non-invasive assessment technologies designed for the detection and management of mTBI.

USU is issuing this Request for Information (RFI) to survey available and/or emerging technologies that have the potential to address the following areas of interest in the detection and management of mTBI:

- 1) Utility of the non-invasive technologies, individually or in combination, as initial diagnostic and/or screening tool(s) for individuals who have been exposed to events associated with mTBI (i.e. individuals who have been exposed to scenarios associated with a risk of mTBI, but in whom the diagnosis has not yet been made). The technology or technologies should be compared against current standard(s) of care.
- 2) Ability of available and/or emerging biomedical non-invasive technologies, individually or in combination, to provide prognostic information that can among other things, predict return to activity/duty time for those who have been diagnosed with concussion/mTBI when compared to current standard(s) of care/return to activity protocols.
- 3) Utility of the non-invasive technologies, individually or in combination, to serve as tools by which inclusion and or exclusion criteria can be determined for entry of individuals into clinical studies of candidate therapeutics in the management of mTBI. Comparative assessment of the technology or technologies should be against current clinical standards (treatment of functional deficits and symptoms related to mTBI will be prioritized).

For each of the three areas of interest, important considerations include:

- 1) Quantitative assessment of added value provided by the technology, or technologies in combination, above and beyond the information provided by standard of care assessments, which at present include Military Acute Concussion Evaluation 2 (MACE2), clinical judgment, and neuroimaging if indicated.
- 2) The clinical settings and or timing from exposure or injury in which the technology or technologies are best applied (e.g. point of injury, inpatient facility or medical center, sub-acute clinic setting or longer-term clinic setting).

2a – The clinical setting(s) in which the technology or technologies are best applied (e.g. emergency department, urgent care, primary care, rehabilitative facility, etc.)

2b – The time from injury that the technology or technologies are best applied, including the timing and course of injury recovery and decision support for treatment and referral.
- 3) Best approaches for producing effectiveness data, training paradigms, clinical support mechanism to improve clinical adoption and use of new approaches and technologies.

Candidate technologies that have FDA approved indications include the following:

- 1) Quantitative EEG-based multimodal technologies
- 2) Blood Biomarkers (requires invasive step of acquiring a blood sample)
- 3) Eye tracking technologies
- 4) Automated neurocognitive testing
- 5) Near Infrared Spectroscopy (NIRS)

Information Requested

To respond to this RFI, please address the following questions below. Responses may involve a single technology or area of interest listed in this announcement, although respondents are encouraged to address more than one of the technologies, including ongoing or future studies on the potential comparability of the technologies in real-world setting (i.e. scenarios associated with mTBI or in cases of known/diagnosed mTBI). Of particular interest to the USU are responses which include ongoing or proposed studies of military populations and outline collaborative approaches with military treatment facilities, military laboratories and/or military researchers.

- 1) What types of clinical studies/methodology can be conducted to assess the utility of one or more of these non-invasive technologies, alone or in comparison with one another? Are any of these options sufficiently developed for interventional (therapeutic/preventative) clinical trial research? This can include study on what phase of care the technologies are best applied (i.e. point of injury versus concussion clinic versus hospital setting). Please describe any relevant research of which you are aware, with brief details about each therapeutic or preventive intervention, and the stage of clinical development in progress. If relevant, include information on Investigational New Drug or Investigational Device Exemption status.
- 2) What novel approaches/methodologies of clinical study can be accomplished to improve the understanding and clinical adoption of one or more of these non-invasive technologies? Although FDA cleared devices exist in all five of the categories of technology, clinical adoption and use of the

technologies is incomplete. How can clinical studies be fashioned to improve the understanding of the optimal use and clinical adoption of these technologies?

3) What novel approaches can be undertaken to differentiate the utility of one or more of these non-invasive technologies in either the military or civilian setting. Are the technologies better suited for use in civilian sports-related injury, civilian non-sport mTBI, blast-related injury (training or combat) in military personnel, and non-blast mTBI (training or combat) in military personnel?

Response and Process

To facilitate review of responses, please clearly mark which of the above technologies/areas of interest are relevant to the response. DO NOT submit cost related or pricing information in response to this RFI. General marketing information or marketing flyers that do not address the Government's requirements outlined herein will not be reviewed.

Please respond no later than 11:59 PM (Eastern) on 27 Jul 2020. Responses should be limited to no more than 5 pages, and must be submitted to mTBItechnologies@usuhs.edu.

Telephone inquiries will not be accepted. Any questions concerning this notice should be submitted via email to mTBItechnologies@usuhs.edu.

All information received in response to this RFI that is marked proprietary will be handled accordingly. The Government reserves the right to use and/or disclose information provided by respondents for any purpose(s) it deems necessary and legally appropriate. Responses to this RFI will not be returned. Respondents are advised that the Government is under no obligation to acknowledge receipt of RFI responses or provide feedback on any information submitted. Responses to this RFI are not offers and cannot be accepted by the Government to form a binding contract or award. Responses do not bind the Government to any further actions related to this RFI topic including requesting follow-on proposals from respondents to this RFI. Responders are solely responsible for all expenses associated with responding to this RFI. Response submission is voluntary and is not required to propose to a future solicitation (if any) on this topic.