MEMORANDUM OF AGREEMENT
BETWEEN
NAVAL SUBMARINE MEDICAL RESEARCH LABORATORY
AND
NATIONAL AERONAUTICS AND SPACE ADMINISTRATION LANGLEY RESEARCH CENTER (NASA LANGLEY)
FOR
RESEARCH ON WARFIGHTER PERFORMANCE

1. Authorities:

- 10 U.S.C. § 2571 – Interchange of Supplies and Services
- 10 U.S.C. § 2358 – Research and Development Projects
- 32 C.F.R. Part 219 – Protection of Human Subjects
- 45 C.F.R. Part 160 – HIPAA Privacy Rule of 1996 (General Requirements) and Part 164 (Security and Privacy)
- 5 U.S.C § 552a, – Privacy Act of 1974, as amended
- 31 U.S.C. § 1535 – Economy Act
- Space Act Authority, 51 U.S.C. § 20113(e)

2. References: This agreement is subject to the rules and procedures contained in the references below:

- DoDM 6025-18 of March 13, 2019, Implementation of the Health Insurance Portability and Accountability Act (HIPPA) Privacy Rule in DoD Health Care Programs .
- DoDI 8580.02 of August 12, 2015, Security of Individually Identifiable Health Information in DoD Health Care Programs.
- DoD Instruction (DoDI) 4000.19 of December 16, 2020, Support Agreements.
- DoDI 3216.02 of April 15, 2020, Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research.
- BUMEDINST 6500.3A of June 17 2016, Research Integrity, Research Conduct in Responsible Education, and Research Misconduct.
- SECNAVINST 5211.5F, Department of the Navy Privacy Program, 20 May 2019.
- DoD 7000.14-R, Department of Defense Financial Management Regulation, current edition.

3. Purpose: This is a non-reimbursable Memorandum of Agreement (MOA) between the Naval Submarine Medical Research Laboratory (NSMRL) and National Aeronautics and Space Administration Langley Research Center (NASA Langley). The purpose of this MOA is to establish the terms and conditions of agreement for collaborative research between NSMRL and NASA Langley. When referred to collectively, NSMRL and NASA Langley are referred to as the "Parties."

4. Background: The collaboration will focus on topics associated with Warfighter cognitive performance under diverse military operational conditions; validate assessment tools and approaches for prediction of military-relevant performance outcomes; evaluate the effectiveness of metrics for determining cognitive readiness/situational readiness and evaluate the effectiveness of and validate tools and approaches for assessment of cognitive performance/readiness in military operational environments.

5. Responsibilities of the Parties:

a. Information Assurance and Data Management: The Parties to this agreement acknowledge the importance of maintaining information security and managing the data exchanged hereunder in compliance with all applicable legal authorities, affording the highest degree of protection practicable. The Parties agree to the following:

(1) Data Collection - The research protocol will describe the exact data to be collected and how it will be shared. All personally identifiable information (PII) or personal health information (PHI) subject to the Health Insurance Portability and Accountability Act (HIPAA) will be de-identified by redaction or another equally effective method. The Parties will ensure that records provided by either Party will be processed in a manner that unauthorized persons cannot retrieve the record by means of computer, remote terminal, or other means.

(2) De-identification Process - The de-identification process requires removal of PHI identifiers from the data set (name, Social Security Number, birth and all types of dates (except year), and other identifiers). This information will be replaced with a new unique identification number if necessary to use the data as contemplated. The Receiving Party is responsible for notifying the Providing Party immediately if data received is not properly de-identified. Exposed data constitutes a data breach.

(3) Investigator Training - Institutional Review Board (IRB). All investigators must be appropriately trained in all applicable authorities, regulations, and policies cited in this Agreement and as required by the IRB research protocol. All investigator training, data collection, data at rest, data storage, use, maintenance, transit, and retention requirements will be outlined in the study protocol as reviewed and approved by the appropriate IRB. The approved study protocol will address data types, data storage, and specimen management such as the use of study subject identification numbers to be used in all data collection instruments.

(4) Data Safeguards - The Parties agree to comply with all applicable privacy standards to secure PII and PHI at all times. The Parties shall use appropriate safeguards in the use, storage, maintenance, transit, and final disposition of data to prevent unauthorized use or disclosure of PII and PHI, consistent with this agreement, all applicable Federal and State laws, and DoD and Navy regulations, as applicable.

(5) Rights to Data - All data generated under this agreement, as well as all rights to that data, will be determined by the specifics in the IRB protocol.

(6) Data sharing - The Parties will share data collected in accordance with the IRB research protocol, to permit collaboration on data analysis to be performed by the Parties.

(7) Data in Transit - The Parties are responsible for ensuring that any data shared is transmitted, protected, and stored in a secured information system network that is fully compliant with all applicable Federal legal authorities and DoD regulations. The data described above may be shared through electronic file transfer via a secure, mutually agreed upon method such as DoD SAFE (https://safe.apps.mil/). Hard copies of such files will be handled per applicable DoD or Service regulations and guidelines.

(8) Certification of Data Destruction - Data destruction will be conducted in accordance with applicable legal authorities, as implemented by DoD at DoDI 8580.02.

b. Regulatory Compliance and Quality Elements:

(1) Analytical work will be conducted in compliance with established best practices for laboratory quality assurance and laboratory and environmental safety rules. All required scientific and regulatory approvals for any human subject research will be obtained as required and agreed upon, prior to each study's implementation.

(2) All personnel engaged in human subject research work will be under an approved DoD Assurance of Compliance with a duly constituted IRB that reviews and approves the protocol on behalf of the assured institutions. The Parties agree to negotiate and finalize any required IRB agreements between them. The approved IRB study protocol will address investigator training, data types, data storage, and specimen management including where applicable, the use of study subject identification numbers to be used in all data collection instruments.

c. Publications:

(1) All Parties involved in the analyses will have an opportunity to contribute their scientific expertise on any resulting manuscripts.

(2) Public Release of Information and Publications. All publications, presentations, abstracts, or information intended to be released to the media, verbally or in writing, will go through the Parties' clearance procedures.

(3) Authored work shall include (as applicable):

> "The views expressed in this [insert type of publication] reflect the results of research conducted by the author(s) and do not necessarily reflect the official policy or position of NASA, the Department of the Navy, Department of Defense, nor the U.S. Government."

(4) All publications and presentations shall disclose all sources of funding, including from within the author's command or institution.

(5) A copyright statement shall be included for all Government work approved in advance and submitted to civilian media for publication:

> "This work was prepared as part of my official duties as a military Service Member [or employee of the U.S. Government]. Title 17 U.S.C. § 105 provides that 'Copyright protection under this title is not available for any work of the U.S. Government.' Title 17 U.S.C. § 101 defines a U.S. Government work as a work prepared by a military service member or employee of the U.S. Government as part of that person's official duties."

6. Personnel: Each Party is responsible for all costs of its personnel, including pay and benefits, support, and travel. Each Party is responsible for supervision and management of its personnel.

7. Health Insurance Portability and Accountability Act (HIPAA): All parties understand and will adhere to the privacy and security requirements of protected health information and personally identifiable information under 45 C.F.R. Parts 160 and 164, HIPAA Security and Privacy Rule of 1996, and the Privacy Act of 1974 in accordance with the following higher authority guidance as applicable: Department of Defense (DoD) Manual 6025.18, Implementation of the HIPAA Privacy Rule in DoD Health Care Programs of March 2019, section 3.3; DoDI 8580.02, Security of Individually Identifiable Health Information in DoD Health Care Programs of August 12, 2015, enclosure (4), paragraph 1i; and SECNAVINST 5211.5F, Department of Navy Privacy Program of May 2019.

8. Effective Period: This agreement is effective upon the date of last signature for a period of five (5) years.

9. Modification, Change, or Amendment: Any modifications, changes, or amendments to this agreement must be in writing, and are contingent upon Bureau of Medicine and Surgery (BUMED-M3) approval via Naval Medical Forces Pacific (NMFP). Subsequent to BUMED approval, the modification, change, or amendment must be signed by all parties.

10. Termination: The agreement may be cancelled at any time by mutual consent of the parties concerned. The agreement may also be terminated by either party upon giving 30 days' written notice to the other party. In the case of mobilization or other emergency, the agreement may be terminated immediately upon written notice by any BUMED party, and it will remain in force during mobilization or other emergency only within (NSMRL's) capabilities.

11. Concurrence: It is agreed that this written statement embodies the entire agreement of the Parties regarding this affiliation, and no other agreements exist between the Parties except as expressed in this document. All Parties to this agreement concur with the level of support and resource commitments that are documented herein. All activities under or pursuant to this agreement are subject to the availability of funds, and no provisions of this Agreement shall be interpreted to require obligation in violation of the Anti-Deficiency Act (31 U.S.C. § 1341).

12. Transferability: This agreement is not transferable except with the written consent of the Parties.

13. Entire Agreement: It is expressly understood and agreed that this MOA embodies the entire agreement between the Parties regarding the MOA's subject matter.

14. Points of Contact:

NASA Langley Research center
Chad Stephens
Phone: 757-864-1547
E-mail: chad.l.stephens@nasa.gov

Navy Submarine Medical Research Laboratory
Dr. Sarah Chabal
Phone: 860-694-2522
E-mail: sarah.a.chabal.civ@mail.mil

15. Priority of Use: Any schedule or milestone in this Agreement is estimated based upon each Party's current understanding of the projected availability of its respective goods, services, personnel, facilities, or equipment. In the event that either Party's projected availability changes, the other party shall be given reasonable notice of that change, so that the schedule and milestones may be adjusted accordingly. The Parties agree that each Party's use of its own goods, services, facilities, equipment, or personnel shall have priority over the usage planned in this Agreement.

16. Liability and Risk of Loss: Each Party agrees to assume liability for its own risks arising from or related to activities conducted under this Agreement.

Liability - Because the parties are both instrumentalities of the United States, all claims will be handled in accordance with the Federal Tort Claims Act (FTCA) and all federal health care providers acting within the scope of this MOA will be covered by the Gonzales Act and the Federal Employees Liability Reform and Tort Compensation Act. In the event that a claim or lawsuit is filed, or that an adverse medical outcome requires an investigation, the party with responsibility for the site where the alleged negligence occurred will be responsible for investigating the allegations and adjudicating the claim or lawsuit. Both parties will cooperate in the investigation of any FTCA claims.

17. Intellectual Property Rights – Data Rights:
NASA Langley and NSMRL agree that information and data exchanged in furtherance of the activities under this Agreement will be exchanged without use and disclosure restrictions unless required by national security regulations (e.g., classified information) or as otherwise provided in this Agreement or agreed to by NASA Langley and NSMRL for specifically identified information or data (e.g., information or data specifically marked with a restrictive notice).

18. Release of General Information to the Public and Media: NASA Langley or NSMRL may consistent with Federal Law and this Agreement, release general information regarding its own participation in this Agreement as desired. Insofar as participation of the other Party in this Agreement is included in a public release, NASA Langley and NSMRL will seek to consult with each other prior to any such release, consistent with the Parties' respective policies.

19. Applicable Law: U.S. Federal law governs this Agreement for all purposes, including but not limited to, determining the validity of the Agreement, the meaning of its provisions, the rights, obligations and remedies of the Parties.

20. Financial Obligations: There will be no transfer of funds between the Parties under this Agreement and each Party will fund its own participation. All activities under or pursuant to this Agreement are subject to the availability of funds, and no provision of this Agreement shall be interpreted to require obligation or payment of funds in violation of the Anti-Deficiency Act (31 U.S.C. § 1341).

21. Signatory Authority:

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION
LANGLEY RESEARCH CENTER

MARY DIJOSEPH Digitally signed by MARY DIJOSEPH Date: 2022.01.25 20:03:17 -06'00'

BY:_____
Mary S. DiJoseph, Director
Aeronautics Research Directorate

DATE:_____

NAVAL SUBMARINE MEDICAL RESEARCH LABORATORY

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BY:_____
CAPT Katharine K. Shobe,
Commanding Officer

DATE:_____