**Department of Defense**

**Human Research Protection Program**

**DEPARTMENT OF DEFENSE (DOD) INDIVIDUAL INVESTIGATOR AGREEMENT**

**Part 1**

**AGREEMENT INFORMATION**

This DoD Individual Investigator Agreement describes the responsibilities of the individual researcher who is engaged in human subject research, not an employee of the assured institution, and is associated with the assured institution for the purpose of conducting research. This Agreement also describes the responsibilities of the assured institution. This Agreement, when signed, becomes part of the engaged institution’s Federal Assurance for the Protection of Human Research Subjects approved by DoD (and may become part of the Federalwide Assurance (FWA) approved by the Department of Health and Human Services (DHHS)).

1. **Name of Investigator:**
2. **Institution with the Assurance**

Name: U.S. Marine Corps

DoD Assurance Number: DoD N-40078

DoD IRB Number\* (if applicable): DON-IRB-00030

DHHS FWA Number (if applicable): N/A

Assurance Expiration Date: 30 November 2028

1. **Scope**

[ ] This Agreement applies to all research performed by this investigator in collaboration with the institution with the assurance, unless specified below.

[ ] This Agreement is applicable only to the research listed in this Agreement and does not apply to other research in which the investigator may be involved. *(List titles and other identifying information.)*

**D.** **Effective Date**

This Agreement is effective as of the date signed by the DoD Component Designated Official, and expires at the conclusion of the research defined in Part 1C or on the date listed in the DoD approval document.

**Part 2**

**INVESTIGATOR RESPONSIBILITIES**

**As the Investigator named in Part 1A above, I:**

1. Have reviewed: a) *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*; b) the U.S. Department of Defense (DoD) regulations for the protection of human subjects at 32 Code of Federal Regulations, Part 219 (32 CFR 219) and DoD Instruction 3216.02; c) the assurance of the institution referenced above; d) the DoD Component policies identified in Part 3 of the DoD Assurance (if applicable); and e) the relevant institutional policies and procedures for the protection of human subjects.
2. Understand and accept the responsibility to comply with the standards and requirements stipulated in the above documents and to protect the rights and welfare of human subjects involved in research conducted under this Agreement.
3. Will comply with all other applicable federal, DoD, international, state, and local laws, regulations, and policies that provide protections for human subjects participating in research conducted under this Agreement.

D. Will complete any education and training required by the institution and the Institutional Review Board(s) (IRB) prior to initiating research covered under this Agreement (attach documentation).

E. Will abide by all determinations of the IRB designated under the institution’s assurance and will accept the final authority and decisions of the IRB, including but not limited to directives to terminate my participation in designated research activities.

F. Will not enroll subjects or engage in research activities under this Agreement prior to the protocol review and approval by the IRB and the institution.

G. Will comply with requirements from the IRB when responsible for enrolling subjects, to include obtaining, documenting, and maintaining records of informed consent for each such subject or each subject’s legally authorized representative as required under DoD regulations at 32 CFR 219.

H. Acknowledge and agree to cooperate with the IRB for initial and continuing review, report for the research referenced above, and provide all information requested by the IRB or institution in a timely fashion.

I. Will seek prior IRB review and approval for all proposed changes in the research except where necessary to eliminate apparent immediate hazards to subjects or others.

J. Will report immediately to the IRB: a) unanticipated problems involving risks to subjects or others and b) serious or continuing non-compliance.

K. Will comply with recordkeeping requirements for research protocols referenced above.

L. Will make all other notifications as specified by the IRB and the institution.

M. Acknowledge my primary responsibility for safeguarding the rights and welfare of each research subject, and that the subject’s rights and welfare will take precedence over the goals and requirements of the research.

**Part 3**

**ASSURED INSTITUTION’S RESPONSIBILITIES**

This institution will apply the terms of its assurance to the Investigator and the research as specified in the Scope of this Agreement, Part 1.

**Part 4**

**AGREEMENT BETWEEN AN INVESTIGATOR AND AN ASSURED INSTITUTION**

The investigator, the investigator’s employer, or an official of the assured institution may unilaterally terminate this agreement upon written notification to other signatories.

**A. Investigator**

I understand my responsibilities as described in this Agreement and the policies referenced in Part 2A above. Iacknowledge and accept my responsibility for protecting the rights and welfare of human research subjects and for complying with all applicable provisions of the institution’s assurance**.**

Signature: Date:

Name:

Rank/Grade: Telephone number:

Title: FAX number:

Mailing Address: Email address:

**B. Acknowledgement by Investigator’s Employer (or DoD Supervisor if DoD Employee)**

I am aware that my employee is entering into this agreement.

Signature: Date:

Name:

Rank/Grade: Telephone number:

Title: FAX number:

Mailing Address: Email address:

**C. Institutional Official of the Assured Institution**

Acting in an authorized capacity on behalf of this institution and with an understanding of the institution’s responsibilities under the institution’s assurance, I will provide oversight of the Investigator and the research conducted under this Agreement.

Signature: Date:

Name: Anthony J. Greco, Jr.

Rank/Grade: SES Telephone number: (703) 784-3730

Title: Institutional Official, U. S. Marine Corps FAX number: (703) 784-0089

Executive Deputy Email address: anthony.greco@usmc.mil

Training and Education Command

Mailing Address:

Commanding General TECOM

(Attn: Dr. Kerry Fosher - HRPP)

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