**Department of the Navy**

**Human Research Protection Program**

**DEPARTMENT OF DEFENSE**

**Institutional Agreement for**

**Institutional Review Board (IRB) review**

**between**

**INSTITUTION RELYING ON THE IRB SERVICES:**

**{Name of the Institution relying on the IRB Services}**

**And**

**INSTITUTION SUPPLYING IRB SERVICES:**

**U. S. MARINE CORPS**

**(USMC)**

Part 1

Institution Information

This Department of Defense (DoD) Institutional Agreement for IRB Review (IAIR) describes the responsibilities of the engaged institution and the institution with the IRB. 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)).

**A. Engaged Institution Relying on the IRB**

Name:

DoD Assurance Number:

DoD Assurance Expiration Date:

DHHS FWA Number (if applicable):

DHHS FWA Expiration Date (if applicable):

**B. Institution Supplying the IRB Review Services**

Name: U. S. Marine Corps (USMC)

DoD Assurance Number: DoD N-40078

DoD Assurance Expiration: 30 November 2028

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

DHHS FWA Number (if applicable): N/A

DHHS IRB Number\* (if applicable): N/A

\*Provide for each IRB that serves as a reviewing IRB and is part of this agreement.

**C. Scope**

This Agreement applies to the following DoD-supported research conducted by the engaged institution:

 [[ ] ] A single DoD-supported research protocol only (list title and other identifying information):

 [[ ] ] A group of DoD-supported research protocols (describe here or attach list):

 [[ ] ] All DoD-supported research performed by this institution.

**D. Effective Dates, Amendments, and Termination**

This Agreement is effective as of the final signature date and will remain in effect as long as the involved institutions maintain valid Assurances, unless cancelled by any involved institution. At any time, this Agreement may be modified, cancelled, or renegotiated upon mutual consent.

Part 2

INSTITUTIONAL Responsibilities

All institutions are responsible for ensuring that their personnel (i.e., the Institutional Official, the IRB, IRB office staff, investigators and research staff, and any other personnel supporting research covered under this Agreement) act in accordance with all applicable federal, state and local laws and regulations (e.g., Title 32 Code of Federal Regulations Part 219 (32 CFR 219); Title 10 United States Code Section 980 (10 USC 980); DoD Directives and Instructions (e.g., DoDI 3216.02); 45 CFR Part 46 (Subparts B, C, and D as made applicable by DoDI 3216.02); DoD Component policies; and the Food and Drug Administration regulations and guidance (e.g., 21 CFR Parts 50, 56, 312, 600, and 812) where applicable in addition to the terms and conditions of the organizations’ DoD Assurance and/or their DHHS FWA.

Specific DoD Component requirements are stated in Part 3 of this document.

All institutions will permit, upon request, the inspection of any facilities used in support of the activities described in the “Scope” and other research areas by federal agencies responsible for oversight of human research protection and proper management of the research within the scope of this agreement.

**A. The Institutional Official of the Engaged Institution Relying on the IRB will:**

 1. Ensure that all institutional personnel involved in the research (covered within the scope of this agreement) have completed education and training requirements.

 2. Verify that scientific review of the research protocol has been conducted and that the IRB considered the feedback from the scientific review.

 3. Verify that the IRB has reviewed the research protocol in accordance with DoD requirements, including those identified in the research contract or agreement.

 4. Ensure institutional personnel comply with requirements and oversight established by the IRB.

 5. Ensure institutional personnel follow the approved research protocol.

 6. Ensure institutional personnel report to the IRB and DoD: (a) unanticipated problems involving risks to subjects or others; (b) serious or continuing non-compliance; (c) suspension or termination of IRB approval; and (d) any other events or circumstances requiring notification.

 7. Ensure institutional personnel maintain current copies of the IRB approved research protocol (initial review, continuing review, amendments, adverse event reports, and final report), all communications with the IRB, this Agreement, and other relevant information in accordance with DoD record keeping requirements.

 8. Verify the IRB has the expertise and policies and procedures needed to review and oversee the research submitted by the institution (in accordance with 32 CFR 219.107, §.103(b)(3) and (4), and §.115).

**B. The Institution Supplying the Reviewing IRB will:**

 1. Verify that personnel involved in the research have completed required education and training for the protection of human research subjects.

 2. Verify that the IRB is properly constituted for reviewing the research.

 3. Fulfill the IRB responsibilities identified in the engaged institution’s assurance.

 4. Provide the Institutional Official of the engaged institution with information about the IRB, such as a list of IRB members or expertise and the written procedures for executing IRB responsibilities in accordance with paragraph A.8 above.

 5. Provide to the engaged institution conducting the research and the Principal Investigator(s) a copy of the IRB review and determinations concerning the research (e.g., IRB minutes or other appropriate documents).

 6. Maintain current copies of the IRB approved research protocol (initial review, continuing reviews, amendments, adverse events reports, and final report), all communications with the institution, this Agreement, and other relevant information in accordance with DoD Component record-keeping requirements.

Part 3

DOD COMPONENT REQUIREMENTS

A. This institution will comply with the requirements of the DoD Component issuing this Agreement. These requirements are identified in Part 3, paragraph B. DoD Components may require that other research, not specifically identified by 32 CFR 219, also comply with the terms of this Agreement (32 CFR 219.101(d)).

B. When this institution conducts research supported by or in collaboration with an organization of another DoD Component, this institution must comply with the policies and procedures of that organization. The requirements of selected DoD Components are identified below:

Department of the Army

* AR 70-25 Use of Volunteers as Subjects of Research, 25 January 1990
* AR 40-38, Clinical Investigation Program, 1 September 1989
* AR 40-7, Use of Investigational Drugs in Humans and the Use of Schedule I Controlled Drug Substances, 19 October 2009

Department of the Navy

* SECNAVINST 3900.39E CH-1, 29 May 2018

Department of the Air Force

* AFI 40-402, Protection of Human Subjects in Research, 10 September 2014

Office of the Secretary of Defense for Personnel and Readiness

* HA Policy 05-003

Part 4

INSTITUTIONAL Agreement

**A. Engaged Institution Relying on the External IRB**

 **1. Institutional Signatory Official at the Engaged Institution**

Acting in an authorized capacity on behalf of this institution and with an understanding of the institution’s responsibilities under its assurance, I assure protections for human subjects as specified above.

Signature: Date:

Name:       Rank/Grade:

Title:

Telephone number:  Email address:

Mailing Address:

 **2. Point of Contact for Human Research Protection at the Engaged Institution**

Signature: Date:

Name:       Rank/Grade:

Title:

Telephone number: Email address:

Mailing Address:

**B. Institution with the Reviewing IRB**

 **1. Institutional Official of Institution with the Reviewing IRB**

. Acting in an authorized capacity on behalf of this institution and with an understanding of the institution’s responsibilities under its assurance, I assure protections for human subjects as specified above.

Signature: Date:

Name: Anthony J. Greco, Jr.

Rank/Grade: SES Telephone Number: (703) 432-0475

Institutional Title: USMC Institutional Official

 Executive Deputy, Training and Education Command (TECOM)

Email Address: anthony.j.greco@usmc.mil

Mailing Address: Commanding General, TECOM

 Attn: Dr. Kerry Fosher (HRPP)

 2007 Elliot Road, Quantico, VA 22134

 **2. Point of Contact for Human Research Protection at the Institution with the Reviewing IRB**

Signature: Date:

Name: Dr. Kerry B. Fosher

Rank/Grade: GS-14

Institutional Title: Director, USMC HRPP

Telephone Number: 571-289-6448 FAX Number: n/a

Email Address: kerry.fosher@usmcu.edu

Mailing Address: Commanding General, TECOM

 Attn: Dr. Kerry Fosher (HRPP)

 2007 Elliot Road, Quantico, VA 22134

**3. Reviewing IRB Chair Agreement**

Acting in an authorized capacity on behalf of the IRB and with an understanding of the institution’s responsibilities under this assurance, I assure protections for human subjects as specified above.

Signature: Date:

Name: Leah B. Watson

Rank/Grade: GS-14

Institutional Title: USMC IRB Chair, Human Research Protection Official

Telephone Number: 571-289-6448 FAX Number: n/a

Email Address: kerry.fosher@usmcu.edu

Mailing Address: Commanding General, TECOM

 Attn: Attn: Dr. Kerry Fosher (HRPP)

 2007 Elliot Road, Quantico, VA 22134