Department of Defense
Human Research Protection Program

DOD INSTITUTIONAL AGREEMENT FOR INSTITUTIONAL REVIEW BOARD (IRB) REVIEW (IAIR)

General Instructions to Institutions and IRBs

- This form should be used when an institution will be engaged in human subject research and will use an Institutional Review Board (IRB) that is not organizationally or legally part of the institution. This Agreement will help ensure that the engaged institution with the federal assurance and the IRB providing the review and approval of the research (in accordance with 32 CFR 219 and DoD Instruction 3216.02) know the responsibilities of each party to this agreement. Contact your DoD Component Headquarters office (or DoD sponsor) for guidance if you want to submit an equivalent agreement or want to alter this form.

- This agreement will become an amendment to your DoD Assurance.

- Contact your DoD Component Headquarters office (or DoD sponsor) for guidance if you have questions.

- Follow your DoD Component Headquarters office (or DoD sponsor) instructions for paper or electronic submission.

- The “Institution Relying on the IRB Services” is the institution engaged in the research. The “Institution supplying the IRB Services” is the IRB or organization with the IRB.

- For DoD-sponsored extramural research: This agreement is needed for only for the external IRBs that will review DoD-sponsored research. It is not needed for any IRBs that review research not supported by DoD.

Department of Defense Human Research Protection Program

DOD INSTITUTIONAL AGREEMENT FOR INSTITUTIONAL REVIEW BOARD (IRB) REVIEW

BETWEEN

INSTITUTION RELYING ON THE IRB SERVICES:

AND

INSTITUTION SUPPLYING IRB SERVICES:

PART 1
INSTITUTION INFORMATION

This DoD Institutional Agreement for IRB Review 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 (if applicable):

Expiration Date:

DHHS FWA Number (if applicable):

Expiration Date:

B. Institution Supplying the IRB Services

Name:

DoD Assurance Number:

DoD IRB Number* (if applicable):

DHHS FWA Number (if applicable):

DHHS IRB Number* (if applicable):

*Provide for each IRB that is part of this agreement.

C. Scope

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

☐ A single research protocol only (list title and other identifying information):

☐ A group of research protocols (describe here or attach list):

☐ All research in which both institutions are jointly engaged:

D. Effective Dates

This Agreement is effective as of the date of the last authorized signature and will remain in effect indefinitely or until rescinded. It may be amended by consent of all parties at any time.

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);; DoD Component policies; and the Food and Drug Administration regulations and guidance (e.g., 21 CFR Parts 50, 56, 312, 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 §.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 study.

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 review, 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.

C. Amendments and Termination

1. This Agreement may be modified, cancelled, or renegotiated upon mutual consent, at any time through an amendment signed by authorized representatives of the organizations. A decision to amend or terminate will be submitted to the DoD Component Designated Oversight Official.

2. The DoD Component Designated Official is not obligated to approve this Agreement.

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 in the references listed 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 U.S. Food and Drug Administration-Regulated Investigational Products in Humans including Schedule I Controlled Drug Substances, 19 October 2009

Department of the Navy

- SECNAVINST 3900.39D, Human Research Protection Program, 6 November 2006

Department of the Air Force

- Air Force Instruction 40-402, Protection of Human Subjects in Biomedical and Behavioral Research, 5 May 2005

Office of the Under Secretary of Defense for Personnel and Readiness

- Office of the Under Secretary of Defense (Personnel and Readiness) Research Regulatory Oversight Office Human Research Protection Program Operating Instruction, 29 September 2014

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: Telephone Number:

Institutional Title: FAX Number:

Mailing Address: Email Address:

2. Primary Contact for Human Research Protection at the Engaged Institution

Name:

Rank/Grade: Telephone Number:

Institutional Title: FAX Number:

Mailing Address: Email Address:

B. Institution with the Reviewing IRB

1. 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:

Rank/Grade: Telephone Number:

Institutional Title: FAX Number:

Mailing Address: Email Address:

2. Institutional Official of Institution with the Reviewing IRB

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

Signature: Date:

Name:

Rank/Grade: Telephone Number:

Institutional Title: FAX Number:

Mailing Address: Email Address:

3. Primary Contact for Human Research Protection at the Institution with the Reviewing IRB

Name:

Rank/Grade: Telephone Number:

Institutional Title: FAX Number:

Mailing Address: Email Address: