Department of the Navy Human Research Protection Program

DEPARTMENT OF DEFENSE INDIVIDUAL INVESTIGATOR AGREEMENT

DIRECTIONS FOR INSTITUTIONS AND UNAFFILIATED INVESTIGATORS

What is an Individual Investigator Agreement (IIA)?

An IIA is a "DoD-harmonized" agreement which allows an individual from a Command/institution not holding an assurance to conduct research involving human subjects under the assurance of a Command/institution who is engaged. Agreements can cover one, several or all protocols with which the investigator is involved." (SECNAVINST 3900.39E CH-1, Enclosure (5), Item 23).

Who must obtain an IIA?

If an institution does not have a Federal assurance, a researcher may use an IIA to associate with an institution having a Federal assurance and thus fulfill the requirement of conducting non-exempt research involving human subjects under an approved Federal assurance. All researchers conducting non-exempt research involving human subjects must be covered either directly under their institution's Federal assurance or indirectly using an IIA (DoDI 3216.02, Enclosure 3, Section 2.a.(2)(a)).

Step-by-Step Directions

1. Complete the agreement as follows: (All sections must be typed)

Part 1: Agreement Information

a. Fill in the gray boxes in sections A and B.

b. Complete section C. If you have any questions about the scope of the agreement, please contact the assured institution or DON HRPP.

Part 2: Investigator Responsibilities

a. HRPP Policies and Procedures: The investigator must understand the terms of the institution's assurance that are relevant to their responsibilities. For the relevant regulations listed in the agreement, contact the assured institution.

b. Education and Training Requirements: The investigator must complete education and training required by DON HRPP, the institution, and the IRB prior to initiating research covered under this agreement.

Contact the assured institution for its specific training requirements. DON HRPP provides access to the Collaborative Institutional Training Initiative (CITI) training program. This web-based training program meets DoD and DON requirements for research ethics training, including human research protection training. In most cases, investigators engaged in human subject research should complete training for "Investigators, Key Research Personnel, and Research Monitors."

Part 3: Assured Institution's Responsibilities

The assured institution will apply the terms of its assurance to the investigator and any research within the scope of the agreement.

Part 4: Agreement between an Investigator and an Assured Institution

Fill in the gray boxes, sign as the investigator, and obtain the signatures of your employer and the Institutional Official (IO) of the assured institution.

a. Section A: Investigator: The investigator completes the requested contact information (must be typed) and signs and dates the agreement. Do not insert multiple signature blocks here – each unaffiliated investigator must complete a separate agreement.

b. Section B: Acknowledgement by Investigator's Employer: The investigator should obtain the contact information and signature of their employer to acknowledge that the employee is entering into this agreement with another institution. For DON personnel, the employer generally is the Commander, Commanding Officer, or Officer-in-Charge.

If the investigator is self-employed, type "N/A – self-employed" in the "Name" field of this section and leave the rest of section B blank.

c. Section C: Institutional Official of the Assured Institution: The IO of the assured institution (i.e., the official who signed the DoD or Federal assurance) completes the requested contact information and signs and dates the agreement.

2. Agreement Effective Date, Amendments, and Termination

The agreement is effective as of the final signature date. The agreement will remain in effect as long as the involved institution maintains a valid assurance, unless cancelled by the investigator, the investigator's employer, or the official of the assured institution upon written notification to other signatories. At any time, the agreement may be modified or renegotiated upon mutual consent.

The unaffiliated investigator must not engage in the research until the IRB and the assured institution have approved the research and the agreement is signed by all parties.

3. DON HRPP Oversight of the Agreement

IIAs should be submitted to DON HRPP as part of the unaffiliated investigator's protocol submissions for headquarter-level review, and should be made available for review at DON HRPP Site Inspections and Assist Visits. IIAs are not required to be submitted to DON HRPP at time of signature.

If any party would like to make substantive changes to the IIA template provided by DON HRPP, it is strongly recommended to send the draft agreement to DON HRPP for review before signing.

4. Investigator and Institutional Responsibilities after Final Signature

Investigators and institutions are responsible for any changes to the agreement. If the institution's DoD or Federal assurance expires, all research being conducted by the investigator under the agreement must stop. The Navy Surgeon General may permit, if requested, specific research to continue if suspending the research would endanger research subjects.

Failure to comply with the terms of the agreement or the institution's assurance may result in restriction, suspension, or termination of the investigator's ability to conduct human subject research.

5. Record Keeping

The institution with the assurance will maintain a copy of the agreement and all documents supporting the institution's HRPP in accordance with the terms of the agreement. These documents will be available for review by the Navy Surgeon General and DON HRPP. Investigators will maintain a copy of the agreement and will be made available for review by DON HRPP.