

Department of the Navy Human Research Protection Program

DEPARTMENT OF DEFENSE INSTITUTIONAL AGREEMENT FOR INSTITUTIONAL REVIEW BOARD REVIEW

DIRECTIONS FOR INSTITUTIONS AND INSTITUTIONAL REVIEW BOARDS

When is an Institutional Agreement for Institutional Review Board (IRB) Review (IAIR) needed?

An IAIR is needed when an institution will be engaged in human subject research and will rely on an IRB that is not organizationally or legally part of its institution. The 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 the agreement.

An IAIR is used when:

- An institution does not have their own IRB and must rely on other institutions' IRBs for all IRB review
- Two or more institutions are collaborating on a study and must reduce the number of IRB reviews
- A particular study requires special expertise to review that the engaged institution's IRB does not have

Institutions may enter into multiple agreements for IRB review and designate multiple IRBs to review research. The Principal Investigator (PI) and the engaged institution must choose the IRB which is appropriate to review the research protocol(s).

If two institutions' IRBs would like to serve as reviewing IRB for each other, depending on the specific research protocol, a 'reciprocal' agreement for IRB review may be appropriate. This would require using a "Reciprocal IAIR" application.

Department of Defense (DoD) institutions may use an IAIR to rely on a non-Federal IRB, as long as the DoD's role in the research is secondary to that of the non-Federal institution. Reliance on a non-Federal IRB will also require a Component-Level Administrative Review (CLAR) prior to DoD engagement in the research. Please contact the Department of the Navy Human Research Protection Program (DON HRPP) for more information.

The engaged institution conducting the research remains responsible for the monitoring and overseeing the DoD-supported research from its inception to conclusion.

Is an IAIR needed if multiple IRB reviews will be conducted?

No, an IAIR is not needed if both institutions' IRBs review the research. However, duplicative reviews shall not be conducted without written justification to the Director, DON HRPP.

Can changes be made to the IAIR template?

Minor changes to the IAIR template provided by DON HRPP are allowed. If substantive changes such as changing of responsibilities or regulatory framework to the template are desired, it is strongly recommended to send the altered draft agreement to DON HRPP for review before signature.

Step-by-Step Directions

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

Part 1: Institution Information

- a. Fill in the gray boxes in sections A and B.
- b. Complete section C. Select the description of the scope that is most appropriate for the

Agreement. Please contact DON HRPP if you have any questions about the scope of the agreement.

Part 2: Institutional Responsibilities

For more information on the relevant regulations listed in Part 2 of the Agreement, contact DON HRPP.

Part 3: DoD Component Requirements

For more information on the relevant DON policies, contact DON HRPP.

Part 4: Institutional Agreement

Complete the information and obtain signatures for the individuals at both the engaged institution and the institution providing the IRB reviewing service. The signature block information must be typed except for the signature and date. Please be sure to include the name, number, or letter of each IRB for which the Chair(s) may sign.

2. Agreement Effective Date and Termination

The agreement is effective as of the final signature date. The agreement will remain in effect as long as the involved institutions maintain valid assurances, unless cancelled by any involved party upon written notification to other signatories. At any time, the agreement may be modified or renegotiated upon mutual consent.

The IRB may not review the research until the agreement is signed by all parties, and the relying institution may not become engaged in the research until it has received IRB approval and command authorization.

3. DON HRPP Oversight of the Agreement

IAIRs should be submitted to DON HRPP as part of the submission of the research reviewed under the agreement, and should be made available for review at DON HRPP Site Inspections and Assist Visits. IAIRs are not required to be submitted to DON HRPP at time of signature. However, if an IAIR will be covering multiple studies (for example, when a command does not have their own IRB and relies on external IRBs for all research), it may be more efficient to submit the IAIR once to DON HRPP at the time of signature instead of attaching it to every study reviewed under the agreement.

4. Institutional Responsibilities after Final Signature

Both institutions are responsible for any changes to the agreement. In order to continue to have the designated IRBs review DoD-supported research with human subjects, institutions are responsible for maintaining a valid, current DoD-DON Assurance or Federalwide Assurance. If the engaged institution's DoD or Federal Assurance expires without renewal, the IRB must stop reviewing DoD-supported research on behalf of the other institution. The Navy Surgeon General may, if requested, permit specific research protocols 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 research being reviewed under the agreement.

5. Record Keeping

Both institutions will maintain all documents supporting the IAIR. These documents will be available for review by the Navy Surgeon General, DON HRPP, and the institutions named in the agreement.