



Walter Reed Army Institute of Research
Standard Operating Procedure

SOP Title	Working with Other Institutions Engaged in Research (Assurances, IAAs, & Deferrals)	SOP No.	UWZ-C-624
		Version	.01
Effective Date	JUN 25 2010	Page	1 of 14

Signatures and Dates:

Author:

QA Review:

For Signatures, Please see the Original Document at DHSP

Approving Authority:

Review/Approval for unchanged documents

Date	Author	QA Review	Approving Authority



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1. **Purpose/Applicability:** This SOP describes the process to be followed with regard to the requirements for conducting research collaboratively with other institutions; this includes the requirement for assurances and explains the process for Institutional Review Board (IRB) deferrals.

This SOP applies to WRAIR investigators, Division of Human Subjects Protection (DHSP) Staff Members, the Institutional Review Board (IRB) Administrative Director, the IRB Chair and members, and the Commander, WRAIR.

2. **Background:** Federal regulations [32CFR219.103(a)] require that each institution "engaged" in research must have an assurance of compliance with regard to human subjects research, unless the research is exempt. (Note: Assurances are not required for research not involving human subjects or non-research projects.) The WRAIR IRB holds two assurances, an Office of Human Research Protections (OHRP) Federal Wide Assurance (FWA) and a Department of Defense Assurance for research conducted by WRAIR faculty and staff (military, civilians, or contractors), or otherwise supported by WRAIR funds/resources. Assurances are required for all institutions associated with a protocol, if engaged in human subjects research activities. This includes situations whereby a research project involves collaboration among multiple institutions, such as when data is being collected in partnership with another institution. Assurances will need to be obtained by institutions that have neither an assurance nor a registered IRB, or work can not occur collaboratively. There are no exceptions to this requirement.

It is the policy of the Department of Defense (DoD) that a registered DoD Institutional Review Board (IRB) must review a human subjects research protocol, if there are DoD personnel, funding, or other resources associated with a human research activity. This means that while non-DoD institutions may defer IRB review to the WRAIR, WRAIR can only defer to other DoD institutions (USUHS, NMRC, MTFs, etc). In situations in which WRAIR researchers are involved in collaborative research projects with investigators at other institutions, one solution is to have the protocol approved by both institutions' IRBs. However, with the agreement of both Institutional Officials, a request can be made that one of institution's IRBs serve as the "DoD IRB of Record" for a particular project. For this to occur, the investigator must request an IRB Authorization Agreement (IAA) (Known is the DOD as an "IAIR"), from the WRAIR DHSP, which will formally establish one IRB as the "DoD IRB of Record" for the study. Such an arrangement must first be agreed to by, and be in compliance with the procedures of, the other institution's IRB and DoD policy. IRB IAAs can only be negotiated between institutions that hold active assurances.

Absent such an agreement, the investigator must seek review and approval of the research protocol (as well as subsequent changes, renewals, reports of unanticipated problems, and so forth) from the WRAIR IRB, as well as from the



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other institution's IRB. When submitting a new protocol for review, investigators must provide the WRAIR IRB with a copy of the approval from the other institution. If such approval has not yet been received at the time of WRAIR IRB review, any approval may be contingent upon providing the Committee with a copy of the other institution's approval notification.

It is the responsibility of each institution to determine if its staff is engaged in human subjects research activities. The WRAIR cannot make a determination for staff members not covered by the WRAIR assurances.

Situations in which WRAIR researchers propose collaborative research projects with institutions that have an assurance, but no internal IRB: WRAIR, acting in consultation with the other institution, should complete an IRB Authorization Agreement authorizing the WRAIR IRB act as "the IRB of Record" for this research project.

Situations in which WRAIR researchers propose collaborative research projects with institutions that have neither an assurance nor a registered IRB: If the collaborator is engaged in human subjects research activities, an assurance must be obtained or no collaborative work (such as use of Federal funds, personnel, resources, etc.) can occur with that organization.

Note: An IAA can also be used for part of the review process. For example, an institution may want its designated IRB to perform initial reviews of projects, but finds that continuing reviews can be deferred to the WRAIR or another IRB. This, too, must be documented in an IAA, with that IRB listed as a registered reviewing body under both assurances.

3. Responsibilities:

- a. The WRAIR IRB and WRAIR IRB Chair (when applicable) are responsible for assuring that all institutions involved in research activities are covered by a current assurance during review of a protocol (or have an IAA, when appropriate).
- b. DHSP Staff members are responsible for making sure each institution listed on a protocol has a current assurance and are responsible for assisting investigators with drafting (see Appendix A Template) and obtaining signature for IAAs from the Commander, WRAIR.
- c. The WRAIR IRB Administrative Director (or designee) is responsible for reviewing each IAA prior to the WRAIR Commander's signature. He/She is also responsible for maintaining a list of current IAAs.



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- d. The Commander, WRAIR is responsible for ensuring that all IAAs are appropriate and in line with DoD and Institutional requirements. He/she is to be the signatory on each IAA, as the Institutional Official.

4. Materials and Equipment: Not Applicable.

5. Procedures:

a) Investigators:

- 1) Work exclusively with those collaborators' whose institutions hold assurances, when engaged in human subjects research activities.
- 2) Provide assurance numbers and expiration dates with protocol submissions and continuing review reports when working with institutions other than WRAIR, this includes those in the U.S. and those internationally.
- 3) Assist DHSP staff members in drafting IAAs, where appropriate, or obtain approvals from each IRB for each version of the protocol.
- 4) Ensure that no research activity occurs without the appropriate active assurances, agreements, or approvals.
- 5) Report to the DHSP any assurances that are about to expire or that have expired and ensure that work is not continued until those assurances have been renewed.

b) The WRAIR IRB (or WRAIR IRB Chair):

- 1) Ensures during the review of protocols, all institutions hold current assurances, when appropriate.
- 2) Assists investigators in understanding the requirements of doing collaborative research with other institutions.
- 3) Reminds investigators that the WRAIR IRB can only make determinations of engagement for those covered under WRAIR's assurances.
- 4) Serves as the IRB of record, when needed per an IAA.
- 5) Requires IRB approvals from all institutions engaged in research, unless an IAA is in place or the collaborating institution has stated



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in writing that its staff is not engaged in human subjects research activities.

c) DHSP Staff Members:

- 1) Ensure that during the pre-review of protocols, all institutions listed in the protocol hold current assurances, when appropriate.
- 2) Assist investigators in understanding the requirements of doing collaborative research with other institutions.
- 3) Obtain and review all IRB approvals from collaborating institutions and require that each institution is approving the same version of the protocol and consent documents.
- 4) Ensure all IAAs contain the appropriate information, when submitted.
- 5) Ensure WRAIR only defers to IRBs from other DoD institutions.
- 6) Assist in writing IAAs and obtaining signature from the Commander, WRAIR, when appropriate.
- 7) Ensure that the IRB Administrative Director (or designee) has reviewed the IAA, when appropriate.
- 8) Provide a copy of the IAA for the IAA binder and ensure a copy is in each protocol binder.

d) The WRAIR IRB Administrative Director:

- 1) Reviews each IAA prior to Commander, WRAIR signature.
- 2) Assists in negotiating IAAs and deferrals, when needed.
- 3) Maintains a list of current IAAs in a designated binder and ensure a copy of the IAA is in each protocol binder.
- 4) Discusses issues with the Army Assurance Office (AHRPO), when needed.

e) The Commander, WRAIR:

- 1) Ensures that all IAAs are appropriate and in line with DoD and Institutional requirements.



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- 2) Requires that all institutions that do business with WRAIR hold a current assurance, when engaged in human subjects research activities.
- 3) Is the signatory on all IAAs, as the Institutional Official.

6. Explanation of Abbreviations and Terms:

DoD Assurance- Each branch of the service has the ability to issue service-specific assurances. WRAIR's assurance begins with a "A" which means it is issued by the U.S. Army assurance office.

FWA – Federal Wide Assurance - An institution's assurance to the Office of Human Research Protections that all sponsored research comply with the ethical principles of the Belmont Report and procedural requirements of 45 CFR 46.

"Engagement" in Human Subjects Research – OHRP considers an institution "engaged" in research when its employees or agents either (i) intervene or interact with living individuals for research purposes, or (ii) obtain or possess individually identifiable private information for research purposes. This includes collecting research specimens, administering drugs, manipulating research participants' environment, making recordings, conducting interviews, or obtaining or archiving private, individually identifiable information for research purposes. This includes situations in which an institution's agents obtain informed consent from research participants.

It does not include organizations that simply permit use of their facilities for intervention or interaction with research participants (as long as the institution's agents are not engaged as described above), nor does it include institutions that perform commercial services for investigators (such as a clinical laboratory), and adhere to professional standards for the maintenance of privacy and confidentiality.

IAIR- DOD INSTITUTIONAL AGREEMENT FOR IRB REVIEW

Registered IRB – An Institutional Review Board, Ethical Review Board, or other review board that is registered with the Office of Human Research Protections (OHRP) or the Department of Defense. For a list of currently registered IRBs with ORHP. see (IORG #)



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7. References:

Reference Number or Authors	Document Title
http://www.hhs.gov/ohrp/	Office of Human Research Protections Website
OHRP	Engagement of Institutions in Research, 1999
http://www.hhs.gov/ohrp/belmontArchive.html	The Belmont Report
Title 32 CFR 219	Protection of Human Subjects (Common Rule)

8. Forms and Appendices:

Appendix A: IAIR Template

9. Document Revision History:

Version Number	Brief Description of Changes	Effective Date
.00	New	15 July 2007
.01	Revised	JUN 25 2010



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APPENDIX A: IAA Template

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 Institutions engaged in the research involving human subjects. This Agreement, when signed, becomes part of each Institution's Federal Assurance for the Protection of Human Research Subjects (e.g., DoD Assurance for the Protection of Human Research Subjects or Department of Health and Human Services (DHHS) Federal Wide Assurance (FWA)).

A. Engaged Institution Relying on the IRB:

Name:
DoD Assurance Number:
DHHS FWA Number [if applicable]:

B. Institution Supplying the IRB Services:

Name:
DoD Assurance Number of the Institution:
DHHS/FWA Number (if applicable):
DoD IRB Number (if applicable):
DHHS IRB Number (if applicable):



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C. Scope.

This Agreement applies to:

- A single research protocol only (list title and other identifying information):
- The groups of research protocols described below:
- All research performed by this Institution.

D. Effective Dates:

This Agreement is effective as of the date approved and signed by the DoD Component Designated Official and expires on the date listed in the approval document.

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., DoDD 3216.02); 45 CFR Part 46 (Subparts B, C, and D as made applicable by DoDD 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 institutions' 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:

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



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

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

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

5. Ensures institutional personnel follow the approved research protocol.

6. Ensures 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. Ensures 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 Component record keeping requirements.

8. Verifies 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:

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

2. Verifies that the IRB is properly constituted for reviewing the study.

3. Fulfills the IRB responsibilities identified in the engaged Institution's Assurance.

4. Provides 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. Provides to the engaged institution conducting the research and the Principal Investigator(s) a copy of the IRB review and determinations concerning the research.

6. Provides relevant sections of the IRB meeting minutes to the engaged Institution.



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7. Maintains 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 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 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, 4 January 1991

Department of the Navy

SECNAVINST 3900.39D of 6 November 2006

Department of the Air Force

Air Force Instruction 40-402, Protection of Human Subjects in Research

Office of the Secretary of Defense for Personnel and Readiness

HA Policy 05-003



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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:

Institutional Title:

Mailing Address:

Telephone number:

FAX number:

Email address:

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

Name:

Rank/Grade:

Institutional Title:

Mailing Address:

Telephone number:

FAX number:

Email address:



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B. Institution with 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:
Institutional Title:
Mailing Address:
Telephone number:
FAX number:
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:
Institutional Title:
Mailing Address:
Telephone number:
FAX number:
Email address

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

Name:



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Rank/Grade:
Institutional Title:
Mailing Address:
Telephone number:
FAX number:
Email address