



Research Regulatory Oversight Office

IP-001
24 June 2015

INFORMATION PAPER
Individual Investigator Agreement (IIA)

Information Papers published by the OUSD(P&R), R2O2 contain background information on specific issues raised to this Office, policies covering the issues and the OUSD(P&R), R2O2 interpretation of those policies. These papers include policy interpretations that are enforceable within and among all institutions in the OUSD(P&R).

Background

Department of Defense (DoD) institutions engaged in non-exempt human subjects research shall have a DoD Assurance for the Protection of Human Subjects (Assurance). Institutions that receive Department of Health and Human Services (HHS) funding to support human subjects research must also obtain and maintain an HHS Federal-Wide Assurance issued by the HHS Office for Human Research Protections (OHRP). Other Common Rule agencies may have additional requirements for Assurances.

Frequently, individuals at institutions that do not have an Assurance (non-Assured institutions) are asked to participate as collaborating investigators on research involving human subjects. These individuals may serve as collaborating investigators if, either 1) his/her institution obtains an Assurance or 2) the individual investigator enters into an agreement with an Assured institution at which the study will be led or, in the case of a multi-site study, a collaborating institution at which the study will be conducted, thus covering that individual investigator under the Assurance at the Assured institution.

Policy

The requirement for an Assurance is set out in Section 103 of the DoD Regulation regarding the protection of human subjects (Part 219 of Title 32, Code of Federal Regulation (CFR)). It states that each institution engaged in research that is covered by the regulation "and which is conducted or supported by a federal department or agency shall provide written assurance satisfactory to the department or agency head that it will comply with the requirements set forth in" 32 CFR 219. DoD Instruction (DoDI) 3216.02, *Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research*, includes a provision for covering individual collaborating investigators from non-Assured institutions under the Assurance of an institution at which the individual investigator is collaborating on research involving human subjects. This agreement is called an Individual Investigator Agreement (IIA), and this provision can be found in Enclosure 3, Section 2.a(2)(a) of DoDI 3216.02.

Guidance on IIAs provided by HHS/OHRP (*Guidance on Extension of an FWA to Cover Collaborating Individual Investigators and Introduction of the Individual Investigator Agreement*) outlines restrictions and requirements for implementation of the IIA (<http://www.hhs.gov/ohrp/policy/guidanceonalternativetofwa.html>).

Policy Interpretation and Implementation Requirements for OUSD(P&R) Institutions

Assured institutions within OUSD(P&R) may use IIAs to extend Assurance coverage to collaborating investigators from non-Assured institutions. Specific implementation requirements of the DoDI 3216.02, Enclosure 3, Section 2.a(2)(a) include:

1. The collaborating investigator from the non-Assured institution shall NOT serve as the Principal Investigator on research involving human subjects at the institution under whose Assurance the IIA covers him/her.

2. The Principal Investigator must be a staff member at an Assured institution in accordance with 32 CFR 219 and DoDI 3216.02.
3. In accordance with HHS/OHRP guidance, the Principal Investigator at the Assured institution “directs and appropriately supervises all of the collaborative research activities to be performed by the collaborating individual investigator outside the Assured institution.”
4. If HHS funds the research, in whole or in part, then the IIA must extend the HHS Federal-Wide Assurance coverage to the collaborating investigator from the non-Assured institution. It may also extend the DoD Assurance coverage to the collaborating investigator.
5. An IIA may cover only one collaborating investigator. If multiple collaborating investigators from non-Assured institutions are participating in research involving human subjects at a single Assured institution, then separate IIAs must be executed for each collaborating investigator.
6. The term “Individual” in “Individual Investigator Agreement” relates to an “Individual Investigator” and NOT to an “Individual Agreement”.

The template OUSD(P&R) IIA is copied beginning at Page 3 of this Information Paper, and a copy of the template is available on the R2O2 website or upon request sent to dha.ncr.reg-support.mbx.r2o2@mail.mil.

Definitions

Collaborating Investigator: an individual from a non-Assured institution who may serve as a co-investigator, but may not serve as the Principal Investigator, on a research study at an Assured institution upon execution of an Individual Investigator Agreement.

Common Rule Agencies: Federal Departments and Agencies that have adopted, through Regulation, the ethical and regulatory standards embodied in the HHS Regulation for the Protection of Human Subjects (45 CFR 46, Subpart A). Most Common Rule Agencies have also adopted, through either Regulation or policy, Subparts B-D.

Individual: a single person (whether subject, principal investigator or collaborating investigator).

Human Subject: a living individual about whom an investigator (whether professional or student) conducting research obtains: 1) Data through intervention or interaction with the individual, or 2) Identifiable private information. (32 CFR 219.102(f)).

Principal Investigator: an individual affiliated with a research study with overall responsibility for the management and conduct of that study. The Principal Investigator must be a member of the staff of an Assured institution.

Research: a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. (32 CFR 219.102(d)).



**Department of Defense
Human Research Protection Program**

DEPARTMENT OF DEFENSE (DOD) INDIVIDUAL INVESTIGATOR AGREEMENT

General Instructions to Institutions and Unaffiliated Investigators

- This form is a tool that can be used when a collaborating investigator is not part of an institution with a federal assurance. 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.
- 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.
- This agreement is applicable only to the research listed in the Scope (Part 1C) and does not apply to other research in which the institution or unaffiliated investigator may be involved.
- Part 4, B. Acknowledgement by Investigator's Employer: The unaffiliated investigator should follow his/her institution's policies for identifying the appropriate official to acknowledge this agreement. The official is acknowledging that their employee is entering into this agreement with another institution.
- Part 4, C. Institutional Official of the Assured Institution: This is the person who signed the federal assurance as the Institutional Official.
- The unaffiliated investigator should not be engaged in the research until this agreement is complete.

**Department of Defense
Human Research Protection Program**

DEPARTMENT OF DEFENSE (DOD) INDIVIDUAL INVESTIGATOR AGREEMENT

**Part 1
AGREEMENT INFORMATION**

This DoD Individual Investigator Agreement describes the responsibilities of the individual researcher who is engaged in human subject research, not an employee of the assured institution, and is associated with the assured institution for the purpose of conducting research. This Agreement also describes the responsibilities of the assured institution. 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. Name of Investigator:

B. Institution with the Assurance

Name:

DoD Assurance Number:

DHHS FWA Number [if applicable]:

C. Scope

This Agreement applies to all research performed by this investigator in collaboration with the institution with the assurance, unless specified below.

Limitation of Scope (if applicable): _____

This Agreement is applicable only to the research listed above and does not apply to other research in which the investigator may be involved.

D. Effective Date

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 INVESTIGATOR RESPONSIBILITIES

As the Investigator named in Part 1A above I:

A. Have reviewed: a) *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*; b) the U.S. Department of Defense (DoD) regulations for the protection of human subjects at 32 Code of Federal Regulations, Part 219 (32 CFR 219) and DoD Directive 3216.02; c) the assurance of the institution referenced above; d) the DoD Component policies identified in Part 3 of the DoD Assurance (if applicable); and e) the relevant institutional policies and procedures for the protection of human subjects.

B. Understand and accept the responsibility to comply with the standards and requirements stipulated in the above documents and to protect the rights and welfare of human subjects involved in research conducted under this Agreement.

C. Will comply with all other applicable federal, DoD, international, state, and local laws, regulations, and policies that provide protections for human subjects participating in research conducted under this Agreement.

D. Will complete any education and training required by the institution and the Institutional Review Board(s) (IRB) prior to initiating research covered under this Agreement (attach documentation).

E. Will abide by all determinations of the IRB designated under the institution's assurance and will accept the final authority and decisions of the IRB, including but not limited to directives to terminate my participation in designated research activities.

F. Will not enroll subjects or engage in research activities under this Agreement prior to the protocol review and approval by the IRB and the institution.

G. Will comply with requirements from the IRB when responsible for enrolling subjects, to include obtaining, documenting, and maintaining records of informed consent for each such subject or each subject's legally authorized representative as required under DoD regulations at 32 CFR 219.

H. Acknowledge and agree to cooperate with the IRB for initial and continuing review, report for the research referenced above, and provide all information requested by the IRB or institution in a timely fashion.

I. Will seek prior IRB review and approval for all proposed changes in the research except where necessary to eliminate apparent immediate hazards to subjects or others.

J. Will report immediately to the IRB: a) unanticipated problems involving risks to subjects or others and b) serious or continuing non-compliance.

K. Will comply with recordkeeping requirements for research protocols referenced above.

L. Will make all other notifications as specified by the IRB and the institution.

M. Acknowledge my primary responsibility for safeguarding the rights and welfare of each research subject, and that the subject's rights and welfare will take precedence over the goals and requirements of the research.

Part 3 ASSURED INSTITUTION'S RESPONSIBILITIES

This institution will apply the terms of its assurance to the Investigator and the research as specified in the Scope of this Agreement, Part 1.

Part 4 AGREEMENT BETWEEN AN INVESTIGATOR AND AN ASSURED INSTITUTION

The investigator or an official of the assured institution may unilaterally terminate this agreement upon written notification to other signatories.

A. Investigator

I understand my responsibilities as described in this Agreement and the policies referenced in Part 2A above. I acknowledge and accept my responsibility for protecting the rights and welfare of human research subjects and for complying with all applicable provisions of the institution's assurance.

Signature: _____ Date: _____
 Name: _____
 Rank/Grade: _____ Telephone number: _____
 Title: _____ FAX number: _____
 Mailing Address: _____ Email address: _____

B. Acknowledgement by Investigator's Employer (or DoD Supervisor if DoD Employee)

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

Signature: _____ Date: _____
 Name: _____
 Rank/Grade: _____ Telephone number: _____
 Title: _____ FAX number: _____
 Mailing Address: _____ Email address: _____

C. Institutional Official of the Assured Institution

Acting in an authorized capacity on behalf of this institution and with an understanding of the institution's responsibilities under the institution's assurance, I will provide oversight of the Investigator and the research conducted under this Agreement.

Signature:

Date:

Name:

Rank/Grade:

Telephone number:

Title:

FAX number:

Mailing Address:

Email address: