

**Department of Defense (DOD) Human Research Protection Program (HRPP)**  
**ASSURANCE FOR THE PROTECTION OF HUMAN RESEARCH SUBJECTS**

Version Date: 1 November 2017

Prior to submitting an application an institution should read and understand the DoD Assurance instructions.

- Part 1. DoD Institution Information, Section A, Institution Information.
  - Institution Information.
    - Enter all requested institutional information required for the Assurance.
    - *If this is a request for a new Assurance, the DoD Component office will provide the DoD Assurance number.*
  - Description of the Institution.
    - *Enter a description of the institution to include any sub-organizations to be covered by this Assurance that are in the jurisdiction of the institution and that operate under a different name. Include the city and state or country where each sub-organization is located.*
    - *Sub-organizations are generally defined as parts of your institution that may be viewed as separate organizations, but remain part of the legal entity or institution. For example, ABC Hospital can list its UVW Branch Clinic and XYZ Branch Clinic as sub- organizations.*
    - **Do not** include organizations that are covered by another DoD Assurance.
    - *The DoD Component office may require changes to the description of the institution.*

*The Institutional Official (IO) signing this Assurance must be authorized to represent the institution providing this Assurance and all sub-organizations listed.*
- Part 1. DoD Institution Information, Section B, Purpose of DoD Assurance.
  - *“New” DoD Assurance, institution’s initial filing.*
  - *Contact your DoD Component office, the office that will receive your completed Assurance, before requesting a new DoD Assurance.*
  - *Complete the entire Assurance application (except for Part 6).*
  - *New Assurances must be signed by all institutional signatories (Part 7) and the DoD Component Designated Official.*
  - "Renewal" of an existing, approved DoD Assurance.
    - *To remain active, the institution must renew its DoD Assurance prior to expiration, even if no changes have occurred.*
    - *Complete the entire Assurance application.*
    - *Renewals must be signed by all institutional signatories (Part 7) and the DoD Component Designated Official.*
    - *The DoD Assurance will be renewed and updated in accordance with the approving DoD Component's policies and procedures.*
    - *Contact your DoD Component office approximately 6 months prior to expiration to establish an Assurance renewal timeline.*

- “Update” to an existing, approved DoD Assurance.
  - *Updates inform the approving DoD Component office of a change to the DoD Assurance. Submit updates in accordance with DoD Component policy.*
  - *After marking “Update”, go to Part 6.*
  - *New expiration dates are generally not issued for updates.*
  - *If the submission includes an update and a renewal, mark both.*
  - *Updates require documentation of IO approval of the change.*
  - *A new IO should sign the DoD Assurance as soon as they have received appropriate Human Research Protection Program (HRPP) training.*
  - *A person cannot perform the duties of the IO until they have received appropriate training.*
  
- Part 2. Ethical Principles, Compliance, and Responsibilities of the Institution.
  
- Part 3. DoD Component Requirements.
  
- Part 4. Designation of Institutional Review Board (IRB).
  - Section A: Indicate if your institution has an internal IRB(s) (Y = Complete Section B), (N = Complete Section C).
  - Section B: Enter the IRB(s) Name(s) or Number(s) and DHHS IRB Registration number(s), which are part of your institution (internal).
    - *Use Table 1 to provide requested information.*
    - *Each IRB Chair must sign the Assurance in Part 7.*
  - Section C: Enter all IRB(s) that are used by, but are not part of, the institution (external). Enter the name(s) of Institution(s) with the IRB, DoD Assurance Number, IRB(s) Name(s) or Number(s) and DHHS IRB Registration number(s).
    - *Use Table 2 to provide requested information.*
    - *When the institution relies upon an IRB operated by another institution for review of research to which the DoD Assurance applies, this will be documented by a written agreement between the relying institution and the institution operating the IRB.*
    - *This agreement will outline its relationship and include a commitment that the IRB will adhere to the requirements of the institution’s DoD Assurance.*
    - *The DoD Institutional Agreement for IRB Review will be used unless the parties involved develop their own agreement, with approval from the DoD Component.*
    - *This agreement must be kept on file at both institutions/organizations.*
    - *The agreement will be available, upon request, to DoD, the DoD Component approving the Assurance, or any U.S. federal department or agency conducting or supporting research to which the DoD Assurance applies.*
    - *If the institution does not have an IRB, attach the DoD Institutional Agreement for IRB Review (IAIR or equivalent) for the IRB to be used most often. The DoD Component office may request submission of the DoD IAIR, or equivalent, for any IRB identified in Part 4, Section C.*

- Part 5. Institutional Policies and Procedures.
  - List the institution's HRPP policies and procedures that describe how the organization will execute the requirements of the Assurance.
  - If this is a new or renewed Assurance, attach the institution's policies and procedures as an Appendix to the Assurance.
  
- Part 6. Assurance Update.
  - Indicate if this is an update to the institution's existing approved DoD Assurance. Check all applicable and submit relevant documentation supporting each Update.
    - Addition or removal of an internal IRB: *Update Part 4m, Section B.*
    - Addition or removal of an external IRB: *Update Part 4, Section C.*
    - Change of Institution Name: *Change institution information at Part 1 and submit documentation of IO approval of the change.*
    - Change in IO: *Update Part 7. Submit documentation of IO appointment, if the IO is not appointed by position in accordance with DoD Component-approved policy.*
    - Change in AIO: *Update Part 7. Submit documentation of AIO appointment, if the AIO is not appointed by position in accordance with DoD Component-approved policy.*
    - Change in IRB Chair and/or membership list: *Update Part 7, Table 3.*
    - Change in primary HRPP POC: *Attach the revised documents with changes marked and documentation of IO approval.*
    - Other: *Describe the institution's Update to this Assurance*
  
- Part 7. Institutional Assurance.
  - Section A, Institutional Official (IO) Assurance.
    - Enter the signature and requested contact information of the IO authorized to represent and commit the entire institution and all of its components to this agreement.
    - *The IO assures that human subject research to which the DoD Assurance applies is conducted in accordance with the terms of Assurance.*
    - *The IO is the senior person authorized to establish and responsible to maintain the HRPP for the institution. See DoDI 3216.02, Glossary.*
  - Section B, IRB Membership Roster.
    - Complete template at Table 3.
    - *Ensure all members identified on this list have been duly appointed in accordance with DoD Component and institutional policies and procedures.*
    - *Please include any institution-specific additional information on a separate sheet and submit with the IRB membership roster.*
    - *The DoD Component office may request appointment documentation.*

- Section C, Authorized Institutional Official (AIO) Assurance.
  - Enter the signature and requested contact information of the AIO authorized to represent and commit the entire institution and all of its components to this agreement.
- Section D, Primary Contact HRPP POC.
  - Enter the signature and requested contact information of the person who will serve as primary point of contact for the institution's system for protecting human research subjects.
- Section E, Internal IRB Chair(s) that are part of the institution as listed in Part 4 B.
  - Enter the signature and requested contact information of the person who Chairs the institution's internal IRB.
  - *If there are multiple IRBs listed in Part 4 B, each Chair should sign the Assurance and provide the information in this section.*
  - *If a Chair presides over multiple IRBs listed in Part 4 B, provide the name and number of each IRB in this section. Enter the signature and requested contact information of the person who will serve as primary point of contact for the institution's system for protecting human research subjects.*

If you have questions about the template, contact the DoD Component office.

**Department of Defense (DOD) Human Research Protection Program (HRPP)  
ASSURANCE FOR THE PROTECTION OF HUMAN RESEARCH SUBJECTS**

Version Date: 1 November 2017

A DOD Assurance is required when a DOD institution becomes engaged in research involving human subjects, referred throughout this document as “human subjects research” (HSR), in accordance with (IAW) the Common Rule, Title 32 Code of Federal Regulations part 219 (32 CFR 219), and DOD Instruction 3216.02.

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**Tips for completing this form:** Hover over the text boxes to view *help* text. To ensure that text is not truncated when printing, use the entire width of the text box when necessary. Only complete applicable fields.

**PART 1  
DOD INSTITUTION**

**A. Institution Information:**

**Name of Institution**

**Alternate Name(s) if applicable**

**City and State or Country**

**DOD Component**

Air Force

Army

Navy

Other

**Mailing Address**

**DOD Assurance Number**

**DOD Assurance Expiration Date** (mm/dd/yyyy)

**DHHS Federalwide Assurance  
(FWA) Number (if applicable)**



## PART 2

# ETHICAL PRINCIPLES, COMPLIANCE AND RESPONSIBILITIES OF THE INSTITUTION

The IO, acting in an authorized capacity on behalf of this institution (including any sub-organizations) and with an understanding of the institution's responsibilities under this Assurance, will ensure protection of human research subjects as specified below.

### **A. Ethical Principles of the Institution:**

1. HSR must be guided by a statement of principles. All of the institution's HSR activities, regardless whether subject to 32 CFR 219, will be guided by a statement of principles governing the institution in the discharge of its responsibilities for protecting the rights and welfare of human subjects in research conducted at or sponsored by the institution. This statement of principles includes the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research entitled *Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (the "Belmont Report").

2. This institution recognizes the principles of respect for persons, beneficence, including minimization of harms and maximization of benefits and justice, as stated in the Belmont Report and will act in accordance with these principles in all research covered by this Assurance.

### **B. Institutional Compliance:**

1. This institution and the institutional review boards (IRBs) upon which it relies for review of non-exempt HSR will comply with 32 CFR 219; Title 10 United States Code Section 980 (10 USC 980); DOD Instruction 3216.02 (DODI 3216.02); 45 CFR Part 46 (Subparts B, C and D as applicable by DODI 3216.02), the Food and Drug Administration (FDA) regulations and guidance (e.g., 21 CFR Parts 50, 56, 312 and 812) where applicable; and any other relevant federal, state and local laws.

2. This institution will comply with the requirements of the DOD Component approving this Assurance. These requirements are identified in Part 3 of this Assurance.

3. When this institution conducts research supported by another DOD Component (e.g., providing subjects or funding), the institution will report to the supporting Component any actions reported to the Assistant Secretary of Defense for Research and Engineering, ASD(R&E) IAW DODI 3216.02.

4. When this institution conducts research supported by another federal department or agency, the institution may be required to comply, through a separate agreement, with the policies and procedures of the federal department or agency. The supporting federal department or agency will inform the institution of any additional requirements.

5. Except when research is exempt from the requirements of 32 CFR 219, or applicability of 32 CFR 219 is waived under 32 CFR 219.101(j), this Assurance applies to all HSR and all other activities related to such research even in part, regardless of whether the research is otherwise subject to federal regulation, if the research is conducted by any employee of this institution in connection with institutional responsibilities.

6. Applicability of the terms of this Assurance is not restricted by other considerations such as location of research, funding source (e.g., intramural or extramural to DOD), funding appropriation, nature of support, program budget activity (e.g., Major Force Program 6, Research and Development, or Major Force Program 8, Training, Medical and Other General Personnel Activities), program title, or security classification.

7. If this institution collaborates with other investigator(s) who are not employed by an institution with a federal Assurance, this institution may extend the applicability of this Assurance to the collaborating investigator(s). This collaborative agreement will be documented by both parties using a DOD Individual Investigator Agreement (IIA), or an equivalent agreement, in accordance with policies of the DOD Component approving this Assurance.

8. HSR conducted or supported by DOD and its Components will be governed by the regulations as implemented by the DOD and its respective Components. DOD retains final judgment as to whether a particular activity conducted or supported by the DOD is covered by the Common Rule. If the institution needs guidance regarding implementation of the Common Rule, DODI 3216.02, DOD Component policies identified in Part 3 of this DOD Assurance, and/or other applicable U.S. federal regulations, the institution should contact their DOD Component office. For DOD institutions, DOD retains final authority for determining whether the institution complies with this Assurance.

9. The institution must not conduct non-exempt HSR unless the institution maintains a valid DOD Assurance approved by the DOD Component and the research has been approved in accordance with DOD Component policies.

**C. Responsibilities of the IO:** Compliance responsibilities are identified in the documents referenced above in Part 2, Section B, Institutional Compliance and below in Part 3, DOD Component Requirements. Select responsibilities are identified in this section. The IO will:

1. Maintain an HRPP in compliance with DODI 3216.02. Select issues that must be addressed in the HRPP are identified below.

a. The HRPP will address when and how an investigator shall seek a determination that the proposed activity does or does not meet the DODI 3216.02 definitions of "research" and "human subject" and a determination that the proposed activity does or does not meet the exemption criteria in 32 CFR 219.

b. The HRPP will provide policies and procedures on implementing the regulations and policies referenced in this Assurance and all other applicable federal, state, local and international requirements.

c. The HRPP will include procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, the head of any U.S. federal department or agency conducting or supporting the research, or designee, and the DOD Component oversight office which will report to ASD(R&E) any:

- (1) Unanticipated problem involving risks to subjects or others (UPIRTSO),
- (2) Serious or continuing noncompliance with the applicable U.S. federal regulations or the requirements or determinations of the IRB(s),
- (3) Suspension or termination of IRB approval and
- (4) Any other event or circumstances requiring notifications IAW DOD or DOD Component policies.

d. The HRPP will include policies and procedures describing how the institution will monitor, evaluate, and improve the HRPP.

2. Bear full responsibility for the conduct of research covered by this Assurance in compliance with applicable federal, state, local, and international laws and requirements. Provide resources to execute the institution's HRPP, including but not limited to: continuing education and training for personnel involved in the HRPP; meeting space for its own IRB(s) if applicable; and staff sufficient to support HRPP functions such as IRB review, scientific review, record-keeping, and oversight of research.

3. Ensure that the IRB(s) that review(s) research covered by the DOD Assurance has established written procedures for:

a. Conducting IRB initial and continuing review, not less than once per year, of research and reporting IRB findings to the investigator and the institution;

b. Determining which projects require IRB review more often than annually and which projects need verification from sources other than the investigator that no material changes have occurred since the previous IRB review; and

c. Ensuring prompt reporting to the IRB of proposed changes in a research activity and for ensuring that such changes in approved research, during the period for which IRB approval has already been granted, may not be initiated without IRB review and approval, except when necessary to eliminate apparent immediate hazards to subjects.

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## **PART 3 DOD COMPONENT REQUIREMENTS**

### **Defense Advanced Research Projects Agency (DARPA)**

DARPA Instruction No. 66, *Protection of Human Subjects in Research*, 19 November 2013

### **Defense Threat Reduction Agency (DTRA)**

DTRA Directive 3216.01, 9 June 2010, updated 18 March 2015

DTRA Instruction 3216.02, dated 21 October 2011, updated 31 July 2015

### **Department of the Air Force (DAF)**

DODI 3216.02\_AFI40-402, *Protection of Human Subjects and Adherence to Ethical Standards in Air Force Supported Research*, 10 September 2014

### **Department of the Army (DA)**

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 Substances*, 19 October 2009

DODI 3216.02, *Protection of Human Subjects and Adherence to Ethical Standards in DOD-Supported Research*, 8 November 2011

### **Department of the Navy (DON)**

DODI 3216.02 *Protection of Human Subjects and Adherence to Ethical Standards in DOD-Supported Research*, 8 November 2011

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

### **National Geospatial-Intelligence Agency (NGA)**

Policy Notice 3216.1

### **National Security Agency (NSA)**

NSA/CSS Policy 10-10, *Protecting Human Subjects of Research*, 19 April 2016

### **Office of the Under Secretary of Defense for Personnel and Readiness (OSD P&R)**

*Research Regulatory Oversight Office Human Research Protection Program Operating Instruction*, 29 September 2014

**PART 4**  
**DESIGNATION OF INSTITUTIONAL REVIEW BOARD(S) (IRBs)**

**A. Does this institution have an internal IRB(s)?**

Yes (If yes, complete Part 4, B.)

No (If no, skip to Part 4, C.)

**B. IRB(s) that are part of this institution (internal):**

**Table 1.** List IRB Name(s) or Number(s) and DHHS Registration Number(s) (if applicable).

- 1
- 2
- 3

**C. IRBs that are not part of this institution (external)**

**Table 2.** List Name(s) of Institution(s) with the IRB, Institution(s) DOD Assurance Number, IRB Name(s) or Number(s), DHHS FWA Number and Registration Number(s) (if applicable).

- 1
- 2
- 3

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**PART 5**  
**INSTITUTIONAL POLICIES AND PROCEDURES**

This institution's HRPP includes policies and procedures that describe how the institution's personnel will execute the requirements provided in this Assurance and how the institution and the IRB(s) within the institution will review, conduct, and oversee HSR. Institutional HRPP policies and procedures (e.g., regulations, instructions, guidelines, and standard operating procedures) are listed below and provided as an Appendix to this Assurance.

**Part 6  
ASSURANCE UPDATE**

**A. Is this an update to the institution's DOD assurance (including references and attachments)?**

Yes (If yes, complete Part 6, B.)  
No (If no, skip to Part 7)

**B. Check all applicable updates and attach relevant documentation.**

- Addition or removal of internal IRB
  - Addition or removal of external IRB
  - Change of Institution Name
  - Change in IO or AIO
  - Change in IRB Chair and/or IRB Roster
  - Change in primary HRPP POC
  - Revision of HRPP Plan and/or associated documentation
  - Other
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**PART 7  
INSTITUTIONAL ASSURANCE**

**A. IO Assurance:** *I acknowledge and accept on behalf of the institution, its responsibilities for protecting the rights and welfare of human research subjects as specified herein.*

**Ink or Electronic Signature**

**Mailing Address**

**Name**

**Title**

**Rank or Grade**

**Telephone Number**

**Email Address**

**B. IRB Membership Roster:** Complete Table 3 template.

**C. AIO Assurance:** *I acknowledge and accept my responsibilities as identified in this institution's HRPP policies and procedures.*

**Ink or Electronic Signature**

**Mailing Address**

**Name**

**Title**

**Rank or Grade**

**Telephone Number**

**Email Address**

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**D. Primary HRPP POC:** *I acknowledge and accept my responsibility to serve as my institution's HRPP POC.*

**Ink or Electronic Signature**

**Mailing Address**

**Name**

**Title**

**Rank or Grade**

**Telephone Number**

**Email Address**

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**E. Internal IRB Chair (as listed in Part 4, A-B.):** *I acknowledge and accept my responsibilities as identified in this institution's HRPP policies and procedures. I will ensure ethical review of HSR for which the IRB is responsible. NOTE: If more than one Chair, attach separate sheet.*

**Ink or Electronic Signature**

**Mailing Address**

**Name**

**Title**

**Rank or Grade**

**Telephone Number**

**Email Address**

