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RESEARCH
AND ENGINEERING

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MEMORANDUM FOR SURGEON GENERAL, U.S. ARMY
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DEPUTY ASSISTANT SECRETARY OF DEFENSE FOR FORCE HEALTH PROTECTION AND READINESS
ASSISTANT SECRETARY OF DEFENSE FOR SPECIAL OPERATIONS/LOW-INTENSITY CONFLICT & INTERDEPENDENT CAPABILITIES

SUBJECT: Minimum Education Requirements for DoD Personnel Involved in Human Research Protection

References: DoDI 3216.02, "Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research"

DoDI 3216.02 requires the Assistant Secretary of Defense for Research and Engineering (ASD(R&E)) to "establish a framework for educational training requirements for DoD personnel in key roles" of a DoD human research protection program (HRPP) (paragraph 1.f. of Enclosure 2). Attached is the requisite framework guidance document for these training requirements. This framework sets the baseline for minimum education requirements for DoD personnel involved in human subject research.

As the Component official responsible for implementing DoDI 3216.02, you may need to support the creation of new educational material to explain the requirements in DoDI 3216.02 to your research institutions. See paragraph 2.b. of Enclosure 2, paragraph 1.c.(5) of Enclosure 3, and section 5 of Enclosure 3 for more information.

My office has coordinated this document with your HRPP offices. My POC for this guidance is Dr. Fred Pearce, (571) 372-6420, Frederick.Pearce@osd.mil.

Patrick A. Mason

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Attachments:
Minimum Education Requirements Framework

cc:
Executive Secretariat to the DoD Coordinating Committee
for Human Research Protection Programs

Minimum Education Requirements for
DoD Personnel Involved in Human Research Protection

The Department of Defense (DoD) is committed to conducting high-quality and ethical research, development, test, and evaluation (RDT&E) involving human subjects. This commitment is reflected in DoD Instruction (DoDI) 3216.02, "Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research." DoDI 3216.02 requires the Assistant Secretary of Defense for Research and Engineering (ASD(R&E)) to "establish a framework for educational training requirements for DoD personnel in key roles" of a DoD human research protection program (HRPP) (paragraph 1.f. of Enclosure 2). This guidance document provides the ASD(R&E)'s framework by identifying the minimum education requirements for the key roles in an HRPP so as to provide a baseline to standardize education across the DoD Components.

DoDI 3216.02 requires education and training for "all DoD personnel involved in the conduct, review, or approval of research involving human subjects," further the "education shall be commensurate with the duties and responsibilities of the DoD personnel" (DoDI 3216.02, section 5 of Enclosure 3). To comply with these requirements, this guidance document, "Minimum Education Requirements for DoD Personnel Involved in Human Research Protection" provides the ASD(R&E)'s framework by grouping the HRPP roles into 10 categories of key roles based on similar duties and responsibilities for the conduct, review, approval, or oversight of research (Table 1). This guidance document identifies and includes a brief description of the minimum educational topics (Table 2) for the key roles. This guidance document then identifies which education topics are required for which HRPP role categories (Table 3). Finally, it offers a standard DoD education certificate template for use among HRPP personnel of different DoD Components (Attachment 1). In doing so, this guidance document affords a baseline by which to standardize education across the DoD Components.

ASD(R&E) has not established specific or detailed course content for each educational topic beyond the descriptions in Table 2. However, it has identified which education topics are required for each HRPP role category. When personnel participate in more than one HRPP role, the person is required to meet the training requirements for each role. To ensure that the educational content is appropriate for each role, DoD Components should tailor the depth of the ethics, regulations, policies, and procedures covered for each topic to the needs of the people in that role.

DoDI 3216.02 requires the DoD Components have policies and procedures to implement the ASD(R&E)'s framework for HRPP education (paragraph 1.c.(5) of Enclosure 3). In addition to complying with training requirements, DoD Components need to evaluate and approve training material to ensure the information is accurate and complete and that the material is at the appropriate breadth and depth for the intended HRPP role. While commercial vendors may provide many of the educational topics, they do not typically provide DoD-specific regulatory content, nor may they be commensurate for the duties and responsibilities of each role requiring that educational topic. DoD Components should carefully assess commercial vendor educational topic modules in light of each HRPP category of key role and be prepared to create training modules to fill any commercial gaps in order to meet the scope of the minimum education requirements.

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DoD Components must also document HRPP training. The documentation shall include the information captured in the sample education certificate template at Attachment 1. The education certificate shall identify the HRPP role(s) for which the appropriate educational topics have been completed, and annotate any other applicable educational topics that were completed. To facilitate collaboration among HRPP personnel of different DoD Institutions, DoD Components are encouraged to use the DoD education certificate at Attachment 1. DoD Components may choose to use a different format to document training, but the document should contain at least the same information as the certificate in Attachment 1. The training certificate, when presented to a DoD institution upon collaboration or reassignment, should satisfy the DoD Component's requirement to ensure that appropriate training has been completed and recorded. (However, a requirement for knowledge of DoD Component-specific policies and procedures may still need to be met). DoD Components are responsible for maintaining descriptive training and education documentation supporting award of the certificate (e.g., course content, hours of training).

DoD personnel will complete their required educational topics before assuming their DoD HRPP duties. They may assume their duty position, but they may not be involved in any HRPP actions until required HRPP training is complete. The required educational topics shall be repeated at least every three years. Due to constantly evolving ethical and regulatory issues, DoD personnel must also participate in continuing education during the intervening years. The ASD(R&E) has not specified content and hours for continuing education. In order to sustain retention of Federal and DoD policies and procedures, DoD Components will consider requiring personnel taking this training for the first time to retake some or all of the educational topics approximately 12 months after their initial training. DoD Components should establish policies and procedures to implement and oversee effective education and training that meets these minimum education requirements.

Table 1. Description of the 10 Categories of Roles in the DoD HRPPs

Common roles in the DoD HRPPs have been grouped into 10 categories based on common education requirements. For each category identified in Table 3, some examples and/or a short description are provided below. Personnel who cannot identify their role in the HRPP or align themselves with a column in the table should contact their Institutional Review Board (IRB) office or DoD Component HRPP headquarters office for guidance.

Category 1.

Senior DoD Component Leadership: Examples include, but are not limited to, the Senior DoD Component Designated Official identified in the Component's HRPP Management Plan, the person(s) responsible for approving and accepting assurances, the DoD Coordinating Committee for Human Research Protection Programs (CCHRPP) member, and other personnel above the organizational level of the DoD Component HRPP Headquarters Oversight office.

Institutional Officials (IO): The senior person authorized to establish and responsible to maintain the HRPP for the DoD institution. If the institution has a Federal assurance, this is the individual in the institution who signs the Federal assurance and is responsible for the institution's compliance with the terms of the assurance.

Category 2.

DoD Component HQ Oversight Personnel: Personnel responsible to the Senior DoD Component Leadership for implementing the Component's HRPP Management Plan and providing day-to-day guidance and oversight to the Component's institutions.

Role Category 3.

Institutional Review Board Members: All members of the IRB (e.g., Chairs, co-Chairs, primary members, alternate members, prisoner representative, community members, etc.). Consultants (i.e., non-voting members) to the IRB are not required to have the same level of education as the voting members, but at a minimum should be educated on the ethics, policies, or other topics for which they are being asked to consult.

Institutional Review Board Support Staff: The personnel supporting the IRB members (e.g., staff who are advising the investigators, conducting preliminary review of protocols before submission to the board, and providing training to HRPP personnel).

Category 4.

Advisors to the Institutional Official: Personnel (e.g., attorneys, ethicists) outside of the IRB and IRB Office who provide an interpretation of part 219 of title 32, Code of Federal Regulations (32 CFR 219), DoDI 3216.02, and other HRPP policies to the institutional official.

Category 5.

Investigators: Personnel who are responsible for creating the research protocol and/or conducting the research. There may be more than one investigator on a protocol.

Category 6.

Research Support Personnel: Personnel who are engaged in the research, but who are participating in a limited and/or defined part of the research protocol under the direct supervision or guidance of an investigator.

Category 7.

Research Monitors, Ombudsman, Subject Advocates, Data Safety Monitoring Boards (DSMBs): Personnel who are not part of the research team and who have been appointed by the IRB or are identified in the IRB-approved protocol to act on behalf of the IRB (e.g., Research Monitor or Ombudsman) or on behalf of the research subject (e.g., Subject Advocate). Personnel in this category should be educated on the ethical and regulatory topics at a depth appropriate for which they are being tasked.

Category 8.

Research Coordinators, Clinical Coordinators, Study Coordinators, and Research Administrators: Personnel, such as the Research Coordinators, Clinical Coordinators, Study Coordinators, and Research Administrators, responsible for conducting the research under the auspices of the investigator(s) or personnel involved in the preparation and administration of research protocols.

Category 9.

Regulatory Oversight of Extramural Human Subject Research: Personnel involved in ensuring the research involving human subjects that is supported by DoD, but conducted by non-DoD institutions, is compliant with DoD Component policies. For extramural contracts, this role is known as the Human Research Protection Official.

Category 10.

Research Subjects: Personnel participating in human subject research.

Table 2. Description of the Educational Topics

Following is a brief outline of the required content for each educational topic. A DoD Component may choose to broaden the scope of each topic. The depth or level of detail covered in each topic should be appropriate for the duties and responsibilities of the HRPP role being undertaken by the DoD personnel.

Educational Topic A. Ethical Principles of and Requirements for a HRPP

- The Belmont Report
- 32 CFR 219
- DoDI 3216.02
- DoD Component Policies (each DoD Component will identify their unique policies and procedures)

Educational Topic B. Defining Human Subject Research and Applying the Exemptions

- The definition of research (as used in 32 CFR 219 and DoDI 3216.02)
- The definition of human subject (as used in 32 CFR 219 and DoDI 3216.02)
- When human subject research can be exempt from requiring the institution to have a Federal assurance and requiring an IRB review of the research (as described in 32 CFR 219 and DoDI 3216.02)
- Limitations for applying the exempt categories to pregnant women, fetuses, neonates, children, and prisoners (as described in 32 CFR 219 and DoDI 3216.02)

Educational Topic C. Identifying and Mitigating Subject Risk and Subject Selection

- Implications of Section 6 of Enclosure 3 of DoDI 3216.02
- Probability and magnitude of harm
- Assessing the subject population
- Assessing risk from the subject's perspective
- Balancing risks and potential benefits
- Minimizing and managing risk
- When documentation of informed consent imposes risk
- Equitable subject selection and implications of section 252 of Public Law 103-160

Educational Topic D. Research with Pregnant Women, Human Fetuses, and Neonates

- Implications of Section 7 of Enclosure 3 of DoDI 3216.02
- When to exclude women of childbearing years versus pregnant women
- Appropriate informed consent language

Educational Topic E. Research with Prisoners

- Implications of Section 7 of Enclosure 3 of DoDI 3216.02
- Special composition of the IRB
- Requirements for additional IRB considerations and DoD approvals

Educational Topic F. Research with Children

- Implications of Section 7 of Enclosure 3 of DoDI 3216.02
- Definitions of "risk" and "minor increase in risk"
- Legal requirements for consent and assent
- Developing assent agreements and obtaining assent for various ages of children

Educational Topic G. Research in an Educational Setting or with Students

- Implications of Sections 7 and 12 of Enclosure 3 of DoDI 3216.02
- Definitions of "risk" and "minor increase in risk"
- Legal requirements for parental consent and child assent
- Identification and mitigation of vulnerabilities of students
- Common DoD and Federal requirements for conducting research in school systems

Educational Topic H. Use of a Research Monitor

- DoDI 3216.02 requirements for the research monitor
- Process to waive the requirement for a research monitor

Educational Topic I. Informed Consent

- Requirements for the overall informed consent process
- Requirement for disclosing DoD support of the research and access to subject data
- Requirements for the informed consent document
- Requirements for waiver of informed consent
- Requirements for waiver of documentation of informed consent
- Requirements for investigator changes to the informed consent process

Educational Topic J. 10 US Code (USC) 980

- 10 USC 980 requirements for informed consent
- Definition of research involving an experimental subject
- Process to waive requirement for informed consent

Educational Topic K. Privacy and Confidentiality

- Definition of and maintaining the privacy of research subjects
- Determining what is public and private data
- Definition of and ensuring confidentiality of research data
- Limitations of "promising" subjects confidentiality of subjects' data
- Federal and state reporting requirements

Educational Topic L. Identifying and Mitigating Conflicts of Interest

- Identifying types of conflicts of interest impacting research involving human subjects
- Tools to mitigate such conflict of interest
- What and when to disclose to the institution, the IRB, and/or the subjects

Educational Topic M. Requirements for IRB Review and Approval

- 32 CFR 219 requirements relevant to criteria for IRB approval of research protocol (including the informed consent process)
- DoDI 3216.02 requirements for DoD Component administrative review
- Requirement for minimizing the number of IRB and oversight reviews
- Requirements for expedited review
- Requirements for continuing review
- Requirements to review changes to the protocol or informed consent process
- Requirements for deception research

Educational Topic N. IRB Operating Requirements

- Requirements, role, authority, and composition of the IRB
- IRB requirements for approving research
- Requirements for expedited and IRB review
- Policies and procedures for reporting and communicating with the investigator, Institutional Official, and DoD Component Headquarters Office

Educational Topic O. Research with the Department of Veteran's Affairs (VA)

- Unique aspects about the VA patient population
- Key applicable VA human subjects protections requirements
- Procedures for conducting research with the VA Medical Centers
- VA office overseeing research involving human subjects
- VA accreditation program
- VA-specific requirements for protection of human subjects
- IRB Requirements

Educational Topic P. International Research

- International and country-specific ethical standards and regulations
- Relationship between United States and DoD requirements and foreign cultures
- U.S. Government guidelines
- Applicable FDA regulations
- Host-nation approval and nations without an approval process
- Local IRBs and obtaining local input to IRB review
- Cultural sensitivity
- Requirement for disclosing DoD support of the research and access to subject data

Educational Topic Q. Internet Research

- Requirements for consent
- Identifying and mitigating privacy issues
- Assessing risk (including the ability to identify)
- Information Technology issues when using the DoD computer or internet

Educational Topic R. Records-Based Research

- Identifying and mitigating privacy and confidentiality risk
- Applying the exempt criteria

- Requirement for convened IRB committee review or expedited review
- Requirements for informed consent or waiver of informed consent

Educational Topic S. Genetics Research

- Identifying, mitigating, and communicating to the subject the risks of harm
- Assessing risk regarding privacy and confidentiality
- Considerations of family members
- Obtaining informed consent
- Using stored samples
- Future use of samples
- Obtaining familial medical history from the subject

Educational Topic T. FDA Regulated Research

- FDA regulations
- Differences between 32 CFR 219 and the FDA regulations
- FDA requirements for emergency use, emergency medicine research, and applicability of 10 USC 980
- FDA required training (e.g., Good Clinical Practices (GCP))

Educational Topic U. Health Insurance Portability and Accountability Act (HIPAA) Regulated Research

- Who is a covered entity
- What is protected health information (PHI)
- Requirements for an authorization for disclosures of PHI
- Requirements for a waiver of an authorization for disclosures of PHI

Table 3. Framework for Minimum Education Requirements for DoD Personnel Involved in Human Research Protection

Educational Topics		HRPP Role Category #									
		1	2	3	4	5	6	7	8	9	10
R = Required A = Required when applicable to the person's scope of research or management responsibilities O = Optional; Person is encouraged to take topics		Senior DoD Component Leadership and Institutional Officials	DoD Component HQ Oversight Personnel	IRB Members and IRB Support Staff	Advisors to the Institutional Official	Investigators	Research Support Personnel	Research Monitors, Ombudsman, Subject Advocates, & DSMBs	Research Coordinators, Clinical Coordinators, Study Coordinators & Research Administrators	Regulatory Oversight of Extramural Human Subject Research	Research Subjects
A	Ethical Principles of & Requirements for an HRPP	R	R	R	R	R	R	R	R	R	O
B	Defining Human Subject Research and Applying the Exemptions	R	R	R	R	R	R	R	R	R	O
C	Identifying and Mitigating Subject Risk and Subject Selection	O	R	R	A	R	O	A	R	R	O
D	Research with Pregnant Women, Human Fetuses, and Neonates	O	R	A	A	A	A	A	A	A	O
E	Research with Prisoners	A	R	A	A	A	A	A	A	A	O
F	Research with Children	A	R	A	A	A	A	A	A	A	O
G	Research in an Educational Setting or with Students	O	R	A	A	A	A	A	A	A	O
H	Use of a Research Monitor	A	R	R	A	R	R	R	R	R	O
I	Informed Consent	O	R	R	A	R	R	R	R	R	O
J	10 USC 980	A	R	R	A	A	O	A	O	R	O
K	Privacy and Confidentiality	A	R	R	A	R	R	R	R	R	O
L	Identifying and Mitigating Conflicts of Interest	R	R	R	R	R	R	R	R	R	O
M	Requirements for IRB Review and Approval	O	R	R	A	R	O	A	A	R	O
N	IRB Operating Requirements	A	R	R	A	O	O	O	A	R	O
O	Research with the Department of Veteran's Affairs	O	A	A	A	A	A	A	A	A	O
P	International Research	O	R	A	A	A	A	A	A	A	O
Q	Internet Research	O	R	A	A	A	A	A	A	A	O
R	Records-Based Research	O	R	A	A	A	A	A	A	A	O
S	Genetics Research	O	R	A	A	A	A	A	A	A	O
T	FDA Regulated Research	O	R	A	A	A	A	A	A	A	O
U	HIPAA Regulated Research	O	R	A	A	A	A	A	A	A	O

DoD Human Research Protection Program (HRPP)
Summary of Education

[Print name]_____ has completed the education requirements for the HRPP role category(s) indicated below and has completed the education requirements in the special topic(s) indicated below.

Date Training Completed: _____

This certificate expires on: _____

Individual validating the education record:

Signature: _____ Date: _____

Printed Name: _____

E-mail: _____ Phone: _____

Completion of Required Educational Topics in the Following Role(s) (check all that apply)

____ Senior DoD Component Leaders & IOs
____ DoD Component HQ Oversight Personnel
____ IRB Members, Consultants, & Staff
____ Advisors to the Institutional Official
____ Investigators
____ Research Support Personnel
____ Research Monitors, Ombudsman, Subject Advocates, DSMBs
____ Research Coordinators, Clinical Coordinators, Study Coordinators, and Research Administrators
____ Regulatory Oversight of Extramural Human Subject Research
____ Research Subjects

Completion of (A) "Other Required When Applicable" and (O) "Optional" Educational Topics(s)

____ Identifying and Mitigating Subject Risk and Subject Selection
____ Research with Pregnant Women, Human Fetuses, and Neonates
____ Research with Prisoners
____ Research with Children
____ Research in an Education Setting or with Students
____ Use of a Research Monitor
____ Informed Consent
____ 10 USC 980
____ Privacy and Confidentiality
____ Requirements for IRB Review and Approval
____ IRB Operating Requirements
____ Research with the Department of Veteran's Affairs
____ International Research
____ Internet Research
____ Records-Based Research
____ Genetics Research
____ FDA Regulated Research
____ HIPAA Regulated Research
____ Other (specify): _____

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