Department of Homeland Security
DHS Directives System
Directive Number: 026-04
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PROTECTION OF HUMAN SUBJECTS

I. Purpose

A. This Directive and the accompanying Instruction establish the Department of Homeland Security (DHS) policy for the protection of Human Subjects in Research[1].

B. This Directive and accompanying Instruction only apply to DHS-managed, implemented, or funded activities.

C. DHS's pending codification of the "Federal Policy for the Protection of Human Subjects"[2] is also known as the Common Rule. Pending that codification, this Directive also adopts those policies and procedures set forth by the Department of Health and Human Services (HHS)[3]. Collectively, these policies and procedures represent the basic foundation for the protection of human subjects in most research conducted or supported by U.S. federal departments and agencies.

II. Scope

This Directive applies to all intramural research involving human subjects (i.e., research conducted at a DHS site and/or by DHS personnel) as well as any extramural research (i.e., DHS-managed or -funded Research that is conducted at non-DHS sites by non-DHS researchers) involving human subjects that is funded or sponsored by any Component through a contract, grant, cooperative agreement, cooperative research and development agreement (CRADA), other transaction agreement, or other arrangement.

III. Authorities

A. Public Law 103-43, "National Institutes of Health Revitalization Act of 1993"

[1] In particular, this Directive adopts the current HHS policies and procedures set forth in Title 45, Code of Federal Regulations (C.F.R.), part 46, subpart A and, pending final codification, will adopt DHS policies and procedures set forth in 6 C.F.R. part 46, subpart A.
[2] 6 C.F.R. part 46, subpart A
[3] 45 C.F.R. part 46, subparts A – D

B. Public Law 108-458, "Intelligence Reform and Terrorism Prevention Act of 2004"

C. Title 42, United States Code (U.S.C.) §§ 289g to 289g-2, "Fetal Research, Research on Transplantation of Fetal Tissue, and Prohibitions regarding Human Fetal Tissue"

D. Title 6, Code of the Federal Regulations (C.F.R.), Part 46, Subpart A, "Protection of Human Subjects"[4]

E. Tile 45 C.F.R. Part 46, Subpart A, "Protection of Human Subjects"

F. Title 45 C.F.R. Part 46, Subpart B, Additional Protections for Pregnant Women, Human Fetuses, and Neonates Involved in Research

G. Title 45 C.F.R. Part 46, Subpart C, "Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects"

H. Title 45 C.F.R. part 46, Subpart D, "Additional Protections for Children Involved as Subjects in Research"

I. Federal Policy on Research Misconduct, Office of Science and Technology Policy, 65 Fed. Reg. 76260 (December 6, 2000)

J. Presidential Memorandum, "Strengthened Protections for Human Subjects of Classified Research," 62 Fed. Reg. 26369 (May 13, 1997)

K. DHS Delegation 10001, "Delegation to the Under Secretary for Science and Technology"

L. DHS Delegation 05001, "Delegation to the Assistant Secretary for Health Affairs and Chief Medical Officer"

IV. Responsibilities

A. The ***Under Secretary for Science and Technology (USST)***

1. Is the DHS Human Subjects Protection Official (HSPO); and

2. Directs, ensures, and supports Department-wide implementation of and compliance with this Directive and the accompanying Instruction. This responsibility does not impact the authority and responsibility of an Institutional Review Board, as established in Section V.B.3 of this Directive.

[4] Pending final codification as of January 2018.

B. The ***Compliance Assurance Program Manager (CAPM)*** serves as the head of the Compliance Assurance Program Office (CAPO), which is responsible for developing and implementing the Department's Human Subjects Research (HSR) compliance program.

C. The ***General Counsel, Office of the General Counsel (OGC)*** (primarily through the Associate General Counsel assigned to the Science and Technology Directorate) provides counsel on all legal matters concerning the Department's compliance with federal laws and regulations pertaining to HSR, and conducts legal reviews of all DHS-conducted, -funded, or -sponsored activities involving HSR.

D. The ***Chief Medical Officer (CMO)*** has general responsibility to support the HSPO in the effort to ensure that DHS fully understands and implements this Directive, the Common Rule, other applicable statutory requirements, and the related regulatory mandates to protect human subjects involved in research conducted, funded, or sponsored by DHS.

E. The ***Officer for Civil Rights and Civil Liberties*** ensures that all oversight of research involving human subjects incorporates appropriate civil rights and civil liberties protections.

F. The ***Chief Privacy Officer*** ensures that all oversight of research involving human subjects incorporates appropriate privacy protections.

G. ***DHS Component Heads*** support Department-wide implementation of and compliance with this Directive and the accompanying Instruction.

V. Policy & Requirements

A. ***Policy***:

1. In research conducted, funded, or sponsored by DHS, the safety and protection of human subjects are paramount concerns that are founded on the basic ethical principles of respect for persons, beneficence, and justice. These considerations must also apply to research involving the experimental and/or prototype testing of new or modified systems or similar equipment, using human operators and/or which involve human subjects/individuals as participants.

2. All research involving human subjects conducted, funded, or sponsored by DHS complies with the requirements of the Common Rule.[5]

[5] 45 C.F.R. part 46, subparts A – D

3. DHS Components that conduct, fund, or sponsor research ensure that the research is conducted in an ethical manner and will monitor and review said research according to procedures and standards established by the HSPO.

4. HSR conducted, funded, or sponsored by DHS outside the United States, including that performed or jointly sponsored by a foreign government, complies with U.S. regulatory and legal standards and requirements, unless the standards of the host country are more stringent. All such HSR is reviewed in advance by the HSPO, CMO, and OGC before the commencement of Research.

B. ***Requirements***:

1. All non-exempt activities conducted, funded, or sponsored by DHS involving human subjects are carried out in accordance with this Directive, the accompanying Instruction, and all Authorities in Section III.

2. All HSR (not otherwise exempt) conducted, funded, or sponsored by DHS is accomplished under an Assurance of compliance approved for Federal-wide use by the Office for Human Research Protections.

3. No research involving human subjects is initiated until it has been reviewed and approved by an Institutional Review Board (IRB) operating under a current Federal-wide Assurance, unless it has been determined to be exempt under the provisions of 45 C.F.R. § 46.102(b) by an appropriate official, above the level of a principal investigator, at an accredited IRB or the CAPO.

4. All personnel involved in the conduct, review, or approval of HSR conducted, funded, or sponsored by DHS are made aware of the Human Subjects protection requirements that are commensurate with their duties in the process and compatible with Office for Human Research Protections policies.

5. Issues related to Research-related injuries and noncompliance with this Directive from any DHS Component or activity thereof is referred within 72 hours to the next higher management level and the CAPO, OGC, CMO, and HSPO to resolve, and to the relevant regulatory Agency as required. No action, administrative or disciplinary, is taken against a person for the act of reporting any such noncompliance.

6. Any activities subject to regulation under the Common Rule that are conducted, funded, or sponsored by DHS involving human subjects, which are not submitted for IRB review and CAPO oversight and which result in an adverse impact[6] or effect[7], may be subject to liability or damages under the Federal Tort Claims Act.

To ensure appropriate human subjects protections, accountability, compliance, and oversight measures for all DHS activities, all personnel must conduct themselves in accordance with the responsibilities set forth in this Directive and the accompanying Instruction, as well as with any subsequently developed and properly approved policy, procedure, or guidance.

VI. Questions

Address any questions or concerns regarding this Directive to the Compliance Assurance Program Manager in the Science and Technology Directorate.

Claire M. Grady
Under Secretary for Management

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Date

[6] 6 C.F.R. § 46.103(d)(1), pending final codification.
[7] 6 C.F.R. § 46.116(f)(3)(iv), pending final codification.