

# PROTECTION OF HUMAN SUBJECTS

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## I. Purpose

This Management Directive (MD) establishes the Department of Homeland Security (DHS) policy for the protection of human subjects in research. In particular, this MD adopts the Department of Health and Human Services (HHS) policies and procedures set forth in 45 Code of Federal Regulations (CFR) Part 46, Subparts A-D. Subpart A of 45 CFR Part 46 is HHS' codification of the Federal Policy for the Protection of Human Subjects (also known as The Common Rule) which represents 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 MD applies to all research involving human subjects conducted by any Component, i.e., intramural research, or research sponsored by any Component through a contract, grant, cooperative agreement, cooperative research and development agreement (CRADA), Other Transaction agreement, or other arrangement, i.e., extramural research.

## III. Authorities

- A. Public Law 103-43, "National Institutes of Health Revitalization Act of 1993"
- B. Public Law 108-458, "Intelligence Reform and Terrorism Prevention Act of 2004"
- C. Title 42, U.S.C., Sections 289g – 289g-2, "Fetal Research, Research on Transplantation of Fetal Tissue, and Prohibitions Regarding Human Fetal Tissue"
- D. Title 45, CFR, Part 46, Subpart A, "Basic HHS Policy for Protection of Human Research Subjects (The Common Rule)"
- E. Title 45, CFR, Part 46, Subpart B, "Additional Protections for Pregnant Women, Human Fetuses, and Neonates Involved in Research"

F. Title 45, CFR, Part 46, Subpart C, “Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects”

G. Title 45, CFR, Part 46, Subpart D, “Additional Protections for Children Involved as Subjects in Research”

H. Federal Register (December 6, 2000), Volume 65, Number 235, Pages 76260-76264, “Federal Policy on Research Misconduct, Office of Science and Technology Policy”

## IV. Definitions

Unless otherwise defined herein, definitions of words and phrases in 45 CFR Part 46 apply to this MD:

A. **Assurance**: A written document provided by an institution engaged in research involving human subjects that is conducted or sponsored by a Federal department or agency that has adopted The Common Rule. Through this document, an institution assures the relevant department or agency head that it will comply with the requirements set forth in The Common Rule. For DHS-conducted or -sponsored research, in lieu of requiring submission of an Assurance to DHS, DHS will accept the existence of an Assurance approved for federal wide use (i.e., available to all federal agencies) by the Office for Human Research Protections (OHRP).

B. **Components**: All the entities that directly report to the Office of the Secretary, which includes the Secretary and his or her staff, Counselors and their staff, Deputy Secretary and his or her staff, and Chief of Staff and his or her staff.

C. **Common Rule**: The regulation adopted by multiple Federal Agencies for the protection of human subjects in research. The HHS implementation of the Common Rule is at 45 CFR Part 46, Subpart A.

D. **Extramural Research**: DHS-managed or -funded research that is conducted at non-DHS sites by non-DHS investigators.

E. **Human Subject**: A living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual, or identifiable private information. Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject. "Private information" includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order to obtain the information to constitute research involving human subjects.

F. **Intramural Research**: Research that is conducted at DHS sites or is conducted by DHS personnel.

G. **Institutional Review Board (IRB)**: An IRB established in accord with and for the purposes expressed in The Common Rule.

H. **IRB Approval**: The determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by any other institutional and federal requirements.

I. **Research**: A systematic investigation, including research, development, testing, and evaluation, designed to develop or contribute to general knowledge. Activities, which meet this definition, constitute research for purposes of this policy, whether or not they are conducted or supported under a program, which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

J. **U.S. Department of Health and Human Services, Office for Human Research Protections**: OHRP provides leadership and oversight on all matters related to the protection of human subjects in research conducted or supported by HHS. OHRP helps ensure that such research is carried out in accordance with the highest ethical standards in an environment where all who are involved in the conduct or oversight of human subjects research understand their primary responsibility for protecting the rights, welfare, and well-being of subjects.

## V. Responsibilities

A. The **Secretary of DHS** (the Secretary) exercises ultimate authority and responsibility for DHS with respect to ensuring the safety and protection of human subjects in research conducted or sponsored by DHS.

B. The **Under Secretary for Science and Technology** is designated by the Secretary as the DHS Human Subjects Protection Official (HSPO) and has the authority to fulfill the Secretary's objectives by ensuring that DHS fully understands, implements, and complies with both the letter and spirit of The Common Rule, any other applicable statutory requirements, and the related regulatory mandates to protect human subjects involved in research conducted or supported by DHS. To this end, HSPO may delegate specific authority to train for, monitor, and oversee human use compliance within DHS to activities and offices within the Science and Technology Directorate.

1. In exercising the authority delegated from the Secretary, the HSPO will establish executive oversight. To do so the HSPO will:
  - a. Closely coordinate all programmatic activities with the Chief Medical Officer (CMO) to ensure that all oversight of research involving human subjects incorporates the highest medical and ethical standards.
  - b. Ensure that the Heads of Components incorporate the provisions of this MD into their policies, procedures, and programs that involve the use of human subjects in research as defined herein.
  - c. Exercise any authority for DHS with respect to any requirements of 45 CFR Part 46, Subparts B-D that would require any action by an official of HHS.
  - d. Approve any further DHS-wide policy, procedure, or guidance to ensure the safety and protection of human subjects used in DHS research.
  - e. Develop procedures and standards for the prevention of research misconduct in DHS that are consistent with Federal Policy on Research Misconduct.
  - f. Closely coordinate all programmatic procedures and policies with the Officers for Privacy and Civil Rights and Civil Liberties to ensure that all oversight of research involving human subjects incorporates civil rights and civil liberties protections.
  - g. Consider recommendations for additional plans, policies, and actions with regard to reported issues of research-related injuries and serious noncompliance with this MD and take action as deemed appropriate.

h. Designate a permanent DHS representative to the Interdepartmental Human Subjects Research Subcommittee of the Committee of Science, National Science and Technology Council.

i. Support budget requests to meet the requirements of this MD.

2. To ensure operational compliance the HSPO will:

a. Develop training and training guidance, as needed, to enable the consistent and effective application of human subjects protection policy DHS-wide and conduct such training for DHS.

b. Monitor Component compliance with the provisions of this MD, as appropriate.

c. Approve any policy, procedure, or guidance concerning the safety and protection of human subjects used in DHS research developed by any Component prior to implementation.

d. Collect and store all Assurance requests submitted by Components to and approved by the OHRP, HHS.

e. Monitor remedial action, as appropriate, with regard to reported issues of research-related injuries and serious non-compliance with this MD.

f. Act as the DHS point of contact for the coordination and response to external requests concerning the conduct and support of human subjects research by DHS.

g. Work with the Privacy Office to develop procedures associated with human subjects research to ensure that individual privacy interests are fully respected.

C. **Office of the General Counsel (OGC)** (primarily through counsel at Science and Technology) will:

1. Conduct legal reviews of all DHS activities, including activities conducted under contracts, grants, and cooperative agreements, CRADAs, and Other Transaction agreements, to ensure compliance with applicable federal laws and regulations pertaining to human subjects research.

2. Support along with the CMO the participation of DHS in the Interdepartmental Human Subjects Research Subcommittee of the Committee of Science, National Science and Technology Council, and other affiliated bodies and any other group pertaining to human subjects research.

3. Be responsible along with the CMO for conducting oversight of the policies and procedures of both internal and external IRBs that review human subjects research conducted or funded by DHS.

D. The **CMO** has general responsibility to support the HSPO in the effort to ensure that the DHS fully understands and implements this MD, The Common Rule, any other applicable statutory requirements, and the related regulatory mandates to protect human subjects involved in research conducted or supported by DHS. The CMO will:

1. Assist in establishing agency-wide policies and procedures to ensure effective implementation of The Common Rule for DHS sponsored human subjects research and prior to implementation, review any policy, procedure, or guidance concerning the safety and protection of human subjects used in DHS research.

2. Be responsible along with the OGC for conducting oversight of the policies and procedures of both internal and external IRBs that review human subjects research conducted or funded by DHS.

3. Support along with the OGC the participation of DHS in the Interdepartmental Human Subjects Research Subcommittee of the Committee of Science, National Science and Technology Council, and other affiliated bodies and any other group pertaining to human subjects research.

4. Coordinate the medical response to any research-related injuries or unanticipated problems that involve risks to human subjects.

E. **Components** will ensure that all human subjects research they conduct or sponsor complies with this MD, The Common Rule, any other applicable statutory requirements, and the related regulatory mandates. In exercising this authority, each Component will:

1. Establish, as needed, any further organization-wide policy, procedure, or guidance to ensure the safety and protection of human subjects used in DHS research and submit such policies, procedures, or guidance through the CMO to the HSPO for approval.

2. Monitor compliance with the provisions of this MD.

3. Prepare all required documentation to gain a federal wide assurance and submit it to OHRP for approval.
4. Provide approved Assurance documentation to the HSPO and upon request provide data on all human subjects research to the HSPO.
5. Ensure that all assigned personnel involved in the conduct or sponsorship of human subjects research are fully trained to ensure the protection of said subjects in accordance with the provisions of this MD.
6. Ensure and document that all extramural research involving human subjects research under contracts, grants, cooperative agreements, CRADAs, Other Transaction agreements, and other arrangements is conducted under an assurance of compliance and reviewed by a properly constituted IRB.
7. Ensure that an accredited IRB reviews all research involving human subjects as required by The Common Rule. Components are not expected to constitute their own IRBs given the highly technical nature of membership and detailed record keeping requirements; however, any referrals to outside IRBs shall be coordinated with the HSPO.
8. Ensure that any issues of research-related injuries and serious noncompliance with this MD within the Component are reported to the CMO and HSPO.
9. Forward all external requests concerning the conduct and support of human subjects research through the CMO to the HSPO for coordination and response.

## **VI. Policy & Procedures**

### **A. Policy.**

1. In research conducted or supported 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 will also apply to research that involves the experimental or prototype testing of detection or similar equipment in which humans may pass through some type of energy field.
2. All research involving human subjects conducted or supported by DHS shall comply with the requirements of The Common Rule at 45 CFR Part 46, Subpart A.

3. All research conducted or supported by DHS involving vulnerable classes of subjects including pregnant women, human fetuses, neonates, prisoners, and children will comply with the provisions of 45 CFR Part 46, Subparts B, C, and D.
4. All human subjects research (not otherwise exempt) conducted or supported by DHS will be accomplished under an Assurance of compliance approved for federal wide use by OHRP.
5. No research involving human subjects will be initiated until it has been reviewed and approved by an IRB operating under a current federal-wide assurance, unless it has been determined to be exempt under the provisions of 45 CFR 46.101(b) by an appropriate official, above the level of a principal investigator, at the institution engaged in the research.
6. Any fetal tissue research supported or conducted by DHS will comply with 42 U.S.C. 289g – 289g-2.
7. Components that conduct or support research shall ensure that the research is conducted in an ethical manner and will monitor and review said research in accordance with the procedures and standards established by the HSPO.
8. All DHS personnel involved in the conduct, review, or approval of human subjects research will be made aware of the human subjects protection requirements that are commensurate with their duties in the process and compatible with OHRP policies.
9. Issues related to research-related injuries and noncompliance with this MD from any Component or activity thereof will be referred immediately to the next higher management level, and the OGC, CMO, and HSPO to resolve. No action, administrative or disciplinary, will be taken against a person for the act of reporting any such noncompliance.
10. Human subjects research conducted outside the United States, including that performed or jointly sponsored by a foreign government, will comply with U.S. regulatory and legal standards and requirements, unless the standards of the host country are more stringent. All such human subjects research will be cleared in advance by the HSPO, CMO, and OGC.



B. **Procedures.**

All officials and employees shall conduct themselves in accordance with the responsibilities set forth in Section V as well as with any subsequently developed and properly approved policy, procedure, or guidance to ensure the safety and protection of human subjects used in DHS research.

## **VII. Questions**

Any questions or concerns regarding this MD should be addressed to the Under Secretary for S&T.