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Federal Policy for the Protection of Human Subjects

AGENCIES: Department of Agriculture; Department of Energy; National Aeronautics and Space Administration; Department of Commerce; Consumer Product Safety Commission; Agency for International Development; Department of Justice; Department of Defense; Department of Education; Department of Veterans Affairs; Environmental Protection Agency; Department of Health and Human Services; National Science Foundation; and Department of Transportation.

ACTION: Final rule; technical amendments.

SUMMARY: The agencies listed in this document are amending the Federal Policy for the Protection of Human Subjects, which was published in the **Federal Register** on June 18, 1991, to change all references to the Office for Protection from Research Risks (OPRR) to the Office for Human Research Protections (OHRP); revise the footnote found at the end of § .101(i) by deleting references to research involving fetuses, pregnant women, or human in vitro fertilization and subpart B of 45 CFR part 46; and update the Control Number for the approval by the Office of Management and Budget (OMB) of the information collection requirements of this Federal Policy.

DATES: Effective Date: June 23, 2005.

FOR FURTHER INFORMATION CONTACT: Michael A. Carome, M.D., OHRP, The Tower Building, Suite 200, 1101 Wootton Parkway, Rockville, MD 20852; telephone: 301-496-7005; facsimile: 301-402-2071; e-mail: mcarome@osophs.dhhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The Federal Policy for the Protection of Human Subjects (hereafter referred to as the Federal Policy) was promulgated by 15 Federal departments and agencies on June 18, 1991 (56 FR 28003). The Central Intelligence Agency also is required to comply with this policy under Executive Order 12333. On July 10, 1996, the Department of Housing and Urban Development revised its codification of the Federal Policy at 24 CFR part 60 to cross-reference the provisions of the Department of Health and Human Services (HHS) regulations at 45 CFR part 46, subpart A (61 FR 36462).

Except for research that is exempt under § .101(b), the Federal Policy applies to all research involving human subjects conducted, supported or otherwise subject to regulation by any Federal department or agency which has taken appropriate administrative action to make the Federal Policy applicable to such research. The basic provisions of the Federal Policy include, among other things, requirements related to the review of human subjects research by an institutional review board, the obtaining and documenting of informed consent of human subjects, and the submission of a written assurance of institutional compliance with the Federal Policy.

II. Description of Changes to the Federal Policy

The Federal Policy has several provisions that reference OPRR. For example, the Federal Policy includes provisions that require submission of certain reports and notices to OPRR (see § .101(i), § .103(a), and § .103(b)(3)). At the time the Federal Policy was promulgated, OPRR was a unit of the National Institutes of Health, HHS, and was responsible for fulfilling responsibilities set forth in section 491 of the Public Health Service Act (42 U.S.C. 289). On June 18, 2000, OPRR was dissolved, OHRP was established, and all responsibilities and authorities for human subject protections held by OPRR were transferred to OHRP (65 FR 37136, June 13, 2000). The Federal Policy is being amended throughout to reflect this name and organizational change from OPRR to OHRP.

At the time the Federal Policy was promulgated, the HHS regulations for the protection of human subjects at 45 CFR part 46 included the following

three subparts that provided additional protections for specific groups of vulnerable subjects: subpart B (Additional Protections Pertaining to Research, Development, and Related Activities Involving Fetuses, Pregnant Women, and Human In Vitro Fertilization); subpart C (Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects); and subpart D (Additional Protections for Children Involved as Subjects in Research). These subparts are not part of the Federal Policy. However, the Federal Policy includes a footnote at the end of § _____.101(i) which states, in part, that "the exemptions at 45 CFR 46.101(b) do not apply to research involving * * * fetuses, pregnant women, or human in vitro fertilization, subparts B * * *."

On November 13, 2001, HHS published a revised version of 45 CFR part 46, subpart B (Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research) after soliciting public comment through a Notice of Proposed Rulemaking (66 FR 56775; 66 FR 35576). The revised subpart B, which became effective on December 13, 2001, states that the exemptions at 45 CFR 46.101(b)(1) through (6) are applicable to this subpart. In order to make the footnote at the end of § _____.101(i) of the Federal Policy consistent with the revised subpart B of 45 CFR part 46, references to research involving fetuses, pregnant women, or human in vitro fertilization and subpart B are being deleted from the footnote.

Finally, the information collection requirements of the Federal Policy (see §§ _____.103, 109, 113, 115, 116, and 117) were approved by OMB on July 30, 1991 under Control Number 9999-0020. OMB approval under Control Number 9999-0020 expired on December 31, 1997. The current OMB approval of the information collection requirements of the Federal Policy is under Control Number 0990-0260. Therefore, all references to Control Number 9999-0020 are being changed to Control Number 0990-0260.

III. Implementation

Pursuant to 5 U.S.C. 553(b)(B) of the Administrative Procedure Act, 5 U.S.C. 551-559, the agencies find that there is good cause to issue these amendments without advance notice and an opportunity for public comment. Because these amendments merely (i) change references in the Federal Policy from the OPRR to the OHRP, to reflect the organizational change that already dissolved OPRR and moved its responsibilities to OHRP; (ii) delete

references to research involving fetuses, pregnant women, or human in vitro fertilization and to subpart B of 45 CFR part 46 to conform the Federal Policy to recent amendments to subpart B of 45 CFR part 46; and (iii) update the Control Number for the approval by OMB of the information collection requirements of the Federal Policy, public comment is unnecessary. Pursuant to 5 U.S.C. 553(d)(3) of the Administrative Procedure Act, the agencies also find there is good cause to make these amendments effective immediately because the changes in the Federal Policy are merely conforming amendments to reflect changes that have already been made and are in effect with respect to OHRP and 45 CFR part 46.

IV. Legal Authority

Department of Agriculture, 5 U.S.C. 301; 42 U.S.C. 300v-1(b). Department of Energy, 5 U.S.C. 301; 42 U.S.C. 7254; 42 U.S.C. 300v-1(b). National Aeronautics and Space Administration, 5 U.S.C. 301; 42 U.S.C. 300v-1(b). Department of Commerce, 5 U.S.C. 301; 42 U.S.C. 300v-1(b). Consumer Product Safety Commission, 5 U.S.C. 301; 42 U.S.C. 300v-1(b). Agency for International Development, 5 U.S.C. 301; 42 U.S.C. 300v-1(b). Department of Justice, 5 U.S.C. 301; 28 U.S.C. 509-510; 42 U.S.C. 300v-1(b). Department of Defense, 5 U.S.C. 301; 42 U.S.C. 300v-1(b). Department of Education, 5 U.S.C. 301; 20 U.S.C. 1221e-3, 3474; 42 U.S.C. 300v-1(b). Department of Veterans Affairs, 5 U.S.C. 301; 38 U.S.C. 501, 7331, 7334; 42 U.S.C. 300v-1(b). Environmental Protection Agency, 5 U.S.C. 301; 42 U.S.C. 300v-1(b). Department of Health and Human Services, 5 U.S.C. 301; 42 U.S.C. 289; 42 U.S.C. 300v-1(b). National Science Foundation, 5 U.S.C. 301; 42 U.S.C. 300v-1(b). Department of Transportation, 5 U.S.C. 301; 42 U.S.C. 300v-1(b).

V. Executive Order 12866

Executive Order 12866 requires that all regulatory actions of Executive Branch departments and agencies reflect consideration of the costs and benefits that they generate and that they meet certain standards, such as avoiding imposition of unnecessary burdens on the affected public. If an action is deemed to fall within the scope of the definition of the term "significant regulatory action" contained in Sec. 3(f) of the order, a pre-publication review by OMB's Office of Information and Regulatory Affairs (OIRA) is necessary. OMB deemed these amendments of the Federal Policy not to be a significant regulatory action. Therefore, these

amendments were not submitted to OIRA for review prior to publication.

VI. Regulatory Flexibility Act

Under the Regulatory Flexibility Act (5 U.S.C. 601-612), an agency is generally required to review proposed regulations to analyze whether they create a significant impact on a substantial number of small entities unless the agency can certify that there is no such impact. Agencies must similarly analyze any final rules that were preceded by proposed rules. Because these technical amendments did not require the agencies to publish a proposed rule, they are not required to prepare a Regulatory Flexibility Act analysis for this final rule. However, even if the agencies were required to consider that impact, the agencies would certify that there was no impact at all on small entities because these amendments make no substantive change to the Federal Policy.

VII. Paperwork Reduction Act of 1995

These amendments to the Federal Policy do not contain any new information collection requirements which are subject to OMB approval under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520).

VIII. Federalism

These amendments to the Federal Policy have been analyzed in accordance with the principles set forth in Executive Order 13132. These amendments to the Federal Policy do not contain policies that have substantial direct effects on the States, on the relationship between the Federal Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the departments and agencies that have promulgated the Federal Policy have concluded that these amendments do not contain policies that have federalism implications as defined in the order and, consequently, a federalism summary impact statement is not required.

Department of Agriculture

7 CFR Part 1c

RIN 0518-AA02

List of Subjects in 7 CFR Part 1c

Human research subjects, Reporting and recordkeeping requirements, Research.

For the reasons stated in the preamble, the Department of Agriculture amends 7 CFR part 1c, as set forth at the end of this document.

The authority for part 1c continues to read as follows:

Authority: 5 U.S.C. 301; 42 U.S.C. 300v–1(b).

Dated: August 18, 2004.

Ann M. Veneman,
Secretary of Agriculture.

Department of Energy

10 CFR Part 745

RIN 1901–AB14

List of Subjects in 10 CFR Part 745

Human research subjects, Reporting and recordkeeping requirements, Research.

For the reasons stated in the preamble, the Department of Energy amends 10 CFR part 745, as set forth at the end of this document.

The authority for part 745 continues to read as follows:

Authority: 5 U.S.C. 301; 42 U.S.C. 7254; 42 U.S.C. 300v–1(b).

Dated: April 5, 2005.

Samuel W. Bodman,
Secretary of Energy.

National Aeronautics and Space Administration

14 CFR Part 1230

RIN 2700–AC99

List of Subjects in 14 CFR Part 1230

Human research subjects, Reporting and recordkeeping requirements, Research.

For the reasons stated in the preamble, the National Aeronautics and Space Administration amends 14 CFR part 1230, as set forth at the end of this document.

The authority for part 1230 continues to read as follows:

Authority: 5 U.S.C. 301; 42 U.S.C. 300v–1(b).

Dated: February 18, 2005.

Richard S. Williams,
Chief Health and Medical Officer, Office of Health and Medical Systems.

Department of Commerce

15 CFR Part 27

RIN 0605–AA17

List of Subjects in 15 CFR Part 27

Human research subjects, Reporting and recordkeeping requirements, Research.

For the reasons stated in the preamble, the Department of Commerce amends 15 CFR part 27, as set forth at the end of this document.

The authority for part 27 continues to read as follows:

Authority: 5 U.S.C. 301; 42 U.S.C. 300v–1(b).

Dated: February 18, 2005.

Michael S. Sade,
Director, Office of Acquisition Management.

Consumer Product Safety Commission

16 CFR Part 1028

RIN 3041–AC21

List of Subjects in 16 CFR Part 1028

Human research subjects, Reporting and recordkeeping requirements, Research.

For the reasons stated in the preamble, the Consumer Product Safety Commission amends 16 CFR part 1028, as set forth at the end of this document.

The authority for part 1028 continues to read as follows:

Authority: 5 U.S.C. 301; 42 U.S.C. 300v–1(b).

Dated: July 22, 2004.

Harold D. Stratton,
Chairman.

Agency for International Development

22 CFR Part 225

RIN 0412–AA53

List of Subjects in 22 CFR Part 225

Human research subjects, Reporting and recordkeeping requirements, Research.

For the reasons stated in the preamble, the Agency for International Development amends 22 CFR part 225, as set forth at the end of this document.

The authority for part 225 continues to read as follows:

Authority: 5 U.S.C. 301; 42 U.S.C. 300v–1(b).

Dated: June 10, 2004.

James D. Shelton,
Cognizant Human Subjects Officer.

Department of Justice

28 CFR Part 46

RIN 1121–AA70

List of Subjects in 28 CFR Part 46

Human research subjects, Reporting and recordkeeping requirements, Research.

For the reasons stated in the preamble, the Department of Justice amends 28 CFR part 46, as set forth at the end of this document.

The authority for part 46 continues to read as follows:

Authority: 5 U.S.C. 301; 28 U.S.C. 509–510; 42 U.S.C. 300v–1(b).

Dated: March 14, 2005.

Alberto R. Gonzales,
Attorney General.

Department of Defense

32 CFR Part 219

RIN 0790–AH79

List of Subjects in 32 CFR Part 219

Human research subjects, Reporting and recordkeeping requirements, Research.

For the reasons stated in the preamble, the Department of Defense amends 32 CFR part 219, as set forth at the end of this document.

The authority for part 219 continues to read as follows:

Authority: 5 U.S.C. 301; 42 U.S.C. 300v–1(b).

Dated: August 4, 2004.

Ronald M. Sega,
Director, Defense Research and Engineering.

Department of Education

34 CFR Part 97

RIN 1890–AA08

List of Subjects in 34 CFR Part 97

Human research subjects, Reporting and recordkeeping requirements, Research.

For the reasons stated in the preamble, the Department of Education amends 34 CFR part 97, as set forth at the end of this document.

The authority for part 97 continues to read as follows:

Authority: 5 U.S.C. 301; 20 U.S.C. 1221e–3, 3474; 42 U.S.C. 300v–1(b).

Dated: June 30, 2004.

Rod Paige,
Secretary of Education.

Department of Veterans Affairs

38 CFR Part 16

RIN 2900–AL99

List of Subjects in 38 CFR Part 16

Human research subjects, Reporting and recordkeeping requirements, Research.

For the reasons stated in the preamble, the Department of Veterans Affairs amends 38 CFR part 16, as set forth at the end of this document.

The authority for part 16 continues to read as follows:

Authority: 5 U.S.C. 301; 38 U.S.C. 501, 7331, 7334; 42 U.S.C. 300v–1(b).

Dated: August 27, 2004.

Anthony J. Principi,
Secretary of Veterans Affairs.

Environmental Protection Agency

40 CFR Part 26

RIN 2080-AA10

List of Subjects in 40 CFR Part 26

Human research subjects, Reporting and recordkeeping requirements, Research.

For the reasons stated in the preamble, the Environmental Protection Agency amends 40 CFR part 26, as set forth at the end of this document.

The authority for part 26 continues to read as follows:

Authority: 5 U.S.C. 301; 42 U.S.C. 300v-1(b).

Dated: May 16, 2005.

Stephen L. Johnson,
Acting Administrator.

Department of Health and Human Services

45 CFR Part 46

RIN 0940-AA10

List of Subjects in 45 CFR Part 46

Human research subjects, Reporting and recordkeeping requirements, Research.

For the reasons stated in the preamble, the Department of Health and Human Services amends 45 CFR part 46, as set forth at the end of this document.

The authority for part 46 continues to read as follows:

Authority: 5 U.S.C. 301; 42 U.S.C. 289; 42 U.S.C. 300v-1(b).

Dated: June 15, 2005.

Ann Agnew,
Executive Secretary to the Department.

National Science Foundation

45 CFR Part 690

RIN 3145-AA42

List of Subjects in 45 CFR Part 690

Human research subjects, Reporting and recordkeeping requirements, Research.

For the reasons stated in the preamble, the National Science Foundation amends 45 CFR part 690, as set forth at the end of this document.

The authority for part 690 continues to read as follows:

Authority: 5 U.S.C. 301; 42 U.S.C. 300v-1(b).

Dated: June 30, 2004.

Lawrence Rudolph,
General Counsel.

Department of Transportation

49 CFR Part 11

RIN 2105-XX97

List of Subjects in 49 CFR Part 11

Human research subjects, Reporting and recordkeeping requirements, Research.

For the reasons stated in the preamble, the Department of Transportation amends 49 CFR part 11, as set forth at the end of this document.

The authority for part 11 continues to read as follows:

Authority: 5 U.S.C. 301; 42 U.S.C. 300v-1(b).

Dated: September 18, 2004.

Norman Y. Mineta,
Secretary of Transportation.

Editorial Note: This document was received at the Office of the Federal Register on June 17, 2005.

■ Accordingly, the Federal Policy for the Protection of Human Subjects is amended as follows:

§ _____.101 [Amended]

■ 1. Amend § _____.101 as follows:

■ a. In paragraph (i), remove the words “Office for Protection from Research Risks, Department of Health and Human Services (HHS),” and add, in their place, “Office for Human Research Protections, Department of Health and Human Services (HHS), or any successor office,”.

■ b. In footnote 1 at the end of paragraph (i), remove the words “prisoners, fetuses, pregnant women, or human in vitro fertilization, subparts B and C.” and add, in their place, “prisoners, subpart C.”.

§ _____.103 [Amended]

■ 2. Amend § _____.103 as follows:

■ a. In paragraph (a), in the second and last sentences, remove the words, “Office for Protection from Research Risks, HHS” and add, in their place, “Office for Human Research Protections, HHS, or any successor office”.

■ b. In paragraph (b)(3), remove the words “Office for Protection from Research Risks, HHS” and add, in their place, “Office for Human Research Protections, HHS, or any successor office”.

■ c. Revise the parenthetical at the end of the section to read as follows:

§ _____.103 Assuring compliance with this policy—research conducted or supported by any Federal Department or Agency.

* * * * *

(Approved by the Office of Management and Budget under Control Number 0990-0260.)

■ 3. Revise the parenthetical at the end of § _____.109 to read as follows:
§ _____.109 IRB review of research.

* * * * *

(Approved by the Office of Management and Budget under Control Number 0990-0260.)

§ _____.110 [Amended]

■ 4. In paragraph (a), remove the words “Office for Protection from Research Risks, National Institutes of Health, HHS, Bethesda, Maryland 20892.” and add, in their place, “Office for Human Research Protections, HHS, or any successor office.”.

■ 5. Revise the parenthetical at the end of § _____.113 to read as follows:

§ _____.113 Suspension or termination of IRB approval of research.

* * * * *

(Approved by the Office of Management and Budget under Control Number 0990-0260.)

■ 6. Revise the parenthetical at the end of § _____.115 to read as follows:

§ _____.115 IRB records.

* * * * *

(Approved by the Office of Management and Budget under Control Number 0990-0260.)

■ 7. Revise the parenthetical at the end of § _____.116 to read as follows:

§ _____.116 General requirements for informed consent.

* * * * *

(Approved by the Office of Management and Budget under Control Number 0990-0260.)

■ 8. Revise the parenthetical at the end of § _____.117 to read as follows:

§ _____.117 Documentation of informed consent.

* * * * *

(Approved by the Office of Management and Budget under Control Number 0990-0260.)

[FR Doc. 05-12394 Filed 6-22-05; 8:45 am]

BILLING CODE 4150-36-P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Part 301

[Docket No. 05-005-2]

Citrus Canker; Quarantined Areas

AGENCY: Animal and Plant Health Inspection Service, USDA.