and final approval given to the proposed change by the department or agency.

§ ___.120 Evaluation and disposition of applications and proposals for research to be conducted or supported by a Federal Department or Agency.

The department or agency head will evaluate all applications and proposals involving human subjects submitted to the department or agency through such officers and employees of the department or agency and such experts and consultants as the department or agency head determines to be appropriate. This evaluation will take into consideration the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained.

(b) On the basis of this evaluation, the department or agency head may approve or disapprove the application or proposal, or enter into negotiations to develop an approvable one.

§ ___.121 [Reserved]

§ ___.122 Use of Federal funds.

Federal funds administered by a department or agency may not be expended for research involving human subjects unless the requirements of this policy have been satisfied.

§ ___.123 Early termination of research support: Evaluation of applications and proposals.

(a) The department or agency head may require that department or agency support for any project be terminated or suspended in the manner prescribed in applicable program requirements, when the department or agency head finds an institution has materially failed to comply with the terms of this policy.

(b) In making decisions about supporting or approving applications or proposals covered by this policy the department or agency head may take into account, in addition to all other eligibility requirements and program criteria, factors such as whether the applicant has been subject to a termination or suspension under paragarph (a) of this section and whether the applicant or the person or persons who would direct or has have directed the scientific and technical aspects of an activity has have, in the judgment of the department or agency head, materially failed to discharge responsibility for the protection of the rights and welfare of human subjects (whether or not the research was subject to federal regulation).

§ ___.124 Conditions.

With respect to any research project or any class of research projects the department or agency head may impose additional conditions prior to or at the time of approval when in the judgment of the department or agency head additional conditions are necessary for the protection of human subjects.

DEPARTMENT OF AGRICULTURE

7 CFR Part 1c

RIN 0518-AA00

List of Subjects in 7 CFR Part 1c

Human subjects, Research, Reporting and record keeping requirements. Title 7 of the Code of Federal Regulations is amended by adding part 1c as set forth at the end of this document.[1]

PART 1c PROTECTION OF HUMAN SUBJECTS

Sec.

1c.101 To what does this policy apply?
1c.102 Definitions.
1c.103 Assuring compliance with this policy—research conducted or supported by any Federal Department or Agency.
1c.104 [Reserved]
1c.105 [Reserved]
1c.106 [Reserved]
1c.107 IRB Membership.
1c.108 IRB functions and operations.
1c.109 IRB review of research.
1c.110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.
1c.111 Criteria for IRB approval of research.
1c.112 Review by institution.
1c.113 Suspension or termination of IRB approval of research.
1c.114 Cooperative research.
1c.115 IRB records.
1c.116 General requirements for informed consent.
1c.117 Documentation of informed consent.
1c.118 Applications and proposals lacking definite plans for involvement of human subjects.
1c.119 Research undertaken without the intention of involving human subjects.
1c.120 Evaluation and disposition of applications and proposals for research to be conducted or supported by a Federal Department or Agency.
1c.121 [Reserved]
1c.122 Use of Federal funds.
1c.123 Early termination of research support: Evaluation of applications and proposals.
1c.124 Conditions.

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

Dated: December 13, 1990.

Charles E. Hess,

Assistant Secretary, Science & Education.

[1] See Footnote 1 on page 28023.

DEPARTMENT OF ENERGY

10 CFR Part 745

RIN 1901-AA13

List of Subjects in 10 CFR Part 745

Human subjects, Research, reporting, and Record-keeping requirements. Title 10 of the Code of Federal Regulations is amended by revising part 745 as set forth at the end of this document.[1]

PART 745 PROTECTION OF HUMAN SUBJECTS

Sec.

745.101 To what does this policy apply?
745.102 Definitions.
745.103 Assuring compliance with this policy—research conducted or supported by any Federal Department or Agency.
745.104 [Reserved]
745.105 [Reserved]
745.106 [Reserved]
745.107 IRB Membership.
745.108 IRB functions and operations.
745.109 IRB review of research.
745.110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.
745.111 Criteria for IRB approval of research.
745.112 Review by institution.
745.113 Suspension or termination of IRB approval of research.
745.114 Cooperating research.
745.115 IRB records.
745.116 General requirements for informed consent.
745.117 Documentation of informed consent.
745.118 Applications and proposals lacking definite plans for involvement of human subjects.
745.119 Research undertaken without the intention of involving human subjects.
745.120 Evaluation and disposition of applications and proposals for research to be conducted or supported by a Federal Department or Agency.
745.121 [Reserved]
745.122 Use of Federal funds.
745.123 Early termination of research support: Evaluation of applications and proposals.
745.124 Conditions.

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

Dated: December 21, 1990.

James D. Watkins,

Secretary of Energy.

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

14 CFR Part 1230

RIN 2700-AA76

List of Subjects in 14 CFR Part 1230

Human subjects, Research, Reporting and Record-keeping requirements. Title 14 of the Code of Federal Regulations is amended by adding part 1230 as set forth at the end of this document.[1]

PART 1230 PROTECTION OF HUMAN SUBJECTS

Sec.

1230.101 To what does this policy apply?
1230.102 Definitions.
1230.103 Assuring compliance with this policy—research conducted or supported by any Federal Department or Agency.
1230.104 [Reserved]
1230.105 [Reserved]
1230.106 [Reserved]
1230.107 IRB Membership.
1230.108 IRB functions and operations.
1230.109 IRB review of research.
1230.110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.
1230.111 Criteria for IRB approval of research.
1230.112 Review by institution.
1230.113 Suspension or termination of IRB approval of research.
1230.114 Cooperative research.
1230.115 IRB records.
1230.116 General requirements for informed consent.
1230.117 Documentation of informed consent.
1230.118 Applications and proposals lacking definite plans for involvement of human subjects.
1230.119 Research undertaken without the intention of involving human subjects.
1230.120 Evaluation and disposition of applications and proposals for research to be conducted or supported by a Federal Department or Agency.
1230.121 [Reserved]
1230.122 Use of Federal funds.
1230.123 Early termination of research support: Evaluation of applications and proposals.
1230.124 Conditions.

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

[1]See Footnote 1 on page 28023.

Dated: December 20, 1990.

Richard H. Truly

Administrator.

DEPARTMENT OF COMMERCE

15 CFR Part 27

RIN 0690-AA17

List of Subjects in 15 CFR Part 27

Human subjects, Research, Reporting and recordkeeping requirements. Title 15 of the Code of Federal Regulations is amended by adding part 27 as set forth at the end of this document.[1]

PART 27 PROTECTION OF HUMAN SUBJECTS

Sec.

27.101 To what does this policy apply?
27.102 Definitions.
27.103 Assuring compliance with this policy—research conducted or supported by any Federal Department or Agency.
27.104 [Reserved]
27.105 [Reserved]
27.106 [Reserved]
27.107 IRB Membership.
27.108 IRB functions and operations.
27.109 IRB review of research.
27.110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.
27.111 Criteria for IRB approval of research.
27.112 Review by institution.
27.113 Suspension or termination of IRB approval of research.
27.114 Cooperative research.
27.115 IRB records.
27.116 General requirements for informed consent.
27.117 Documentation of informed consent.
27.118 Applications and proposals lacking definite plans for involvement of human subjects.
27.119 Research undertaken without the intention of involving human subjects.
27.120 Evaluation and disposition of applications and proposals for research to be conducted or supported by a Federal Department or Agency.
27.121 [Reserved]
27.122 Use of Federal funds.
27.123 Early termination of research support: Evaluation of applications and proposals.
27.124 Conditions.

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

Dated: December 21, 1990.

Robert Mosbacher,

Secretary of Commerce.

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1028

RIN 3041-AA95

List of Subjects in 16 CFR Part 1028

Human subjects, Research, Reporting and recordkeeping requirements. Title 16 of the Code of Federal Regulations is amended by revising part 1028 as set forth at the end of this document.[1]

PART 1028 PROTECTION OF HUMAN SUBJECTS

Sec.

1028.101 To what does this policy apply?
1028.102 Definitions.
1028.103 Assuring compliance with this policy—research conducted or supported by any Federal Department or Agency.
1028.104 [Reserved]
1028.105 [Reserved]
1028.106 [Reserved]
1028.107 IRB Membership.
1028.108 IRB functions and operations.
1028.109 IRB review of research.
1028.110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.
1028.111 Criteria for IRB approval of research.
1028.112 Review by institution.
1028.113 Suspension or termination of IRB approval of research.
1028.114 Cooperative research.
1028.115 IRB records.
1028.116 General requirements for informed consent.
1028.117 Documentation of informed consent.
1028.118 Applications and proposals lacking definite plans for involvement of human subjects.
1028.119 Research undertaken without the intention of involving human subjects.
1028.120 Evaluation and disposition of applications and proposals for research to be conducted or supported by a Federal Department or Agency.
1028.121 [Reserved]
1028.122 Use of Federal funds.
1028.123 Early termination of research support: Evaluation of applications and proposals.
1028.124 Conditions.

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

Dated: January 11, 1991.

Sheldon D. Butts,

Acting Secretary.

INTERNATIONAL DEVELOPMENT COOPERATION AGENCY, AGENCY FOR INTERNATIONAL DEVELOPMENT

22 CFR Part 225

RIN 0412-AA17

List of Subjects in 22 CFR Part 225

Human subjects, Research, Reporting and record-keeping requirements. Title 22 of the Code of Federal Regulations is amended by adding part 225 at set forth at the end of this document.[1]

PART 225 PROTECTION OF HUMAN SUBJECTS

Sec.

225.101 To what does this policy apply?
225.102 Definitions.
225.103 Assuring compliance with this policy—research conducted or supported by any Federal Department or Agency.
225.104 [Reserved]
225.105 [Reserved]
225.106 [Reserved]
225.107 IRB Membership.
225.108 IRB functions and operations.
225.109 IRB review of research.
225.110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.
225.111 Criteria for IRB approval of research.
225.112 Review by institution.
225.113 Suspension or termination of IRB approval of research.
225.114 Cooperative research.
225.115 IRB records.
225.116 General requirements for informed consent.
225.117 Documentation of informed consent.
225.118 Applications and proposals lacking definite plans for involvement of human subjects.
225.119 Research undertaken without the intention of involving human subjects.
225.120 Evaluation and disposition of applications and proposals for research to be conducted or supported by a Federal Department or Agency.
225.121 [Reserved]
225.122 Use of Federal funds.
225.123 Early termination of research support: Evaluation of applications and proposals.
225.124 Conditions.

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

[1]See Footnote 1 on page 28023.

Dated: December 13, 1990.

Richard E. Bissell,

Assistant Administrator for Science and Technology.

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Part 60

RIN 2501-AA15

List of Subjects in 24 CFR Part 60

Human subjects, Research, Reporting and record-keeping requirements. Title 24 of the Code of Federal Regulations is amended by adding part 60 as set forth at the end of this document.[1]

PART 60 PROTECTION OF HUMAN SUBJECTS

Sec.

60.101 To what does this policy apply?
60.102 Definitions.
60.103 Assuring compliance with this policy—research conducted or supported by any Federal Department or Agency.
60.104 [Reserved]
60.105 [Reserved]
60.106 [Reserved]
60.107 IRB Membership.
60.108 IRB functions and operations.
60.109 IRB review of research.
60.110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.
60.111 Criteria for IRB approval of research.
60.112 Review by institution.
60.113 Suspension or termination of IRB approval of research.
60.114 Cooperative research.
60.115 IRB records.
60.116 General requirements for informed consent.
60.117 Documentation of informed consent.
60.118 Applications and proposals lacking definite plans for involvement of human subjects.
60.119 Research undertaken without the intention of involving human subjects.
60.120 Evaluation and disposition of applications and proposals for research to be conducted or supported by a Federal Department or Agency.
60.121 [Reserved]
60.122 Use of Federal funds.
60.123 Early termination of research support: Evaluation of applications and proposals.
60.124 Conditions.

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

Dated: January 16, 1991.

Jack Kemp,

Secretary, U.S. Department of Housing and Urban Development.

DEPARTMENT OF JUSTICE

28 CFR Part 46

RIN 1105-AA13

List of Subjects in 28 CFR Part 46

Human subjects, Research, Reporting and record-keeping requirements.

Title 28 of the Code of Federal Regulations is amended by adding part 46 as set forth at the end of this document.[1]

PART 46—PROTECTION OF HUMAN SUBJECTS

Sec.

46.101 To what does this policy apply?
46.102 Definitions.
46.103 Assuring compliance with this policy—research conducted or supported by any Federal Department or Agency.
46.104 [Reserved]
46.105 [Reserved]
46.106 [Reserved]
46.107 IRB Membership.
46.108 IRB functions and operations.
46.109 IRB review of research.
46.110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.
46.111 Criteria for IRB approval of research.
46.112 Review by institution.
46.113 Suspension or termination of IRB approval of research.
46.114 Cooperative research.
46.115 IRB records.
46.116 General requirements for informed consent.
46.117 Documentation of informed consent.
46.118 Applications and proposals lacking definite plans for involvement of human subjects.
46.119 Research undertaken without the intention of involving human subjects.
46.120 Evaluation and disposition of applications and proposals for research to be conducted or supported by a Federal Department or Agency.
46.121 [Reserved]
46.122 Use of Federal funds.
46.123 Early termination of research support: Evaluation of applications and proposals.
46.124 Conditions.

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

Dated: December 24, 1990.

Dick Thornburgh,

Attorney General.

DEPARTMENT OF DEFENSE

32 CFR Part 219

RIN 0790-AC80

List of Subjects in 32 CFR Part 219

Human subjects, Research, Reporting and record-keeping requirements.

Title 32 of the Code of Federal Regulations is amended by revising part 219 as set forth at the end of this document.[1]

PART 219—PROTECTION OF HUMAN SUBJECTS

Sec.

219.101 To what does this policy apply?
219.102 Definitions.
219.103 Assuring compliance with this policy—research conducted or supported by any Federal Department or Agency.
219.104 [Reserved]
219.105 [Reserved]
219.106 [Reserved]
219.107 IRB Membership.
219.108 IRB functions and operations.
219.109 IRB review of research.
219.110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.
219.111 Criteria for IRB approval of research
219.112 Review by institution.
219.113 Suspension or termination of IRB approval of research.
219.114 Cooperative research.
219.115 IRB records.
219.116 General requirements for informed consent.
219.117 Documentation of informed consent.
219.118 Applications and proposals lacking definite plans for involvement of human subjects.
219.119 Research undertaken without the intention of involving human subjects.
219.120 Evaluation and disposition of applications and proposals for research to be conducted or supported by a Federal Department or Agency.
219.121 [Reserved]
219.122 Use of Federal funds.
219.123 Early termination of research support: Evaluation of applications and proposals.
219.124 Conditions.

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

[1] See Footnote 1 on page 28023.

Dated: January 9, 1991.

Linda M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

DEPARTMENT OF EDUCATION

34 CFR Part 97

RIN 1875-AA07

List of Subjects in 34 CFR Part 97

Human subjects, Research, Reporting and record-keeping requirements.

Title 34 of the Code of Federal Regulations is amended by adding part 97 as set forth at the end of this document.[1]

PART 97—PROTECTION OF HUMAN SUBJECTS

Sec.

97.101 To what does this policy apply?
97.102 Definitions.
97.103 Assuring compliance with this policy-research conducted or supported by any Federal Department or Agency.
97.104 [Reserved]
97.105 [Reserved]
97.106 [Reserved]
97.107 IRB Membership.
97.108 IRB functions and operations.
97.109 IRB review of research.
97.110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.
97.111 Criteria for IRB approval of research.
97.112 Review by institution.
97.113 Suspension or termination of IRB approval of research.
97.114 Cooperative research.
97.115 IRB records.
97.116 General requirements for informed consent.
97.117 Documentation of informed consent.
97.118 Applications and proposals lacking definite plans for involvement of human subjects.
97.119 Research undertaken without the intention of involving human subjects.
97.120 Evaluation and disposition of applications and proposals for research to be conducted or supported by a Federal Department or Agency.
97.121 [Reserved]
97.122 Use of Federal funds.
97.123 Early termination of research support: Evaluation of applications and proposals.
97.124 Conditions.

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

Dated: June 6, 1991.

Lamar Alexander,

U.S. Secretary of Education.

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 16

RIN 2900-AE29

List of Subjects in 38 CFR Part 16

Human subjects, Research, Reporting and record-keeping requirements.

Title 38 of the Code of Federal Regulations is amended by adding part 16 as set forth at the end of this document.[1]

PART 16—PROTECTION OF HUMAN SUBJECTS

Sec.

16.101 To what does this policy apply?
16.102 Definitions.
16.103 Assuring compliance with this policy-research conducted or supported by any Federal Department or Agency.
16.104 [Reserved]
16.105 [Reserved]
16.106 [Reserved]
16.107 IRB Membership.
16.108 IRB functions and operations.
16.109 IRB review of research.
16.110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.
16.111 Criteria for IRB approval of research.
16.112 Review by institution.
16.113 Suspension or termination of IRB approval of research.
16.114 Cooperative research.
16.115 IRB records.
16.116 General requirements for informed consent.
16.117 Documentation of informed consent.
16.118 Applications and proposals lacking definite plans for involvement of human subjects.
16.119 Research undertaken without the intention of involving human subjects.
16.120 Evaluation and disposition of applications and proposals for research to be conducted or supported by a Federal Department or Agency.
16.121 [Reserved]
16.122 Use of Federal funds.
16.123 Early termination of research support: Evaluation of applications and proposals.
16.124 Conditions.

Authority: 5 U.S.C. 301; 38 U.S.C. 210(c)(1), 4131, 4134; 42 U.S.C. 300v–1(b).

Dated: February 19, 1991.

Edward J. Derwinski

Secretary of Veterans Affairs.

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 26

RIN 2080–AA04

List of Subjects in 40 CFR Part 26

Human subjects, Research, Reporting and record-keeping requirements.

Title 40 of the Code of Federal Regulations is amended by adding part 26 as set forth at the end of this document.[1]

PART 26—PROTECTION OF HUMAN SUBJECTS

Sec.

26.101 To what does this policy apply?
26.102 Definitions.
26.103 Assuring compliance with this policy—research conducted or supported by any Federal Department or Agency.
26.104 [Reserved]
26.105 [Reserved]
26.106 [Reserved]
26.107 IRB Membership.
26.108 IRB functions and operations.
26.109 IRB review of research.
26.110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.
26.111 Criteria for IRB approval of research.
26.112 Review by institution.
26.113 Suspension or termination of IRB approval of research.
26.114 Cooperative research.
26.115 IRB records.
26.116 General requirements for informed consent.
26.117 Documentation of informed consent.
26.118 Applications and proposals lacking definite plans for involvement of human subjects.
26.119 Research undertaken without the intention of involving human subjects.
26.120 Evaluation and disposition of applications and proposals for research to be conducted or supported by a Federal Department or Agency.
26.121 [Reserved]
26.122 Use of Federal funds.
26.123 Early termination of research support: Evaluation of applications and proposals.
26.124 Conditions.

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

[1] See Footnote 1 on page 28023.

Dated: January 28, 1991.

William K. Reilly,

Administrator.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 46

RIN 0991–AA71

List of Subjects in 45 CFR Part 46

Human subjects, Research, Reporting and record-keeping requirements.

Title 45 of the Code of Federal Regulations part 46 is amended, as follows:

1. An authority citation for subpart A is added to read as follows:

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

2. Subpart A is revised to read as set forth at the end of this document.[1]

PART 46—PROTECTION OF HUMAN SUBJECTS

Subpart A—Basic HHS Policy for Protection of Human Research Subjects

Sec.

46.101 To what does this policy apply?
46.102 Definitions.
46.103 Assuring compliance with this policy—research conducted or supported by any Federal Department or Agency.
46.104 [Reserved]
46.105 [Reserved]
46.106 [Reserved]
46.107 IRB Membership.
46.108 IRB functions and operations.
46.109 IRB review of research.
46.110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.
46.111 Criteria for IRB approval of research.
46.112 Review by institution.
46.113 Suspension or termination of IRB approval of research.
46.114 Cooperative research.
46.115 IRB records.
46.116 General requirements for informed consent.
46.117 Documentation of informed consent.
46.118 Applications and proposals lacking definite plans for involvement of human subjects.
46.119 Research undertaken without the intention of involving human subjects.
46.120 Evaluation and disposition of applications and proposals for research to be conducted or supported by a Federal Department or Agency.
46.121 [Reserved]
46.122 Use of Federal funds.
46.123 Early termination of research support: Evaluation of applications and proposals.
46.124 Conditions.

Dated: March 29, 1991.

Louis W. Sullivan,

Secretary of Health and Human Services.

NATIONAL SCIENCE FOUNDATION

45 CFR Part 690

RIN 3145–AA18

List of Subjects in 45 CFR Part 690

Human subjects, Research, Reporting and record-keeping requirements.

Title 45 of the Code of Federal Regulations is amended by adding part 690 as set forth at the end of this document.[1]

PART 690—PROTECTION OF HUMAN SUBJECTS

Sec.

690.101 To what does this policy apply?
690.102 Definitions.
690.103 Assuring compliance with this policy—research conducted or supported by any Federal Department or Agency.
690.104 [Reserved]
690.105 [Reserved]
690.106 [Reserved]
690.107 IRB Membership.
690.108 IRB functions and operations.
690.109 IRB review of research.
690.110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.
690.111 Criteria for IRB approval of research.
690.112 Review by institution.
690.113 Suspension or termination of IRB approval of research.
690.114 Cooperative research.
690.115 IRB records.
690.116 General requirements for informed consent.
690.117 Documentation of informed consent.
690.118 Applications and proposals lacking definite plans for involvement of human subjects.
690.119 Research undertaken without the intention of involving human subjects.
690.120 Evaluation and disposition of applications and proposals for research to be conducted or supported by a Federal Department or Agency.
690.121 [Reserved]
690.122 Use of Federal funds.
690.123 Early termination of research support: Evaluation of applications and proposals.
690.124 Conditions.

Dated: December 17, 1990.

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

Frederick M. Bernthal,

Acting Director.

DEPARTMENT OF TRANSPORTATION

49 CFR Part 11

RIN 2105–AB74

List of Subjects in 49 CFR Part 11

Human subjects, Research, Reporting and record-keeping requirements.

Title 49 of the Code of Federal Regulations is amended by adding part 11 as set forth at the end of this document.[1]

[1]Due to an error in the order of the document pages submitted to the Office of the Federal Register, the text of the common rule appears at the end of the common preamble for this document at page 28012.

PART 11—PROTECTION OF HUMAN SUBJECTS

Sec.

11.101 To what does this policy apply?
11.102 Definitions.
11.103 Assuring compliance with this policy—research conducted or supported by any Federal Department or Agency.
11.104 [Reserved]
11.105 [Reserved]
11.106 [Reserved]
11.107 IRB Membership.
11.108 IRB functions and operations.
11.109 IRB review of research.
11.110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.
11.111 Criteria for IRB approval of research.
11.112 Review by institution.
11.113 Suspension or termination of IRB approval of research.
11.114 Cooperative research.
11.115 IRB records.
11.116 General requirements for informed consent.
11.117 Documentation of informed consent.
11.118 Applications and proposals lacking definite plans for involvement of human subjects.
11.119 Research undertaken without the intention of involving human subjects.
11.120 Evaluation and disposition of applications and proposals for research to be conducted or supported by a Federal Department or Agency.
11.121 [Reserved]
11.122 Use of Federal funds.
11.123 Early termination of research support: Evaluation of applications and proposals.
11.124 Conditions.

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

Dated: February 4, 1991.

Samuel K. Skinner,

Secretary of Transportation.

[FR Doc. 91–14258 Filed 6–17–91; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Agency Forms Submitted to the Office of Management and Budget for Clearance

The following request has been submitted to the Office of Management and Budget (OMB) for clearance in compliance with the Paperwork Reduction Act (44 U.S.C. chapter 35). Expedited review by OMB has been requested as described below.

(Call PHS Reports Clearance Officer on 202–245–2100 for copies of submission)

Federal Policy for the Protection of Human Subjects—New—This submission is for approval of the information requirements associated with the common rule for the protection of human subjects of research conducted, supported or regulated by the following Federal departments and 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 Housing and Urban Development, Department of Justice, Department of Defense, Department of Education, Department of Veterans' Affairs, Environmental Protection Agency, Department of Transportation, Central Intelligence Agency, and Department of Health and Human Services.

Adoption of the common Federal policy by these departments and agencies will implement a recommendation of the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research. The Office of Science and Technology Policy established an Interagency Human Subjects Coordinating Committee under the Federal Coordinating Council for Science Engineering and Technology. This group prepared a proposed Model Federal Policy for the Protection of Human Subjects that was published as a proposed policy in 1986 and again as a proposed common rule on November 10, 1988. After revision of the proposed common rule in response to public comments, the final common rule is being published elsewhere in this issue of the **Federal Register.** The common rule is based on Department of Health and Human Services (DHHS) regulations (45 CFR part 46, subpart A), the basic HHS Policy for the Protection of Human Subjects.

Respondents: Individuals or households, State or local governments, businesses or other for-profit, Federal agencies or employees, non-profit institutions, small businesses or organizations.

The total number of respondents affected by these information requirements is estimated at 3,831. The total annual response burden for these requirements including all Federal departments and agencies subject to the common rule, is estimated at 187,408 hours divided as follows: 22,982 hours for recordkeeping requirements and 164,426 hours for reporting and disclosure requirements.

Additional Information:

DHHS has submitted this request for approval to OMB on behalf of all Departments and Agencies governed by this final rule. It is critical to receive OMB review and approval for the information requirements so that the common rule for the Protection of Human Subjects may be effective 60 days after publication. Federal Departments and Agencies have ongoing research programs to which the common rule will apply, and they are seeking the most expeditious time frame in which to begin protection of human subject policies and procedures. In addition, institutions supported or regulated by the involved Departments and Agencies have requested implementation of the final rule as soon as possible to lessen burden of compliance with numerous, sometimes inconsistent, procedures for the protection of human subjects required by the various Federal Departments and Agencies.

OMB has been requested to review and approve the information requirements in the common rule on an expedited basis no later than August 2, 1991. In keeping with the requirements for expedited review, we are publishing this announcement in the same issue as the proposed final rule. The information requirements are separately identified in the preamble to the rule, printed elsewhere in this issue. There are no separate forms or instructions for which approval is being sought.

OMB Desk Officer: Shannah Koss-McCallum.

Because of the time frame in which OMB has been asked to act on this request, any comments and recommendations for the proposed information collection should be provided directly to the OMB Desk Officer designated above by telephone at (202) 395–7316 or by express mail at the following address: Human Resources and Housing Branch, New Executive Office Building, room 3002, Washington, DC 20503.

Dated: May 31, 1991.

Sandra K. Mahkorn,

Deputy Assistant Secretary for Public Health Policy.

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