subpart H of part 30, Modification, Suspension, and Termination).

(b) *State programs approved in lieu of Federal programs.* State compliance with applicable public participation requirements in programs specified in §25.2(a) (6) and (7) and administered by approved States shall be monitored by EPA during the annual review of the State's program, and during any financial or program audit or review of these programs. EPA may withdraw an approved program from a State for failure to comply with applicable public participation requirements.

(c) *Other covered programs.* Assuring compliance with these public participation requirements for programs not covered by paragraphs (a) and (b) of this section is the responsibility of the Administrator of EPA. Citizens with information concerning alleged failures to comply with the public participation requirements should notify the Administrator. The Administrator will assure that instances of alleged non-compliance are promptly investigated and that corrective action is taken where necessary.

§25.13 Coordination and non-duplication.

The public participation activities and materials that are required under this part should be coordinated or combined with those of closely related programs or activities wherever this will enhance the economy, the effectiveness, or the timeliness of the effort; enhance the clarity of the issue; and not be detrimental to participation by the widest possible public. Hearings and meetings on the same matter may be held jointly by more than one agency where this does not conflict with the policy of this paragraph. Special efforts shall be made to coordinate public participation procedures under this part and applicable regulations elsewhere in this chapter with environmental assessment and analysis procedures under 40 CFR part 6. EPA encourages interstate agencies in particular to develop combined proceedings for the States concerned.

§25.14 Termination of reporting requirements.

All reporting requirements specifically established by this part will terminate on (5 years from date of publication) unless EPA acts to extend the requirements beyond that date.

PART 26—PROTECTION OF HUMAN SUBJECTS

Sec.

Subpart A—Basic EPA Policy for Protection of Subjects in Human Research Conducted or Supported by EPA

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.
26.104–26.106 [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.

Subpart B—Prohibition of Research Conducted or Supported by EPA Involving Intentional Exposure of Human Subjects who are Children or Pregnant or Nursing Women

26.201 To what does this subpart apply?
26.202 Definitions.

26.203 Prohibition of research conducted or supported by EPA involving intentional exposure of any human subject who is a pregnant woman (and therefore her fetus), a nursing woman, or child.

Subpart C—Observational Research: Additional Protections for Pregnant Women and Fetuses Involved as Subjects in Observational Research Conducted or Supported by EPA

26.301 To what does this subpart apply?
26.302 Definitions.
26.303 Duties of IRBs in connection with observational research involving pregnant women and fetuses.
26.304 Additional protections for pregnant women and fetuses involved in observational research.
26.305 Protections applicable, after delivery, to the placenta, the dead fetus, or fetal material.

Subpart D—Observational Research: Additional Protections for Children Involved as Subjects in Observational Research Conducted or Supported by EPA

26.401 To what does this subpart apply?
26.402 Definitions.
26.403 IRB duties.
26.404 Observational research not involving greater than minimal risk.
26.405 Observational research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects.
26.406 Requirements for permission by parents or guardians and for assent by children.

Subparts E–J [Reserved]

Subpart K—Basic Ethical Requirements for Third-Party Human Research for Pesticides Involving Intentional Exposure of Non-pregnant, Non-nursing Adults

26.1101 To what does this subpart apply?
26.1102 Definitions.
26.1103–26.1106 [Reserved]
26.1107 IRB membership.
26.1108 IRB functions and operations.
26.1109 IRB review of research.
26.1110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.
26.1111 Criteria for IRB approval of research.
26.1112 Review by institution.
26.1113 Suspension or termination of IRB approval of research.
26.1114 Cooperative research.
26.1115 IRB records.
26.1116 General requirements for informed consent.
26.1117 Documentation of informed consent.
26.1118–26.1122 [Reserved]
26.1123 Early termination of research.
26.1124 [Reserved]
26.1125 Prior submission of proposed human research for EPA review.

Subpart L—Prohibition of Third-Party Research for Pesticides Involving Intentional Exposure of Human Subjects who are Children or Pregnant or Nursing Women

26.1201 To what does this subpart apply?
26.1202 Definitions.
26.1203 Prohibition of research involving intentional exposure of any human subject who is a pregnant woman (and therefore her fetus), a nursing woman, or a child.

Subpart M—Requirements for Submission of Information on the Ethical Conduct of Completed Human Research

26.1301 To what does this subpart apply?
26.1302 Definitions.
26.1303 Submission of information pertaining to ethical conduct of completed human research.

Subpart N [Reserved]

Subpart O—Administrative Actions for Noncompliance

26.1501 To what does this subpart apply?
26.1502 Lesser administrative actions.
26.1503 Disqualification of an IRB or an institution.
26.1504 Public disclosure of information regarding revocation.
26.1505 Reinstatement of an IRB or an institution.
26.1506 Debarment.
26.1507 Actions alternative or additional to disqualification.

Subpart P—Review of Proposed and Completed Human Research

26.1601 EPA review of proposed human research.
26.1602 EPA review of completed human research.
26.1603 Operation of the Human Studies Review Board.

Subpart Q—Ethical Standards for Assessing Whether To Rely on the Results of Human Research in EPA Actions

26.1701 To what does this subpart apply?
26.1702 Definitions.
26.1703 Prohibition of reliance on research involving intentional exposure of human

subjects who are pregnant women (and therefore their fetuses), nursing women, or children.
26.1704 Prohibition of reliance on unethical human research with non-pregnant, non-nursing adults conducted before April 7, 2006.
26.1705 Prohibition of reliance on unethical human research with non-pregnant, non-nursing adults conducted after April 7, 2006.
26.1706 Criteria and procedure for decisions to protect public health by relying on otherwise unacceptable research.

AUTHORITY: 5 U.S.C. 301; 7 U.S.C. 136w(a)(1); 21 U.S.C. 346a(e)(1)(C); section 201 of Public Law No. 109–54; and 42 U.S.C. 300v–1(b).

SOURCE: 56 FR 28012, 28022, June 18, 1991, unless otherwise noted.

Subpart A—Basic EPA Policy for Protection of Subjects in Human Research Conducted or Supported by EPA

§ 26.101 To what does this policy apply?

(a) Except as provided in paragraph (b) of this section, this policy applies to all research involving human subjects conducted, supported or otherwise subject to regulation by any Federal department or agency which takes appropriate administrative action to make the policy applicable to such research. This includes research conducted by Federal civilian employees or military personnel, except that each department or agency head may adopt such procedural modifications as may be appropriate from an administrative standpoint. It also includes research conducted, supported, or otherwise subject to regulation by the Federal Government outside the United States.

(1) Research that is conducted or supported by a Federal department or agency, whether or not it is regulated as defined in §26.102(e), must comply with all sections of this policy.

(2) Research that is neither conducted nor supported by a Federal department or agency but is subject to regulation as defined in §26.102(e) must be reviewed and approved, in compliance with §26.101, §26.102, and §26.107 through §26.117 of this policy, by an institutional review board (IRB) that operates in accordance with the pertinent requirements of this policy.

(b) Unless otherwise required by department or agency heads, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from this policy:

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:

(i) Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and

(ii) Any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

(3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if:

(i) The human subjects are elected or appointed public officials or candidates for public office; or

(ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

(4) Research, involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

(5) Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed

to study, evaluate, or otherwise examine:

(i) Public benefit or service programs;

(ii) Procedures for obtaining benefits or services under those programs;

(iii) Possible changes in or alternatives to those programs or procedures; or

(iv) Possible changes in methods or levels of payment for benefits or services under those programs.

(6) Taste and food quality evaluation and consumer acceptance studies,

(i) If wholesome foods without additives are consumed or

(ii) If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

(c) Department or agency heads retain final judgment as to whether a particular activity is covered by this policy.

(d) Department or agency heads may require that specific research activities or classes of research activities conducted, supported, or otherwise subject to regulation by the department or agency but not otherwise covered by this policy, comply with some or all of the requirements of this policy.

(e) Compliance with this policy requires compliance with pertinent Federal laws or regulations which provide additional protections for human subjects.

(f) This policy does not affect any State or local laws or regulations which may otherwise be applicable and which provide additional protections for human subjects.

(g) This policy does not affect any foreign laws or regulations which may otherwise be applicable and which provide additional protections to human subjects of research.

(h) When research covered by this policy takes place in foreign countries, procedures normally followed in the foreign countries to protect human subjects may differ from those set forth in this policy. [An example is a foreign institution which complies with guidelines consistent with the World Medical Assembly Declaration (Declaration of Helsinki amended 1989) issued either by sovereign states or by an organization whose function for the protection of human research subjects is internationally recognized.] In these circumstances, if a department or agency head determines that the procedures prescribed by the institution afford protections that are at least equivalent to those provided in this policy, the department or agency head may approve the substitution of the foreign procedures in lieu of the procedural requirements provided in this policy. Except when otherwise required by statute, Executive Order, or the department or agency head, notices of these actions as they occur will be published in the FEDERAL REGISTER or will be otherwise published as provided in department or agency procedures.

(i) Unless otherwise required by law, department or agency heads may waive the applicability of some or all of the provisions of this policy to specific research activities or classes of research activities otherwise covered by this policy. Except when otherwise required by statute or Executive Order, the department or agency head shall forward advance notices of these actions to the Office for Human Research Protections, Department of Health and Human Services (HHS), or any successor office, and shall also publish them in the FEDERAL REGISTER or in such other manner as provided in department or agency procedures.[1]

[56 FR 28012, 28022, June 18, 1991, 56 FR 29756, June 28, 1991, as amended at 70 FR 36328, June 23, 2005]

[1] Institutions with HHS-approved assurances on file will abide by provisions of title 45 CFR part 46 subparts A–D. Some of the other Departments and Agencies have incorporated all provisions of title 45 CFR part 46 into their policies and procedures as well. However, the exemptions at 45 CFR 46.101(b) do not apply to research involving prisoners, subpart C. The exemption at 45 CFR 46.101(b)(2), for research involving survey or interview procedures or observation of public behavior, does not apply to research with children, subpart D, except for research involving observations of public behavior when