such evaluation at any point in the project period, and will do so whenever it believes that an assisted agency may have failed to meet public participation requirements.

(ii) *Remedial actions.* Whenever EPA determines that an assisted agency has not fully met public participation requirements, EPA shall take actions which it deems appropriate to mitigate the adverse effects of the failure and assure that the failure is not repeated. For ongoing projects, that action shall include, at a minimum, imposing more stringent requirements on the assisted agency for the next budget period or other period of the project (including such actions as more specific output requirements and milestone schedules for output achievement; interim EPA review of public participation activities and materials prepared by the agency, and phased release of funds based on compliance with milestone schedules.) EPA may terminate or suspend part or all financial assistance for non-compliance with public participation requirements, and may take any further actions that it determines to be appropriate in accordance with parts 30 and 35 of this chapter (see, in particular, §§30.340, Noncompliance and 30.615–3, Withholding of Payments, and 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.

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

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

§ 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 Protection from Research Risks, Department of Health and Human Services (HHS), 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]

[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, fetuses, pregnant women, or human in vitro fertilization, subparts B and 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 the investigator(s) do not participate in the activities being observed.