

which written consent is normally required outside of the research context.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

(Approved by the Office of Management and Budget under control number 9999-0020)

§ 11.118 Applications and proposals lacking definite plans for involvement of human subjects.

Certain types of applications for grants, cooperative agreements, or contracts are submitted to departments or agencies with the knowledge that subjects may be involved within the period of support, but definite plans would not normally be set forth in the application or proposal. These include activities such as institutional type grants when selection of specific projects is the institution's responsibility; research training grants in which the activities involving subjects remain to be selected; and projects in which human subjects' involvement will depend upon completion of instruments, prior animal studies, or purification of compounds. These applications need not be reviewed by an IRB before an award may be made. However, except for research exempted or waived under § 11.101 (b) or (i), no human subjects may be involved in any project supported by these awards until the project has been reviewed and approved by the IRB, as provided in this policy, and certification submitted, by the institution, to the department or agency.

§ 11.119 Research undertaken without the intention of involving human subjects.

In the event research is undertaken without the intention of involving human subjects, but it is later proposed to involve human subjects in the research, the research shall first be reviewed and approved by an IRB, as provided in this policy, a certification submitted, by the institution, to the department or agency, and final approval given to the proposed change by the department or agency.

§ 11.120 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.

§ 11.121 [Reserved]

§ 11.122 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.

§ 11.123 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 paragraph (a) of this section and whether the applicant or the person or persons who would direct or has/have directed the

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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).

§ 11.124 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.

PART 17—INTERGOVERNMENTAL REVIEW OF DEPARTMENT OF TRANSPORTATION PROGRAMS AND ACTIVITIES

Sec.

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AUTHORITY: Executive Order 12372, July 14, 1982 (47 FR 30959), as amended April 8, 1983 (48 FR 15887); sec. 401 of the Intergovernmental

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Cooperation Act of 1968, as amended (31 U.S.C. 6506); sec. 204 of the Demonstration Cities and Metropolitan Development Act of 1966, as amended (42 U.S.C. 3334).

SOURCE: 48 FR 29272, June 24, 1983, unless otherwise noted

§ 17.1 What is the purpose of these regulations?

(a) The regulations in this part implement Executive Order 12372, "Intergovernmental Review of Federal Programs," issued July 14, 1982, and amended on April 8, 1983. These regulations also implement applicable provisions of section 401 of the Intergovernmental Cooperation Act of 1968 and section 204 of the Demonstration Cities and Metropolitan Development Act of 1966.

(b) These regulations are intended to foster an intergovernmental partnership and a strengthened Federalism by relying on state processes and on state, areawide, regional and local coordination for review of proposed Federal financial assistance and direct Federal development.

(c) These regulations are intended to aid the internal management of the Department, and are not intended to create any right or benefit enforceable at law by a party against the Department or its officers.

§ 17.2 What definitions apply to these regulations?

Department means the U.S. Department of Transportation.

Order means Executive Order 12372, issued July 14, 1982, and amended April 8, 1983, and titled "Intergovernmental Review of Federal Programs."

Secretary means the Secretary of the U.S. Department of Transportation or an official or employee of the Department acting for the Secretary under a delegation of authority.

State means any of the 50 states, the District of Columbia, the Commonwealth of Puerto Rico, the Commonwealth of the Northern Mariana Islands, Guam, American Samoa, the U.S. Virgin Islands, or the Trust Territory of the Pacific Islands.