

§ 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

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 15—PROTECTION OF SENSITIVE SECURITY INFORMATION

Sec.

- 15.1 Scope.
- 15.3 Terms used in this part.
- 15.5 Sensitive security information.
- 15.7 Covered persons.
- 15.9 Restrictions on the disclosure of SSI.
- 15.11 Persons with a need to know.
- 15.13 Marking SSI.
- 15.15 SSI disclosed by DOT.
- 15.17 Consequences of unauthorized disclosure of SSI.
- 15.19 Destruction of SSI.

AUTHORITY: 49 U.S.C. 40119.

SOURCE: 69 FR 28078, May 18, 2004, unless otherwise noted.

§ 15.1 Scope.

(a) *Applicability.* This part governs the maintenance, safeguarding, and disclosure of records and information that the Secretary of DOT has determined to be Sensitive Security Information, as defined in § 15.5. This part does not apply to the maintenance, safeguarding, or disclosure of classified national security information, as defined by Executive Order 12968, or to other sensitive unclassified information that is not SSI, but that nonetheless may be exempt from public disclosure under the Freedom of Information Act. In addition, in the case of information that has been designated as critical infrastructure information under section 214 of the Homeland Security Act, the receipt, maintenance, or disclosure of such information by a