

(1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or

(2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for 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 0990-0260)

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

§ 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

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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

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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

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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 Federal agency or employee is governed by section 214 and any implementing regulations, not by this part.

(b) *Delegation.* The authority of the Secretary under this part may be further delegated within DOT.

§ 15.3 Terms used in this part.

In addition to the terms in § 15.3 of this chapter, the following terms apply in this part:

Administrator means the Under Secretary of Transportation for Security referred to in 49 U.S.C. 114(b), or his or her designee.

Coast Guard means the United States Coast Guard.

Covered person means any organization, entity, individual, or other person described in § 15.7. In the case of an individual, *covered person* includes any individual applying for employment in a position that would be a covered person, or in training for such a position, regardless of whether that individual is receiving a wage, salary, or other form of payment. *Covered person* includes a person applying for certification or other form of approval that, if granted, would make the person a covered person described in § 15.7.

DHS means the Department of Homeland Security and any directorate, bureau, or other component within the Department of Homeland Security, including the United States Coast Guard.

DOT means the Department of Transportation and any operating administration, entity, or office within the Department of Transportation, including the Saint Lawrence Seaway Development Corporation and the Bureau of Transportation Statistics.

Federal Flight Deck Officer means a pilot participating in the Federal