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U.S.C. 552a(b)(1) are exempt from subsections (c)(3) (Accounting of Certain Disclosures) and (d) (Access to Records) of 5 U.S.C. 552a:

1. Investigative Record System (DOT/FAA 815) maintained by the Federal Aviation Administration at the Office of Civil Aviation Security in Washington, DC; the FAA regional Civil Aviation Security Divisions; the Civil Aviation Security Division at the Mike Monroney Aeronautical Center in Oklahoma City, Oklahoma; the FAA Civil Aviation Security Staff at the FAA Technical Center in Atlantic City, New Jersey; and the various Federal Records Centers located throughout the country.

2. Insider Threat Program (DOT/ALL 26).

The purpose of these exemptions is to prevent the disclosure of material authorized to be kept secret in the interest of national defense or foreign policy, in accordance with 5 U.S.C. 552(b)(1) and 552a(k)(1).

H. The following systems of records are exempt from subsection (d) (Access to Records) of the Privacy Act, 5 U.S.C. 552a, to the extent that they contain investigatory material compiled for law enforcement purposes, in accordance with 5 U.S.C. 552a(k)(2):

1. Aviation Consumer Complaint Appropriation System, maintained by the Office of the Assistant General Counsel for Aviation Enforcement and Proceedings in the Office of the Secretary (DOT/OST 102).

This exemption is justified because granting an individual access to investigatory records could interfere with the overall law enforcement process by revealing a sensitive investigative technique, or confidential sources or information.

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting appendix A to part 10, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at www.fdsys.gov.

PART 11—PROTECTION OF HUMAN SUBJECTS

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

SOURCE: 82 FR 7274, Jan. 19, 2017, unless otherwise noted.

§ 11.101 To what does this policy apply?

(a) Except as detailed in § 11.104, this policy applies to all research involving human subjects conducted, supported, or otherwise subject to regulation by any Federal department or agency that 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. Institutions that are engaged in research described in this paragraph and institutional review boards (IRBs) reviewing research that is subject to this policy must comply with this policy.

(b) [Reserved]

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

policy and this judgment shall be exercised consistent with the ethical principles of the Belmont Report.⁶²

(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 Federal 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 that provide additional protections for human subjects.

(f) This policy does not affect any state or local laws or regulations (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe) that may otherwise be applicable and that provide additional protections for human subjects.

(g) This policy does not affect any foreign laws or regulations that may otherwise be applicable and that 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. 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, provided the alternative procedures to be followed are consistent with the principles of the Belmont Report.⁶³ 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, or to the equivalent office within the appropriate Federal department or agency, and shall also publish them in the FEDERAL REGISTER or in such other manner as provided in department or agency procedures. The waiver notice must include a statement that identifies the conditions under which the waiver will be applied and a justification as to why the waiver is appropriate for the research, including how the decision is consistent with the principles of the Belmont Report.

(j) Federal guidance on the requirements of this policy shall be issued only after consultation, for the purpose of harmonization (to the extent appropriate), with other Federal departments and agencies that have adopted this policy, unless such consultation is not feasible.

(k) [Reserved]

(l) Compliance dates and transition provisions:

(1) *Pre-2018 Requirements.* For purposes of this section, the *pre-2018 Requirements* means this subpart as published in the 2016 edition of the Code of Federal Regulations.

(2) *2018 Requirements.* For purposes of this section, the *2018 Requirements* means the Federal Policy for the Protection of Human Subjects requirements contained in this part. The general compliance date for the 2018 Requirements is January 21, 2019. The compliance date for § 11.114(b) (cooperative research) of the 2018 Requirements is January 20, 2020.

(3) *Research subject to pre-2018 requirements.* The pre-2018 Requirements shall apply to the following research, unless

⁶²The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.— Belmont Report. Washington, DC: U.S. Department of Health and Human Services. 1979.

⁶³*Id.*

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the research is transitioning to comply with the 2018 Requirements in accordance with paragraph (1)(4) of this section:

(i) Research initially approved by an IRB under the pre-2018 Requirements before January 21, 2019;

(ii) Research for which IRB review was waived pursuant to §11.101(i) of the pre-2018 Requirements before January 21, 2019; and

(iii) Research for which a determination was made that the research was exempt under §11.101(b) of the pre-2018 Requirements before January 21, 2019.

(4) *Transitioning research.* If, on or after July 19, 2018, an institution planning or engaged in research otherwise covered by paragraph (1)(3) of this section determines that such research instead will transition to comply with the 2018 Requirements, the institution or an IRB must document and date such determination.

(i) If the determination to transition is documented between July 19, 2018, and January 20, 2019, the research shall:

(A) Beginning on the date of such documentation through January 20, 2019, comply with the pre-2018 Requirements, except that the research shall comply with the following:

(1) Section 11.102(l) of the 2018 Requirements (definition of research) (instead of §11.102(d) of the pre-2018 Requirements);

(2) Section 11.103(d) of the 2018 Requirements (revised certification requirement that eliminates IRB review of application or proposal) (instead of §11.103(f) of the pre-2018 Requirements); and

(3) Section 11.109(f)(1)(i) and (iii) of the 2018 Requirements (exceptions to mandated continuing review) (instead of §11.103(b), as related to the requirement for continuing review, and in addition to §11.109, of the pre-2018 Requirements); and

(B) Beginning on January 21, 2019, comply with the 2018 Requirements.

(ii) If the determination to transition is documented on or after January 21, 2019, the research shall, beginning on the date of such documentation, comply with the 2018 Requirements.

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(5) *Research subject to 2018 Requirements.* The 2018 Requirements shall apply to the following research:

(i) Research initially approved by an IRB on or after January 21, 2019;

(ii) Research for which IRB review is waived pursuant to paragraph (i) of this section on or after January 21, 2019; and

(iii) Research for which a determination is made that the research is exempt on or after January 21, 2019.

(m) *Severability:* Any provision of this part held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this part and shall not affect the remainder thereof or the application of the provision to other persons not similarly situated or to other dissimilar circumstances.

[82 FR 7274, Jan. 19, 2017, as amended at 83 FR 2894, Jan. 22, 2018; 83 FR 28519, June 19, 2018]

§ 11.102 Definitions for purposes of this policy.

(a) *Certification* means the official notification by the institution to the supporting Federal department or agency component, in accordance with the requirements of this policy, that a research project or activity involving human subjects has been reviewed and approved by an IRB in accordance with an approved assurance.

(b) *Clinical trial* means a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

(c) *Department or agency head* means the head of any Federal department or agency, for example, the Secretary of HHS, and any other officer or employee of any Federal department or agency to whom the authority provided by these regulations to the department or agency head has been delegated.