

§ 2584.101 To what does this part apply?

(a) Except as detailed in § 2584.104, this part 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 part.

(b) [Reserved]

(c) Department or agency heads retain final judgment as to whether a particular activity is covered by this part and this judgment shall be exercised consistent with the ethical principles of the Belmont Report. ¹

¹ The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research (Apr. 18, 1979).

(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 part comply with some or all of the requirements of this part.

(e) Compliance with this part requires compliance with pertinent Federal laws or regulations that provide additional protections for human subjects.

(f) This part 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 part 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 part takes place in foreign countries, procedures normally followed in the foreign countries to protect human subjects may differ from those set forth in this part. 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 part, the department or agency head may approve the substitution of the foreign procedures in lieu of the procedural requirements provided in this part. 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, the department or agency head may waive the applicability of some or all of the provisions of this part to specific research activities or classes of research activities otherwise covered by this part, provided the alternative procedures to be followed are consistent with the principles of the Belmont Report. ² 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.

² Id.

(j) Federal guidance on the requirements of this part 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)-(l) [Reserved]

(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.