

## Code of Federal Regulations Title 21-Food and Drugs, Part 46 – Protection of Human Subjects

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## Title 45

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### PART 46 - PROTECTION OF HUMAN SUBJECTS

**Authority:** 5 U.S.C. 301; 42 U.S.C. 289(a); 42 U.S.C. 300v-1(b).**EDITORIAL NOTE**

**Editorial Note:** The Department of Health and Human Services issued a notice of waiver regarding the requirements set forth in part 46, relating to protection of human subjects, as they pertain to demonstration projects, approved under section 1115 of the Social Security Act, which test the use of cost-sharing, such as deductibles, copayment and coinsurance, in the Medicaid program. For further information see 47 FR 9208, Mar. 4, 1982.

#### Subpart A - Basic HHS Policy for Protection of Human Research Subjects

**Source:** 82 FR 7259, 7273, Jan. 19, 2017, unless otherwise noted.

##### § 46.101 To what does this policy apply?

- (a) Except as detailed in § 46.104, 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.<sup>[62]</sup>