

§ 46.401 To what does this subpart apply?

(a) The *pre-2018 Requirements* means 45 CFR part 46, subpart A, as revised October 1, 2016. The *2018 Requirements* means 45 CFR part 46, subpart A, as revised October 1, 2018.

(b) This subpart applies to all research involving children as subjects, conducted or supported by the Department of Health and Human Services.

(1) This includes research conducted by Department employees, except that each head of an Operating Division of the Department may adopt such nonsubstantive, procedural modifications as may be appropriate from an administrative standpoint.

(2) It also includes research conducted or supported by the Department of Health and Human Services outside the United States, but in appropriate circumstances, the Secretary may, under § 46.101(i) of the pre-2018 Requirements or the 2018 Requirements, waive the applicability of some or all of the requirements of this subpart for research of this type.

(c) The application of the exemptions to this subpart is as follows:

(1) For research subject to the pre-2018 Requirements and this subpart, the exemptions at § 46.101(b)(1) and (b)(3) through (6) of the pre-2018 Requirements are applicable to this subpart. The exemption at § 46.101(b)(2) of the pre-2018 Requirements regarding educational tests also is applicable to this subpart. However, the exemption at § 46.101(b)(2) for research involving survey or interview procedures or observations of public behavior does not apply to research covered by this subpart, except for research involving observation of public behavior when the investigator(s) do not participate in the activities being observed.

(2) For research subject to the 2018 Requirements and this subpart, the exemptions at § 46.104(d)(1), (4), (5), (6), (7), and (8) of the 2018 Requirements are applicable to this subpart. The exemptions at § 46.104(d)(2)(i) and (ii) of the 2018 Requirements may only apply to research subject to this subpart that involves educational tests or the observation of public behavior when the investigator(s) do not participate in the activities being observed. The exemptions at § 46.104(d)(2)(iii) and (d)(3) of the 2018 Requirements may not be applied to research subject to this subpart.

(d) The exceptions, additions, and provisions for waiver as they appear in § 46.101(c) through (i) of the pre-2018 Requirements or the 2018 Requirements are applicable to this subpart.

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