

§ 46.301 Applicability.

(a) The regulations in this subpart are applicable to all biomedical and behavioral research conducted or supported by the Department of Health and Human Services involving prisoners as subjects.

(b) Nothing in this subpart shall be construed as indicating that compliance with the procedures set forth herein will authorize research involving prisoners as subjects, to the extent such research is limited or barred by applicable State or local law.

(c) The requirements of this subpart are in addition to those imposed under the other subparts in this part and includes the pre-2018 Requirements and the 2018 Requirements, as applicable. 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.

[43 FR 53655, Nov. 16, 1978, as amended at 89 FR 84825, Oct. 24, 2024]