

13-1602.

~~THIS SUBTITLE DOES NOT APPLY TO RESEARCH THAT IS EXEMPT UNDER TITLE 45, § 46.101(B) OF THE CODE OF FEDERAL REGULATIONS FROM FEDERAL REGULATIONS ON THE PROTECTION OF HUMAN SUBJECTS.~~

~~(A) A PERSON MAY NOT CONDUCT RESEARCH USING A HUMAN SUBJECT UNLESS THE PERSON CONDUCTS THE RESEARCH IN ACCORDANCE WITH THE FEDERAL REGULATIONS ON THE PROTECTION OF HUMAN SUBJECTS.~~

~~(B) NOTWITHSTANDING ANY PROVISION IN THE FEDERAL REGULATIONS ON THE PROTECTION OF HUMAN SUBJECTS THAT LIMITS THE APPLICABILITY OF THE FEDERAL REGULATIONS TO CERTAIN RESEARCH, SUBSECTION (A) OF THIS SECTION APPLIES TO ALL RESEARCH USING A HUMAN SUBJECT.~~

13-1603.

~~(A) THIS SECTION DOES NOT APPLY IF, UNDER THE FEDERAL REGULATIONS ON THE PROTECTION OF HUMAN SUBJECTS, RESEARCH MAY BE CONDUCTED WITHOUT INFORMED CONSENT.~~

~~(B) SUBJECT TO THE GRANT OF A WAIVER BY AN INSTITUTIONAL REVIEW BOARD UNDER SUBSECTION (C) OF THIS SECTION, A PERSON MAY NOT CONDUCT RESEARCH USING A HUMAN SUBJECT UNLESS, IN ACCORDANCE WITH FEDERAL REGULATIONS ON THE PROTECTION OF HUMAN SUBJECTS, THE PERSON HAS OBTAINED:~~

~~(1) THE VOLUNTARY WRITTEN INFORMED CONSENT OF THE HUMAN SUBJECT;~~

~~(2) IF THE HUMAN SUBJECT IS A MINOR WHO DOES NOT HAVE THE AUTHORITY UNDER STATE LAW TO CONSENT TO A TREATMENT OR PROCEDURE INVOLVED IN THE RESEARCH, THE VOLUNTARY WRITTEN INFORMED CONSENT OF A PARENT OR GUARDIAN OF THE MINOR; OR~~

~~(3) IF THE HUMAN SUBJECT IS INCAPABLE OF GIVING INFORMED CONSENT, THE VOLUNTARY WRITTEN INFORMED CONSENT OF A LEGALLY AUTHORIZED REPRESENTATIVE ON BEHALF OF THE HUMAN SUBJECT.~~

~~(C) IN ACCORDANCE WITH FEDERAL REGULATIONS ON THE PROTECTION OF HUMAN SUBJECTS, AN INSTITUTIONAL REVIEW BOARD MAY WAIVE:~~

~~(1) INFORMED CONSENT;~~

~~(2) CERTAIN ELEMENTS OF INFORMED CONSENT; OR~~

~~(3) WRITTEN DOCUMENTATION OF INFORMED CONSENT.~~

13-1604.

~~(A) THIS SECTION DOES NOT APPLY IF, UNDER FEDERAL REGULATIONS ON THE PROTECTION OF HUMAN SUBJECTS, RESEARCH MAY BE CONDUCTED WITHOUT INSTITUTIONAL REVIEW BOARD REVIEW.~~