made for soliciting the permission of each child’s parent(s) or guardian(s). If parental permission is to be obtained, the IRB may find that the permission of one parent is sufficient for research to be conducted under §97.404 or §97.405. If research is covered by §§97.406 and 97.407 and permission is to be obtained from parents, both parents must give their permission unless one parent is deceased, unknown, incompetent, or not reasonably available, or if only one parent has legal responsibility for the care and custody of the child.

(c) In addition to the provisions for waiver contained in §97.116, if the IRB determines that a research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children), it may waive the consent requirements in subpart A of this part and paragraph (b) of this section, provided an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and provided further that the waiver is not inconsistent with Federal, State, or local law. The choice of an appropriate mechanism depends upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, status, and condition.

(d) Permission by parents or guardians must be documented in accordance with and to the extent required by §97.117.

(e) If the IRB determines that assent is required, it shall also determine whether and how assent must be documented.


PART 98—STUDENT RIGHTS IN RESEARCH, EXPERIMENTAL PROGRAMS, AND TESTING

§98.1 Applicability of part.

(a)(1) Was transferred to the Department by the Department of Education Organization Act (DEOA); and