***LINCOLN UNIVERSITY Reviewer Guidelines for Research Involving Children***

**45 CFR 46, Subpart D**

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|  | **Yes / No / N/A** |
| 1. [**Category 1, 45 CFR 46.404]** The IRB finds that **no greater than minimal** **risk** to children is presented. The children are capable of providing assent and adequate provisions are made for soliciting the assent of the children |  |
| 1. The capability of some or all of the children is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, the assent of the children is not a necessary condition for proceeding with the research. |  |
| 1. The children are capable of providing assent but adequate provisions for soliciting the assent of the children has not been provided in the application. |  |
| 1. Will assent be documented? |  |
| 1. Is the process of obtaining/documenting assent adequate? |  |
| 1. Adequate provisions are made for soliciting the permission of each child's parents or guardian. The permission of one parent is required. |  |
| 1. Adequate provisions are made for soliciting the permission of each child's parents or guardian has not been provided. The permission of one parent is required. |  |
| 1. The 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. An appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and the waiver is not inconsistent with Federal, State, or local law. |  |
| 1. The 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. However, an appropriate mechanism for protecting the children who will participate as subjects in the research has not been provided |  |
| 1. **[Category 2, 45 CFR 46.405]** The IRB finds that **more than minimal risk** to children is presented by an intervention or procedure that **holds out the prospect of direct benefit** for the individual subject, or by a monitoring procedure that is likely to contribute to the subject's well-being. The IRB finds that: (a) the risk is justified by the anticipated benefit to the subjects; (b) the relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches. |  |
| 1. The children are capable of providing assent and adequate provisions are made for soliciting the assent of the children. |  |
| 1. Will assent be documented? |  |
| 1. Is the process for obtaining/documenting assent adequate? |  |
| 1. The capability of some or all of the children is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, the assent of the children is not a necessary condition for proceeding with the research. |  |
| 1. The children are capable of providing assent but adequate provisions for soliciting the assent of the children has not been provided in the application. |  |
| 1. Adequate provisions are made for soliciting the permission of each child's parents or guardian. The permission of one parent is required. |  |
| 1. Adequate provisions are made for soliciting the permission of each child's parents or guardian has not been provided. The permission of one parent is required. |  |
| 1. The 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. An appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and the waiver is not inconsistent with Federal, State, or local law. |  |
| 1. The 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. However, an appropriate mechanism for protecting the children who will participate as subjects in the research has not been provided. |  |
| 1. **[Category 3, 45 CFR 46.406]** The IRB finds that **more than minimal risk** to children is presented by an intervention or procedure that **does not hold out the prospect of direct benefit** for the individual subject, or by a monitoring procedure which is not likely to contribute to the well-being of the subject. However the IRB finds that: (a) the risk represents a minor increase over minimal risk; (b) the intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations; (c) the intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition. |  |
| 1. The children are capable of providing assent and adequate provisions are made for soliciting the assent of the children. |  |
| 1. Will assent be documented? |  |
| 1. Is the process for obtaining/documenting assent adequate? |  |
| 1. The capability of some or all of the children is so limited that they cannot reasonably be consulted; the assent of the children is not a necessary condition for proceeding with the research. |  |
| 1. The children are capable of providing assent but adequate provisions for soliciting the assent of the children has not been provided in the application. |  |
| 1. Adequate provisions are made for soliciting the permission of each child's parents or guardian. Both parents must give their permission unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child. |  |
| 1. Adequate provisions are made for soliciting the permission of each child's parents or guardian has not been provided. Both parents must give their permission unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child. |  |

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| 1. [**Category 4, 45 CFR 46.407**] **Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children**. DHHS will conduct or fund research that the IRB does not believe meets the above requirements only if: (a) the IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children; and (b) the Secretary, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, education, ethics, law) and following opportunity for public review and comment, has determined either: (1) that the research in fact satisfies the conditions of 45 CFR §46.404, §46.405, or §46.406, as applicable, or (2) the following: (i) the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children; (ii) the research will be conducted in accordance with sound ethical principles; (iii) adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians. |  |

***Additional Comments (optional):***

**45 CFR 46, Subpart D**

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| For IRB Reviewers and/or Investigators’ Reference Only |
| California Education Code 51513  No test, questionnaire, survey, or examination containing any questions about the pupil's beliefs or practices in sex, family life, morality, and religion, or any questions about the pupil's parents' or guardians' beliefs and practices in sex, family life, morality, and religion, shall be administered to any pupil in kindergarten or grades 1 to 12, inclusive, unless the parent or guardian of the pupil is notified in writing that this test, questionnaire, survey or examination is to be administered and the parent or guardian gives written permission for the pupil to take this test, questionnaire, survey or examination. |
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| **Family Educational Rights and Privacy Act (FERPA)**  The Family Educational Rights and Privacy Act (FERPA) (20 U.S.C. § 1232g; 34 CFR Part 99) is a Federal law that protects the privacy of student education records. The law applies to all schools that receive funds under an applicable program of the U.S. Department of Education.  FERPA gives parents certain rights with respect to their children's education records. These rights transfer to the student when he or she reaches the age of 18 or attends a school beyond the high school level. Students to whom the rights have transferred are "eligible students."   * Parents or eligible students have the right to inspect and review the student's education records maintained by the school. Schools are not required to provide copies of records unless, for reasons such as great distance, it is impossible for parents or eligible students to review the records. Schools may charge a fee for copies. * Parents or eligible students have the right to request that a school correct records which they believe to be inaccurate or misleading. If the school decides not to amend the record, the parent or eligible student then has the right to a formal hearing. After the hearing, if the school still decides not to amend the record, the parent or eligible student has the right to place a statement with the record setting forth his or her view about the contested information. * Generally, schools must have written permission from the parent or eligible student in order to release any information from a student's education record. However, FERPA allows schools to disclose those records, without consent, to the following parties or under the following conditions (34 CFR § 99.31):   + School officials with legitimate educational interest;   + Other schools to which a student is transferring;   + Specified officials for audit or evaluation purposes;   + Appropriate parties in connection with financial aid to a student;   + Organizations conducting certain studies for or on behalf of the school;   + Accrediting organizations;   + To comply with a judicial order or lawfully issued subpoena;   + Appropriate officials in cases of health and safety emergencies; and   + State and local authorities, within a juvenile justice system, pursuant to specific State law.   -Schools may disclose, without consent, "directory" information such as a student's name, address, telephone number, date and place of birth, honors and awards, and dates of attendance. However, schools must tell parents and eligible students about directory information and allow parents and eligible students a reasonable amount of time to request that the school not disclose directory information about them. Schools must notify parents and eligible students annually of their rights under FERPA. The actual means of notification (special letter, inclusion in a PTA bulletin, student handbook, or newspaper article) is left to the discretion of each school. |
| **Protection of Pupil Rights Amendment (PPRA)**  The Protection of Pupil Rights Amendment (PPRA) (20 U.S.C. § 1232h; 34 CFR Part 98) applies to programs that receive funding from the U.S. Department of Education (ED). PPRA is intended to protect the rights of parents and students in two ways:   * It seeks to ensure that schools and contractors make instructional materials available for inspection by parents if those materials will be used in connection with an ED-funded survey, analysis, or evaluation in which their children participate; and * It seeks to ensure that schools and contractors obtain written parental consent before minor students are required to participate in any ED-funded survey, analysis, or evaluation that reveals information concerning:   1. Political affiliations;   2. Mental and psychological problems potentially embarrassing to the student and his/her family;   3. Sex behavior and attitudes;   4. Illegal, anti-social, self-incriminating and demeaning behavior;   5. Critical appraisals of other individuals with whom respondents have close family relationships;   6. Legally recognized privileged or analogous relationships, such as those of lawyers, physicians, and ministers; or   7. Income (other than that required by law to determine eligibility for participation in a program or for receiving financial assistance under such program).   Parents or students who believe their rights under PPRA may have been violated may file a complaint with ED by writing the Family Policy Compliance Office. Complaints must contain specific allegations of fact giving reasonable cause to believe that a violation of PPRA occurred. |