

Human Subject Research

The only type of human subject research allowed by the Lakota Science and Engineering Fair (LSEF) is that which is “exempt” from review by an Institutional Review Board (IRB). Please email your name, grade, and a description of the type of human research you want to do for your project to LakotaScienceFair@gmail.com for us to determine if your research is exempt from review. You must receive our approval before beginning any human testing. ALL PROJECTS THAT INVOLVE HUMAN RESEARCH MUST RECEIVE OUR APPROVAL, REGARDLESS OF WHETHER OR NOT YOU BELIEVE THEY WILL BE EXEMPT.

Exempt Human Subject Research

Exemption from IRB review will be determined by the LSEF on a case-by-case basis. Not all types of exempt project research are included below, but to give you an idea of types of research that would be considered exempt, some types of exempt projects are listed below:

- (1) Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. **(may include kids as subjects)**
- (2) Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) **for adults only** if at least one of the following criteria is met:
 - a. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
 - b. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
 - c. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).
- (3) Research involving benign behavioral interventions in conjunction with the collection of information from an **adult subject** through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:
 - a. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
 - b. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

- (4) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).
- a. For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.
 - b. If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.
- (5) Secondary research for which consent is not required: Secondary research uses of identifiable private information **from adults or kids**, if at least one of the following criteria is met:
- a. The identifiable private information is publicly available;
 - b. Information is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;
 - c. The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b);
- (6) Taste and food quality evaluation and consumer acceptance studies **(may include kids as subjects)**:
- a. If wholesome foods without additives are consumed, or
 - b. If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Please email LakotaScienceFair@gmail.com with your name, grade, and a detailed description of the type of human research you want to do for your project (including whether the research will involve adults or children and where the research will take place). Do not proceed with any human research until you receive our approval to do so.