IRB Categories of Review

Exempt Categories:

Category 1: Educational Research

45 CFR 46.104(d)(1): Research involving 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:

i. Most research on regular and special education instructional strategies

ii. Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management.

Category 2: Educational Tests, Surveys, Interviews, or Observations

45 CFR 46.104 (d)(2): Research that only includes interaction involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior (including visual or auditory recording)

i. Information obtained is recorded by the investigator in such a manner that the identity of human subjects cannot be readily ascertained, directly or through identifiers linked to the subjects

ii. Any disclosure of the human subjects' responses outside of 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;

iii. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can be readily ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by 45 CFR 46.111(a)(7).

Category3: Benign Behavioral Interventions

45 CFR 46.104(d)(3): Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collected:

i. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot be readily ascertained, directly or through identifiers linked to the subjects;

ii. 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

iii. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can be readily ascertained directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by 45 CFR 46.111(a)(7).

Category 4: Secondary Research of Identifiable Private Information or Biospecimens

45 CFR 46.104(d)(4): Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens:

i. The identifiable private information or identifiable biospecimens are publically available

ii. Information, which may include information about biospecimens, 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 subjects, and the investigator will not reidentify subjects

iii. The research involves only information collection and analysis involving the investigator's use of identifiable heai23D [(i)-h-4.6(nv)1ik-cde2.u9.2(e.u)10.lR(t)-4.6(i)-2(c)-1.72.6(h)2(a)6(i)-a-4.682(h)ik-cde

Category 6: Taste and Food Quality Evaluations

45 CFR 46.104(d)(6): Taste and food quality evaluation and consumer acceptance studies

i. Wholesome foods without additives are consumed

ii. 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

Expedited Categories:

Category 1: 45 CFR 46.110 (1): Clinical studies of drugs and medical devices only conditions (a) or (b) is met:

a)

45 CFR 46.110 (8c): Where the remaining research activities are limited to data analysis.

Category 9: 45 CFR 46.110 (9): Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

Full Board:

Proposed human subject's research which does not fall into either the exempt or expedited categories must be submitted for full committee review.