

2018 Exempt Category 2
Surveys, Tests, Interviews, Observations
 (Use after January 21, 2019)
 [Exempt Research: 45CFR46.104 (d) (2)]

START
 Meets the definition of research.*

↓ YES

Will the research only include educational tests, surveys, interviews, or public observation?
 [This exemption is for data collection ONLY. May include visual or auditory recording but MAY NOT include intervention**.]

↓ YES

Will minor children be involved in the educational testing or observation of public behavior?

YES

NO NO

Will the researcher (investigator) be participating in the activity?
 [Activities can include minor children only when researcher does not participate.]

YES

Criteria 1
 Information obtained will be 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.
Will your information be de-identified?

NO

YES

Criteria 2
 Disclosure of the human subject's responses outside the research would not place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, educational advancement, or reputation.
Would your subjects be at risk if their responses were disclosed?

YES

NO

OR

May qualify as Exempt Category 2 if a limited IRB review approves the plan for the privacy and confidentiality of the data.
 [Cannot include information regarding minor children.]

Qualifies for Exempt Category 2 if *Criteria 1 OR 2* is met
 Submit Application for Exempt Research Designation

Does not qualify for Exempt Category 2
 Submit a Non-Exempt Application

*"Research" means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.
 **"Intervention" includes both physical procedures by which information or biospecimens are gathered and manipulations of the subject or the subject's environment that are performed for research purposes.