

DOES EXEMPTION 45 CFR 46.104(d)(2) FOR EDUCATIONAL TESTS, SURVEYS, INTERVIEWS, OR OBSERVATION OF PUBLIC BEHAVIOR APPLY?

NOTE: This chart is consistent with the 2018 Requirements (i.e., the revised Common Rule)

For use after January 20, 2019



TO BE EXEMPT, NO NONEXEMPT ACTIVITIES CAN BE INVOLVED. RESEARCH THAT INCLUDES BOTH EXEMPT AND NONEXEMPT ACTIVITIES IS NOT EXEMPT. RESEARCH MAY INVOLVE ACTIVITIES EXEMPT UNDER MORE THAN ONE EXEMPTION CATEGORY.



Does the research only include interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recordings)?



No

Is the information obtained 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?
[45 CFR 46.104(d)(2)(i)]

Or

Is it the case that 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?
[45 CFR 46.104(d)(2)(ii)]

Or

Is the information obtained 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 has an IRB conducted a limited review to make the determination required by 45 CFR 46.111(a)(7)?
[45 CFR 46.104(d)(2)(iii)]



No



The exemption may apply. However, when the subjects are children, this may only apply to research involving educational tests or the observation of public behavior when the investigator **does not participate** in the activities being observed.
[45 CFR 46.104(b)(3)]

The exemption may apply unless the research involves children. This condition **does not apply** to research subject to Subpart D.
[45 CFR 46.104(b)(3)]

The research is not exempt under 45 CFR 46.104(d)(2). Go to the other exemption decision charts to see if any other exemptions apply.