Chart 4: Does Exemption 45 CFR 46.101(b)(2) or (b)(3) (for Tests, Surveys, Interviews, Public Behavior Observation) Apply?

February 16, 2016

From Chart 2

Does the research involve only** the use of educational tests, survey procedures, interview procedures, or observation of public behavior?

** "Only" means that no non-exempt activities are involved. Research that includes exempt and non-exempt activities is not exempt.

YES

Does the research involve children to whom 45 CFR part 46, subpart D applies?

YES

Only research involving only** educational tests or observation of public behavior without participation by the investigator in the activities being observed is exempt under 45 CFR 46.101(b)(2).

NO

Research is not eligible for exemption under 45 CFR 46.101(b)(2).

Research is not eligible for exemption under 45 CFR 46.101(b)(2) or (b)(3).

YES

Is the information obtained recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and could any disclosure of the human subjects' responses outside the research reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation?

YES

Research is eligible for exemption under 45 CFR 46.101(b)(3) from 45 CFR part 46 requirements.

NO

Research is not eligible for exemption under 45 CFR 46.101(b)(3).

NO

Are the human subjects elected or appointed public officials or candidates for public office? (Applies to senior officials, such as mayor or school superintendent, rather than a police officer or teacher.)

NO

Does any Federal statute require without exception that the confidentiality of personally identifiable information will be maintained throughout the research and thereafter?

NO

Return to Chart 2 and consider whether 45 CFR 46.101(b)(4) exemption applies.

YES

Research is eligible for exemption under 45 CFR 46.101(b)(3) from 45 CFR part 46 requirements.