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

From Chart 2

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

YES

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

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?

NO

Does the research involve survey procedures, interview procedures, or observation of public behavior where the investigator participates in the activities being observed? [45 CFR 46.401(b)]

NO

Research is not exempt under 45 CFR 46.101(b)(2).

However, the 45 CFR 46.101(b)(3) exemption might apply.

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

Research is not exempt under 45 CFR 46.101(b)(2) or (b)(3).

Go to Chart 8

YES

Research is exempt under 45 CFR 46.101(b)(3) from all 45 CFR part 46 requirements.

September 24, 2004