Has HHS prohibited exemption of the human subjects research? (All research involving prisoners, some research involving children) [Footnote 1 to 45 CFR 46.101(i), 45 CFR 46.401(b)]

Will the only** involvement of human subjects be in one or more of the following categories?

**"Only" means that non-exempt activities are involved. Research that includes exempt and non-exempt activities is not exempt.

Yes

Research conducted in established or commonly accepted educational settings, involving normal education practices?

Exemption 45 CFR 46.101(b)(1) may apply

GO TO CHART 3

Research involving the use of educational tests, survey procedures, interview procedures, or observation of public behavior?

Exemption 45 CFR 46.101(b)(2) or (b)(3) may apply

GO TO CHART 4

Research involving collection or study of existing data, documents, records, or pathological or diagnostic specimens?

Exemption 45 CFR 46.101(b)(4) may apply

GO TO CHART 5

Research studying, evaluating, or examining public benefit or service programs?

Exemption 45 CFR 46.101(b)(5) may apply

GO TO CHART 6

Research involving taste and food quality evaluation or consumer acceptance studies?

Exemption 45 CFR 46.101(b)(6) may apply

GO TO CHART 7

No exemptions to 45 CFR part 46 apply. Provisions of 45 CFR subpart A apply, and subparts B, C, and D also apply if subjects are from covered vulnerable populations

GO TO CHART 8

Source: http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html#c2