

Chart 2: Is the Research Involving Human Subjects Eligible for Exemption Under 45 CFR 46.101(b)?

From Chart 1

September 24, 2004

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)]

NO

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

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

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

YES

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

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AND/OR

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

YES

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

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AND/OR

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

YES

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

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AND/OR

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

YES

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

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AND/OR

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

YES

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

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NO

YES

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.

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