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

From Chart 1

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)]

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

NO

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

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

If not exempt under (b)(1)

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

If not exempt under (b)(2) or (b)(3)

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

If not exempt under (b)(4)

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

If not exempt under (b)(5)

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

If not exempt under (b)(6)

YES

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

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

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

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

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

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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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