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

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.

From Chart 1

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?

AND/OR

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

AND/OR

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

AND/OR

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

AND/OR

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

YES

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

Go to Chart 3

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

Go to Chart 4

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

Go to Chart 5

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

Go to Chart 6

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

Go to Chart 7

NO

Go to Chart 8

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.