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)]

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?
  - YES → Go to Chart 3
  - NO → 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. Go to Chart 4
  - NO → 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. Go to Chart 5
  - NO → AND/OR

- Research studying, evaluating, or examining public benefit or service programs?
  - YES → Exemption 45 CFR 46.101(b)(5) may apply. Go to Chart 6
  - NO → AND/OR

- Research involving taste and food quality evaluation or consumer acceptance studies?
  - YES → Exemption 45 CFR 46.101(b)(6) may apply. Go to Chart 7
  - NO → Go to Chart 8

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.