

Chart 1: Is an Activity Research Involving Human Subjects Covered by 45 CFR part 46?

September 24, 2004

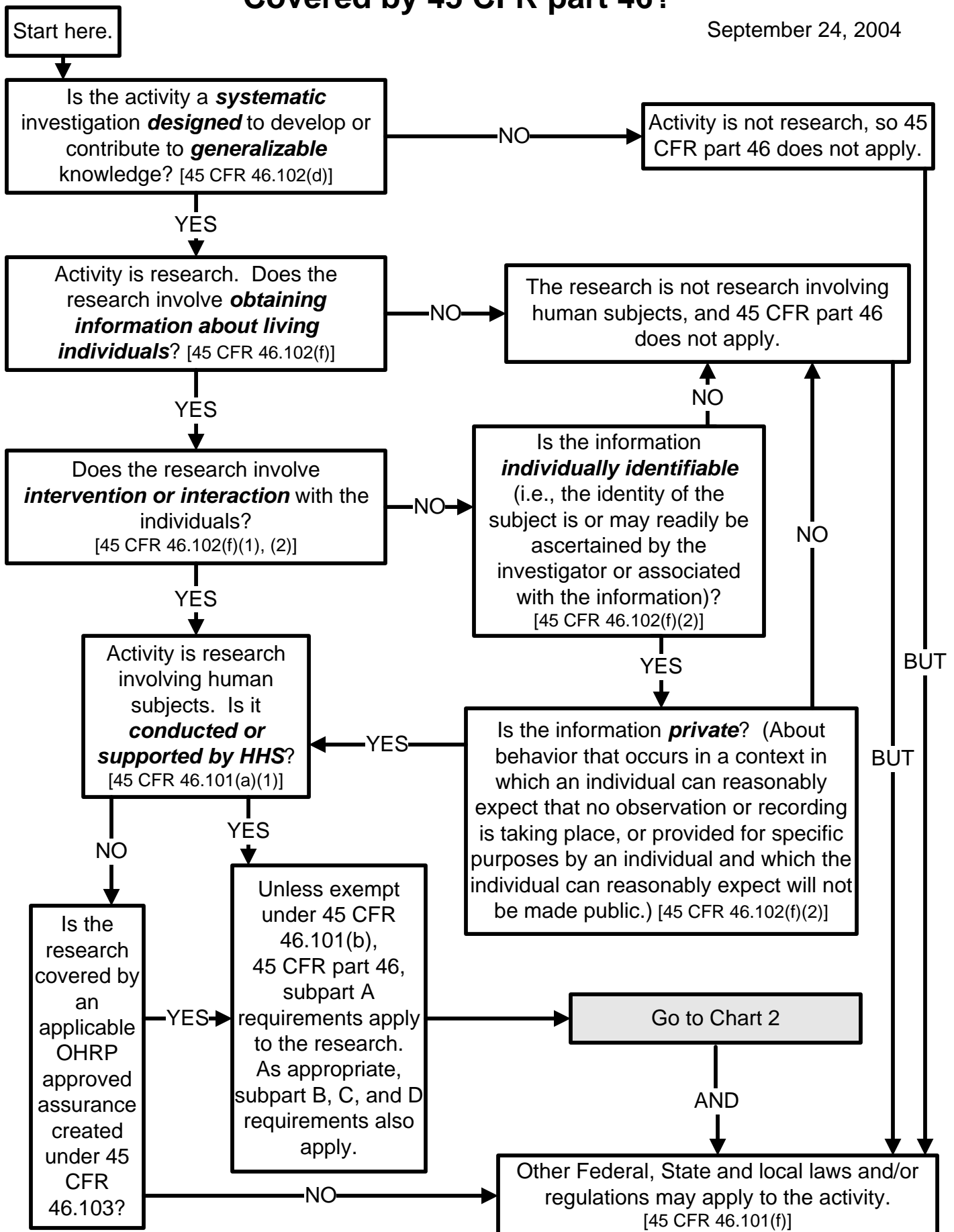


Chart 2: Is the Research Involving Human Subjects Eligible for Exemption Under 45 CFR 46.101(b)?

September 24, 2004

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)]

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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Chart 3: Does Exemption 45 CFR 46.101(b)(1) (for Educational Settings) Apply?

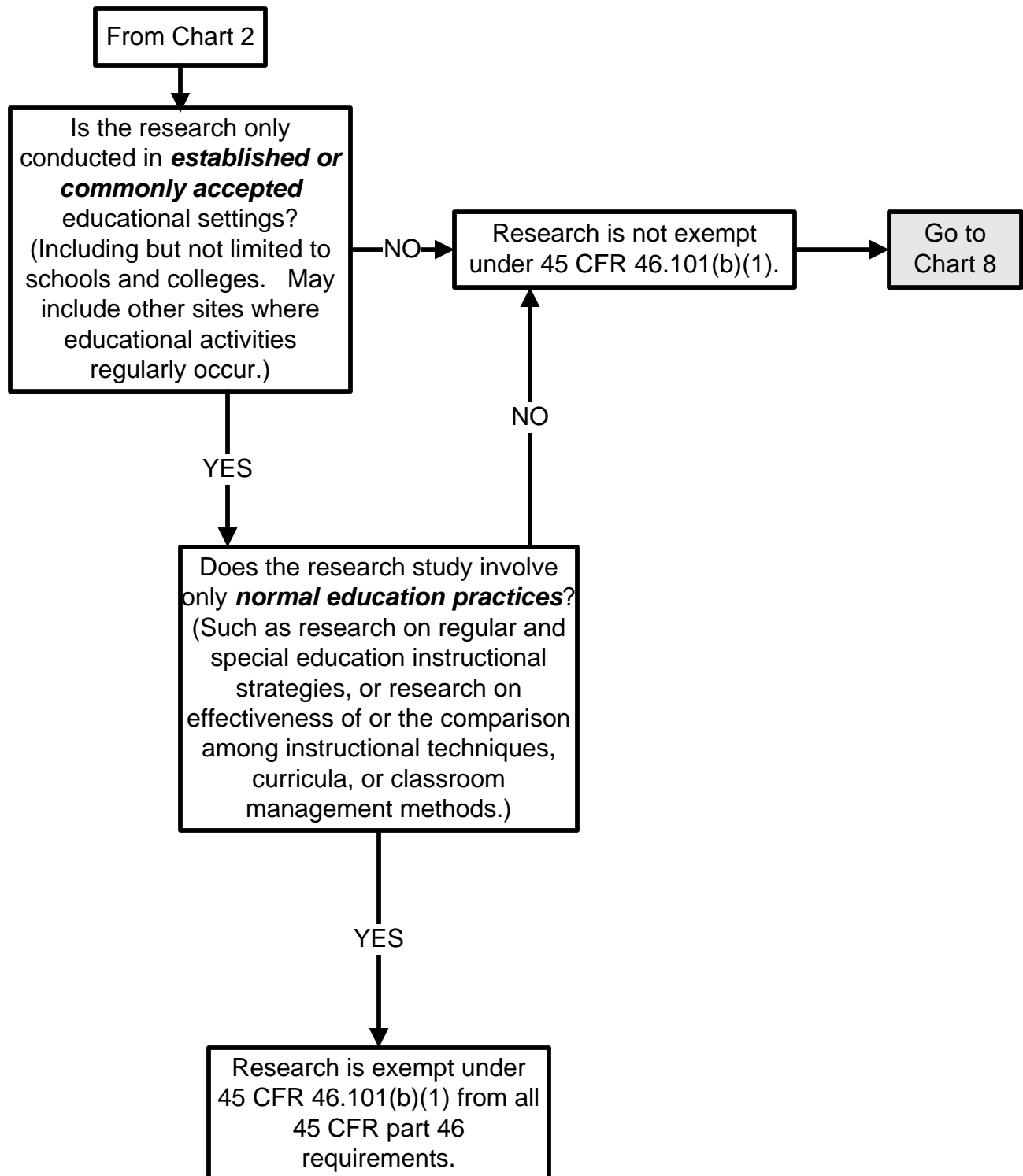


Chart 4: Does Exemption 45 CFR 46.101(b)(2) or (b)(3) (for Tests, Surveys, Interviews, Public Behavior Observation) Apply?

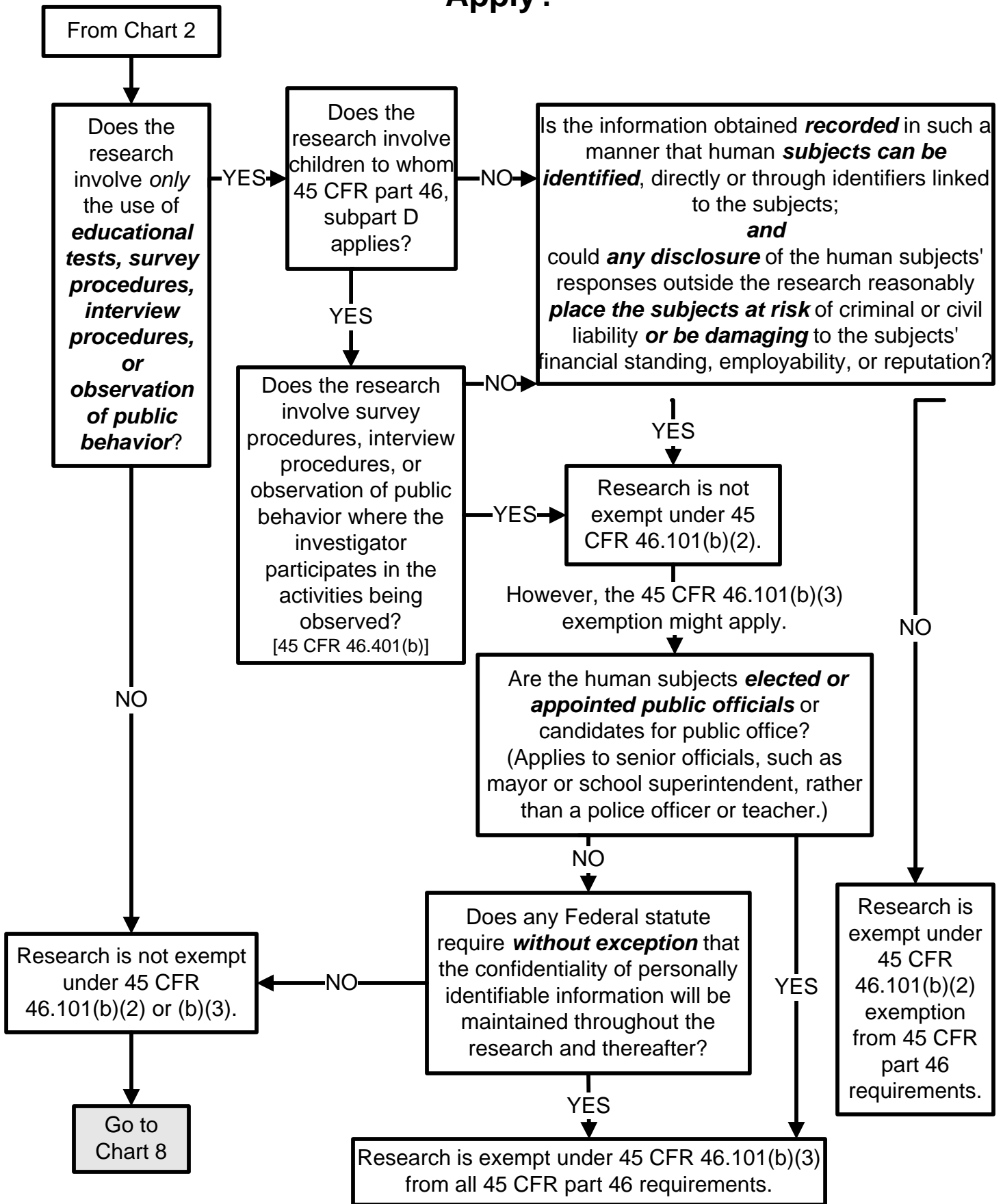
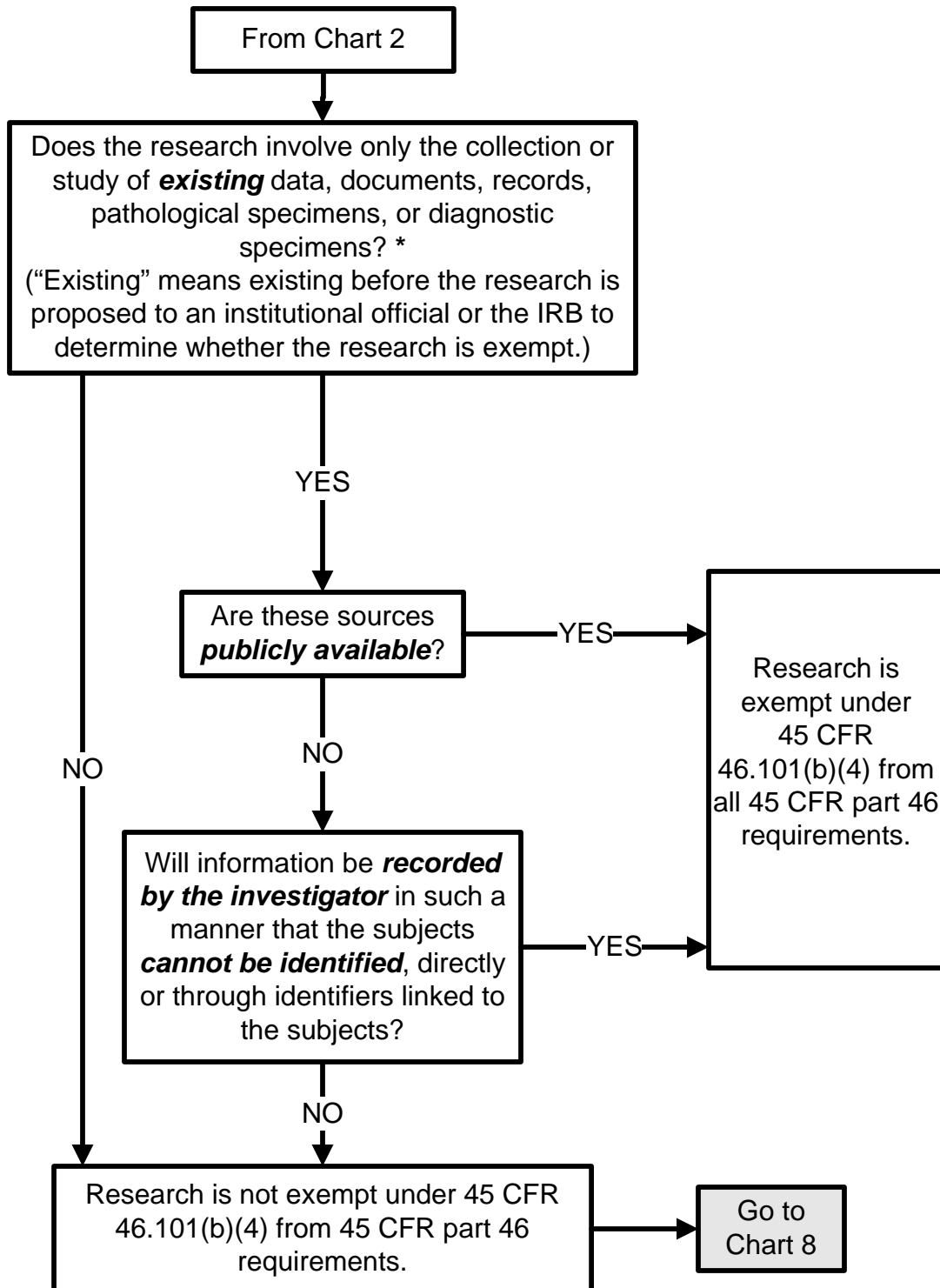
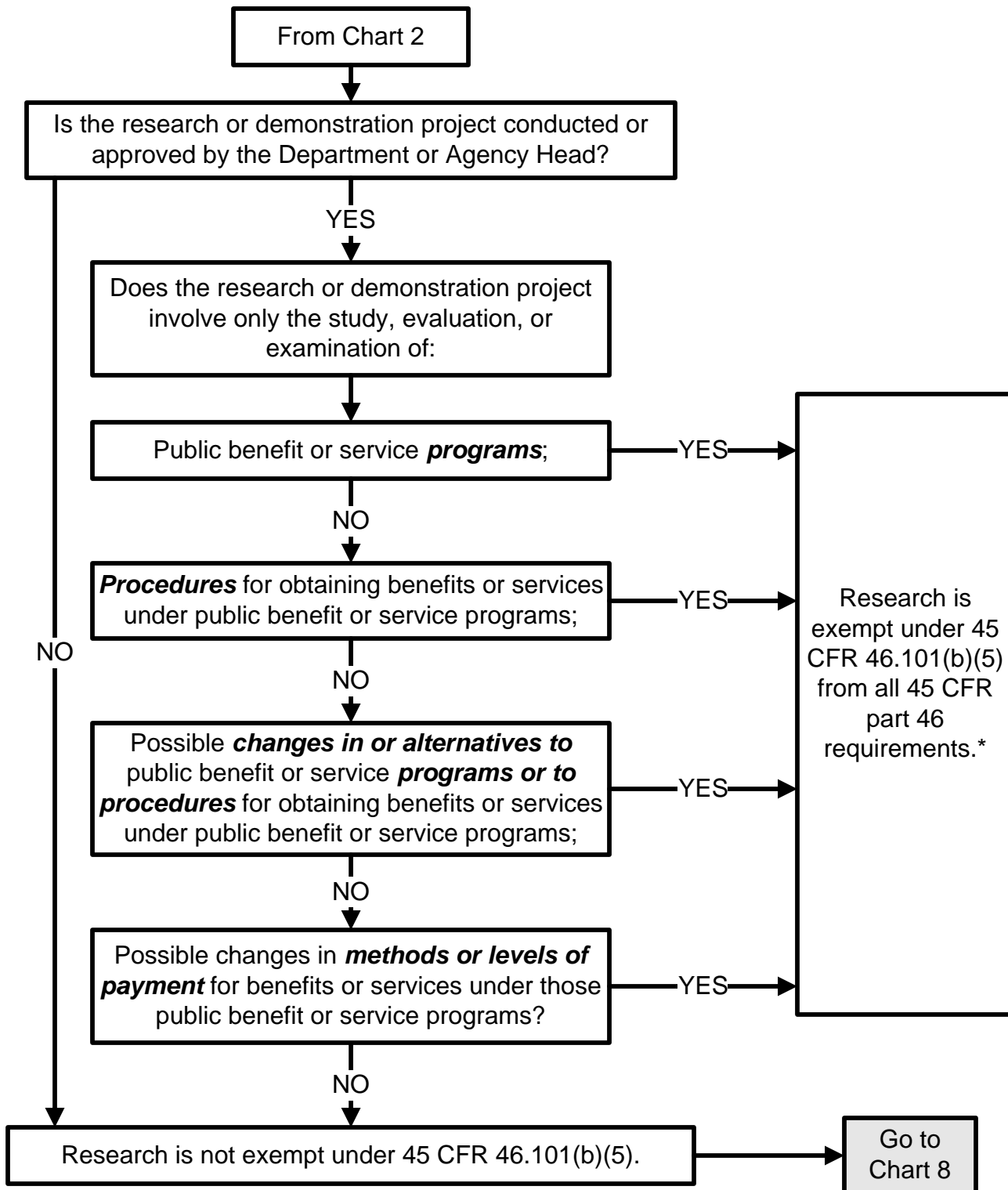


Chart 5: Does Exemption 45 CFR 46.101(b)(4) (for Existing Data Documents and Specimens) Apply?



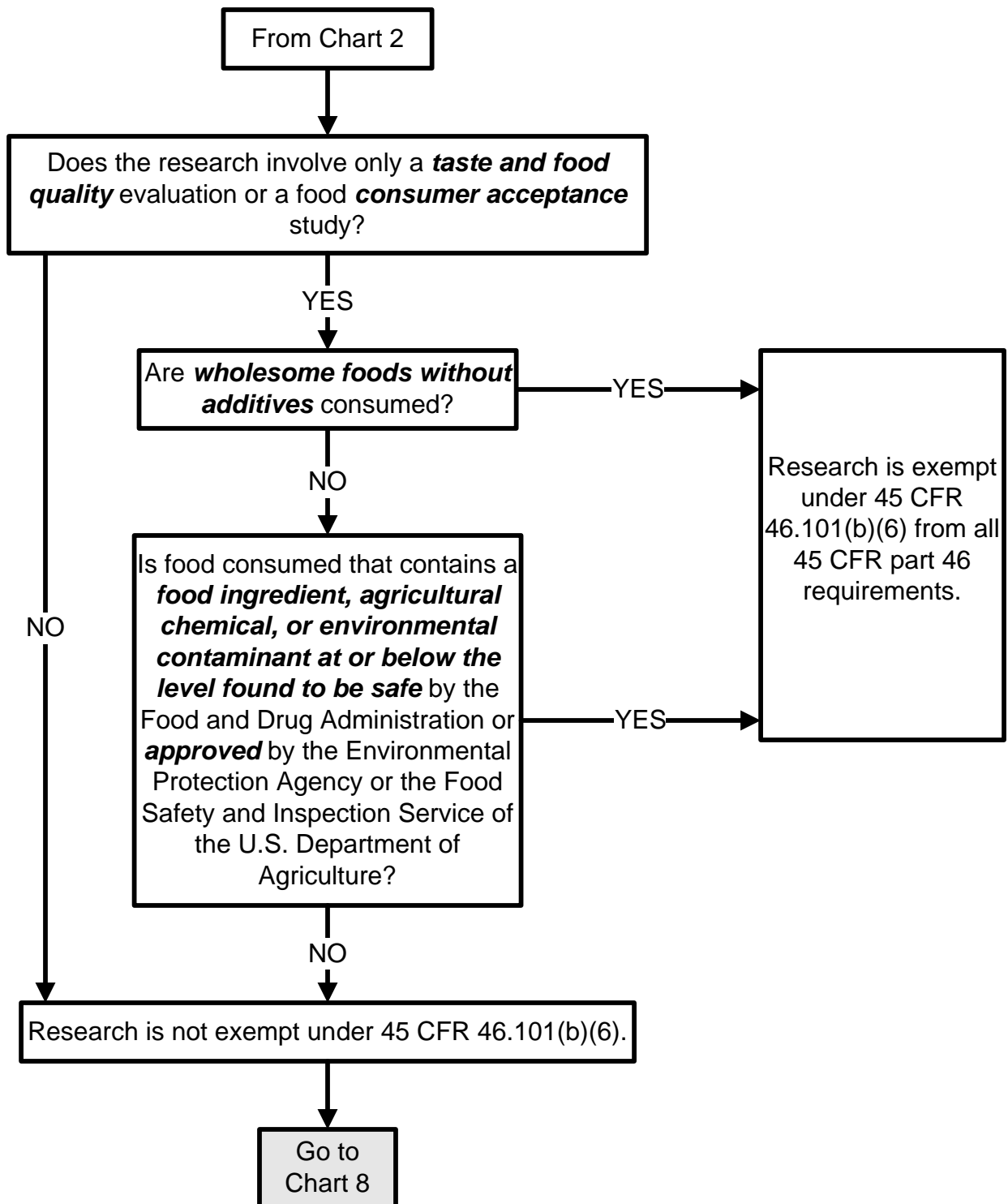
* Note: See **OHRP** guidance on research use of stored data or tissues and on stem cells at <http://www.hhs.gov/ohrp/policy/index.html#tissues> and [#stem](http://www.hhs.gov/ohrp/policy/index.html#stem), and on coded data or specimens at [#coded](http://www.hhs.gov/ohrp/policy/index.html#coded) for further information on those topics.

Chart 6: Does Exemption 45 CFR 46.101(b)(5) (for Public Benefit or Service Programs) Apply?



* Note: See **OHRP** guidance on exemptions at <http://www.hhs.gov/ohrp/policy/index.html#exempt> for further description of requirements for this exemption.

Chart 7: Does Exemption 45 CFR 46.101(b)(6) (for Food Taste and Acceptance Studies) Apply?



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Chart 8: May the IRB Review Be Done by Expedited Procedures Under 45 CFR 46.110?*

* Note: See expedited review categories and OHRP guidance on the use of expedited review procedures at <http://www.hhs.gov/ohrp/policy/index.html#expedited> for further information on expedited review.

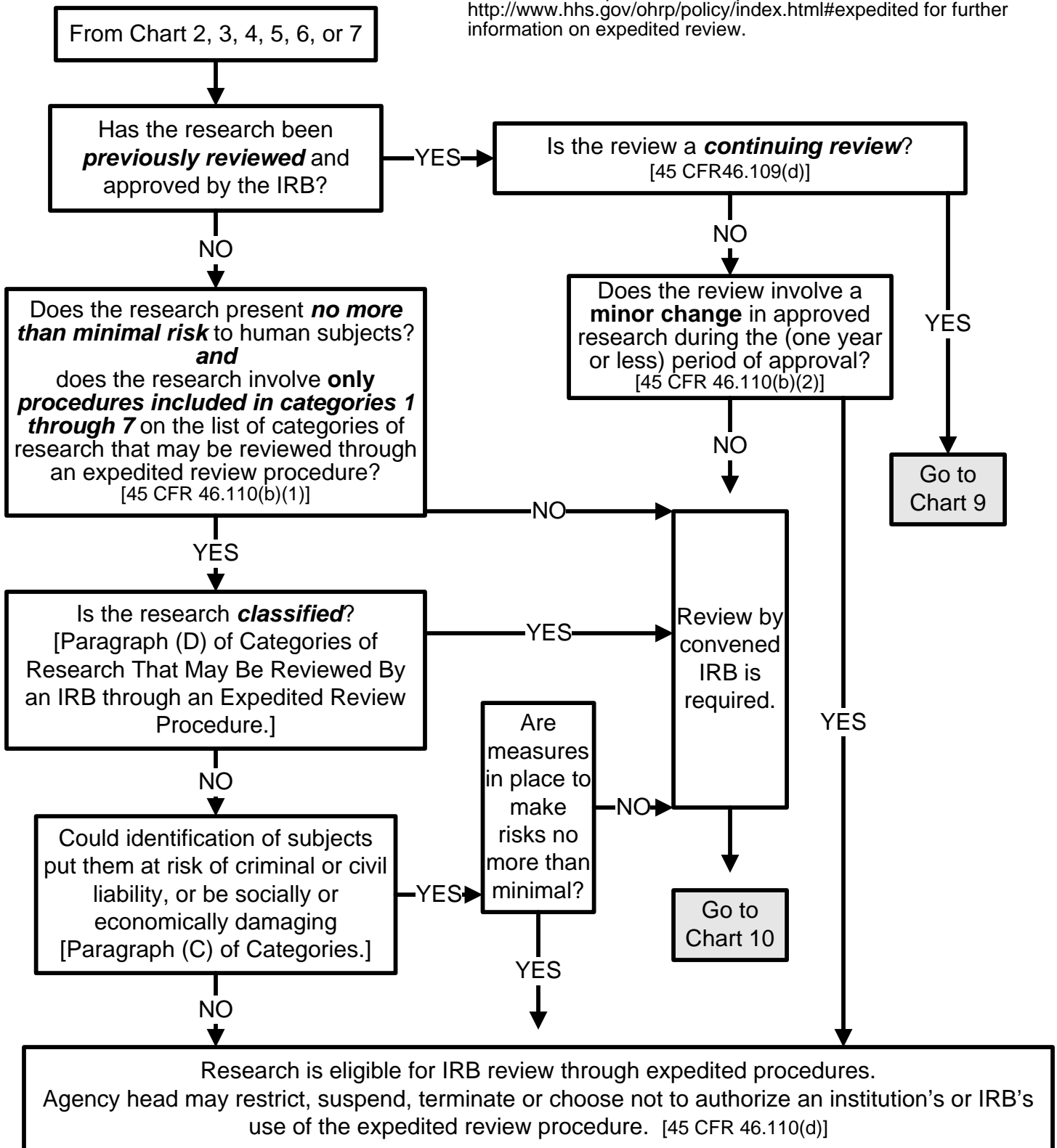


Chart 9: Can Continuing Review be Done by Expedited Procedures Under 45 CFR 46.110?

* Note: See expedited review categories, OHRP guidance on the use of expedited review procedures and on continuing review at <http://www.hhs.gov/ohrp/policy/index.html#expedited> and #continuing for further information on expedited review.

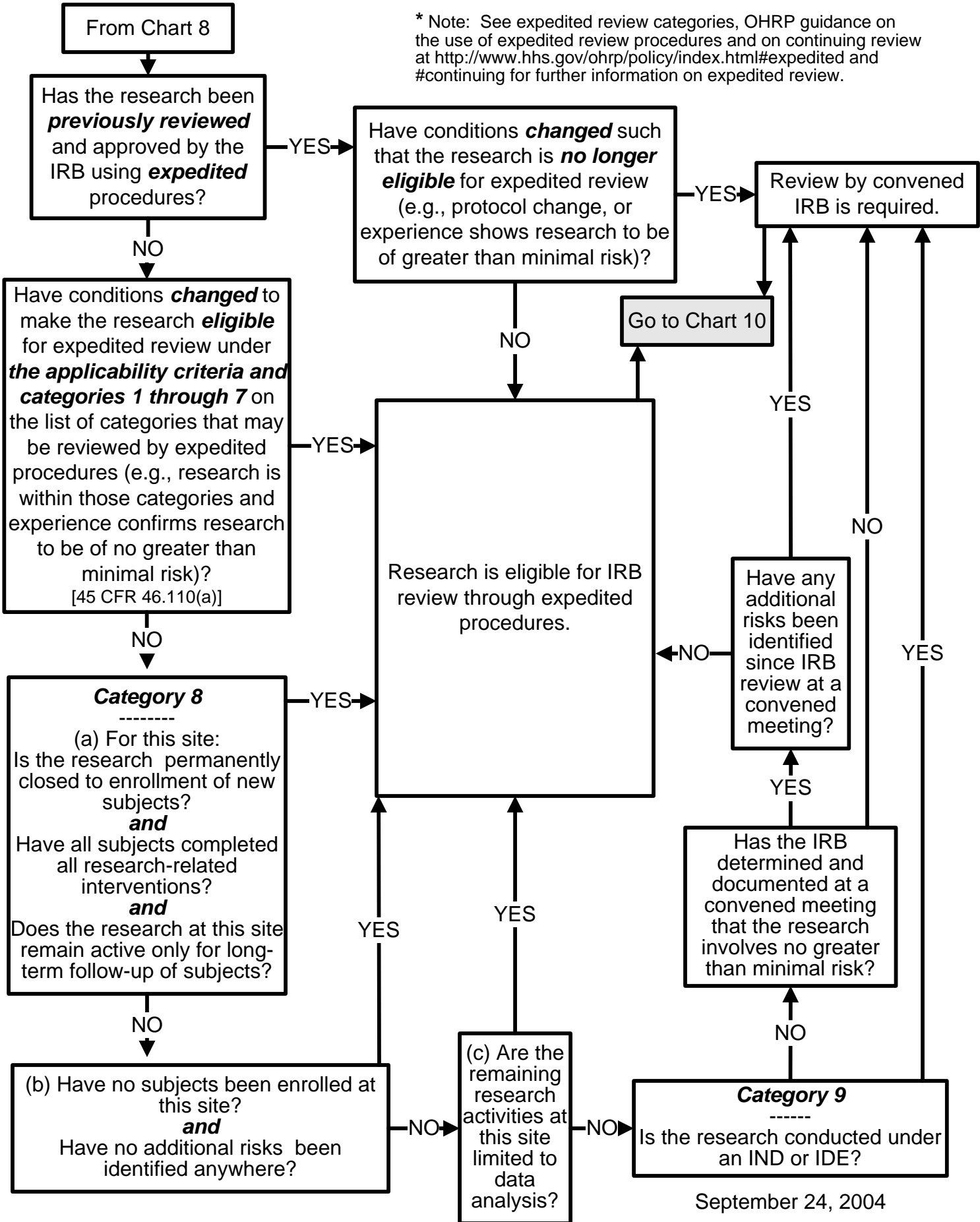
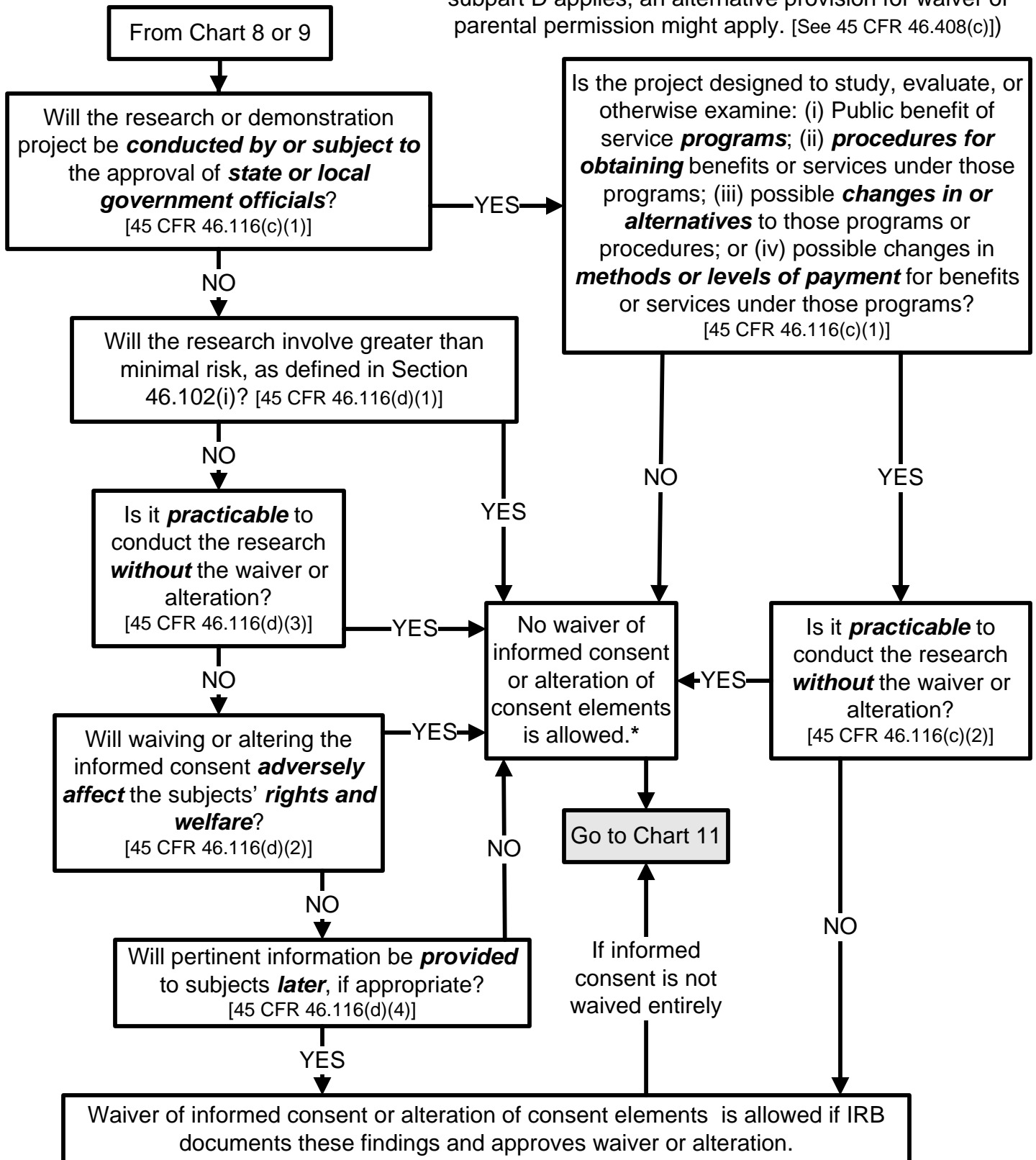


Chart 10: Can Informed Consent Be Waived or Consent Elements Be Altered Under 45 CFR 46.116(c) or (d)?**

** (Note: If subjects include children to whom 45 CFR part 46, subpart D applies, an alternative provision for waiver of parental permission might apply. [See 45 CFR 46.408(c)])



* Note: See OHRP guidance on informed consent requirements in emergency research at <http://www.hhs.gov/ohrp/policy/index.html#emergency> for further information on emergency research informed consent waiver.

Chart 11: Can Documentation of Informed Consent Be Waived Under 45 CFR 46.117(c)?

