

Chart 1: Is an Activity Research Involving Human Subjects?

February 16, 2016

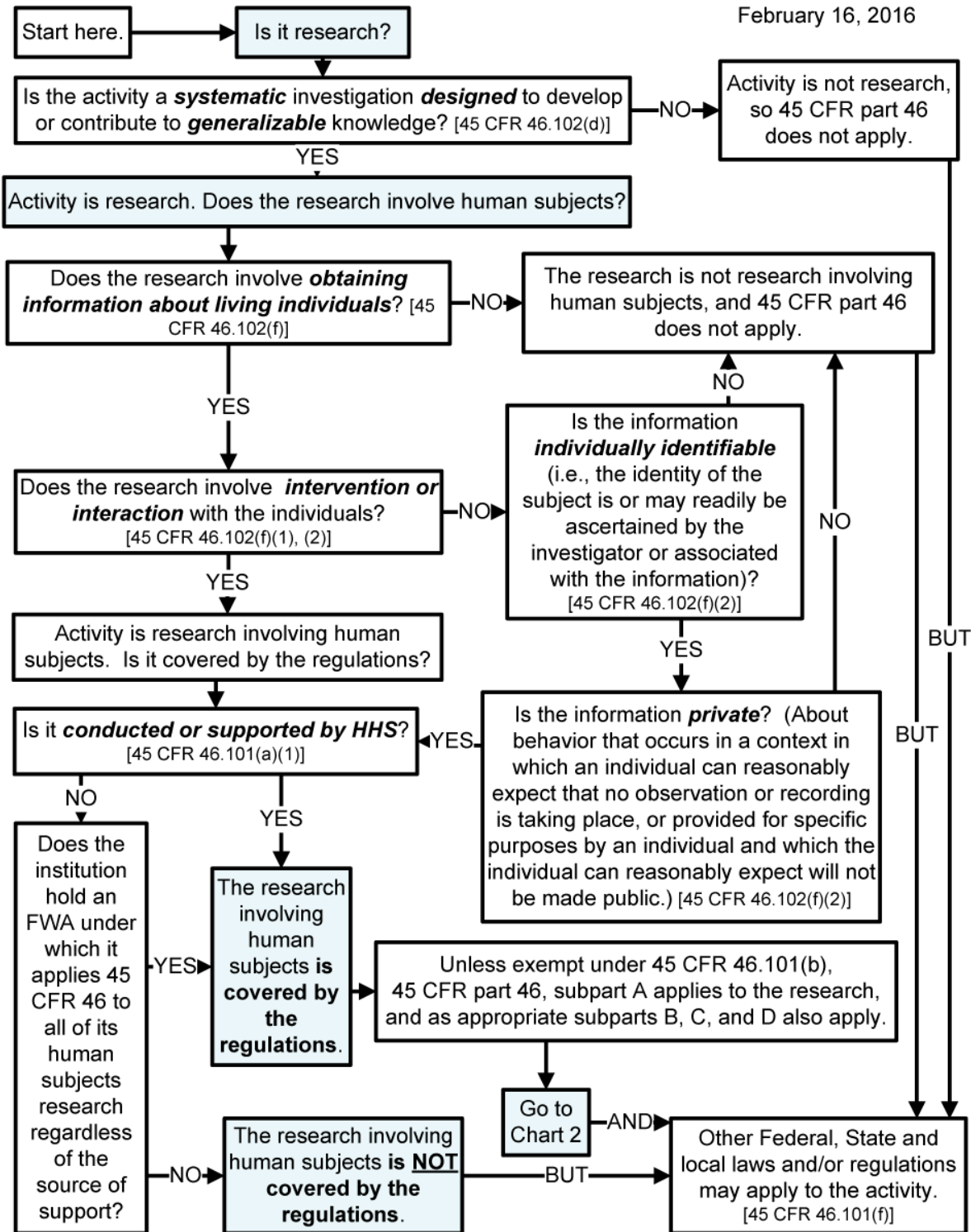


Chart 2: Is the Human Subjects Research Eligible for Exemption?

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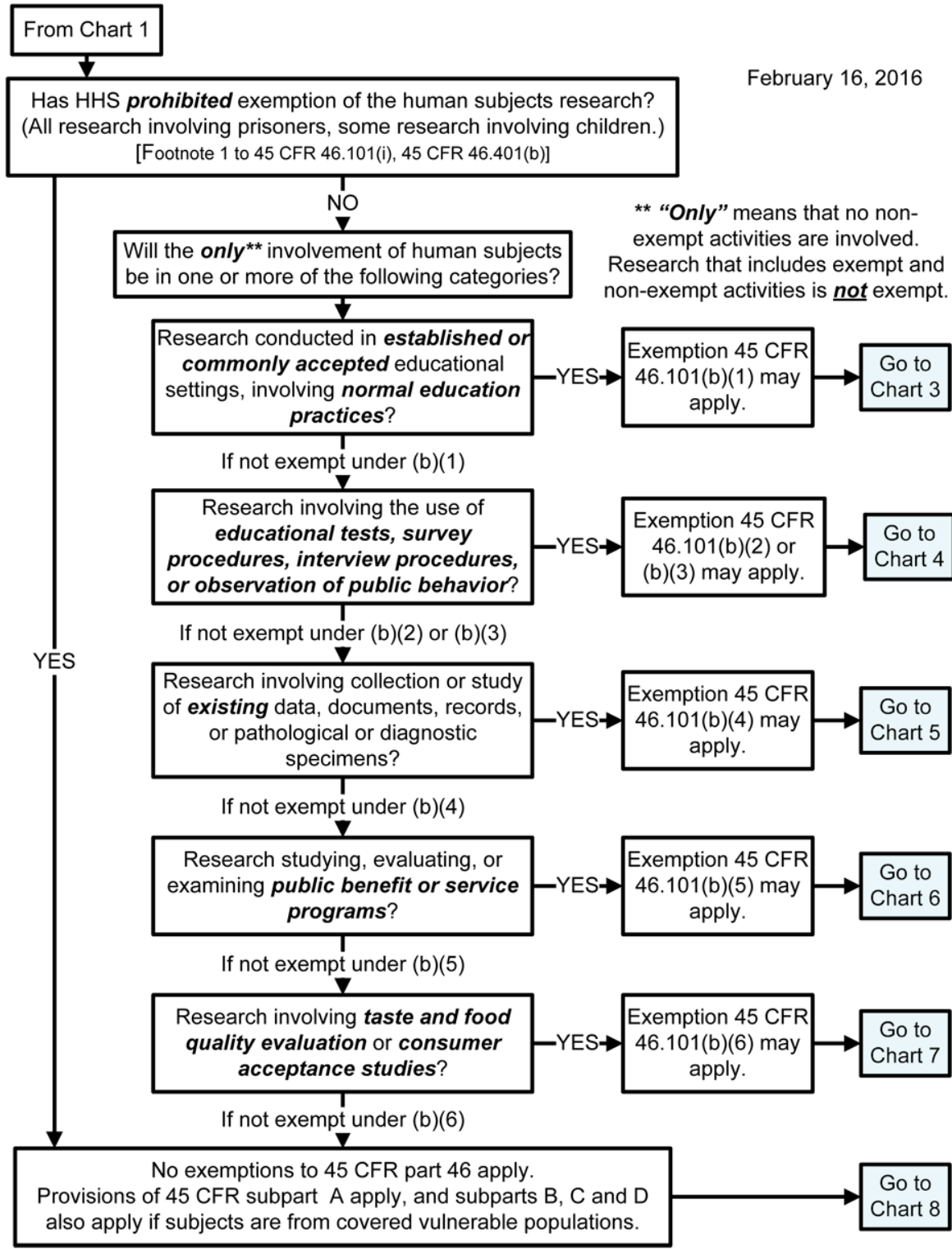


Chart 3: Does Exemption 45CFR 46.101(b)(1) (for Education Settings) Apply?

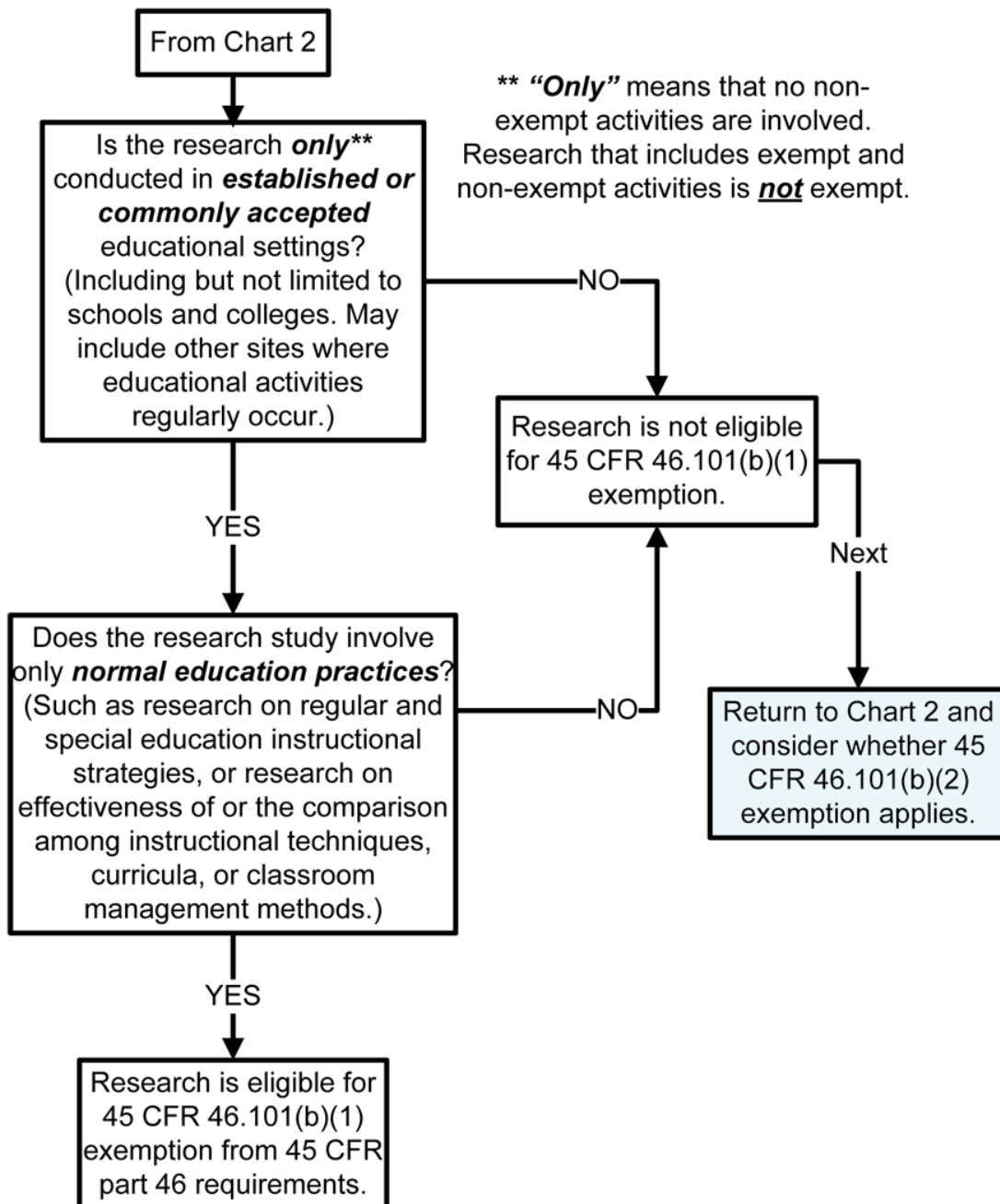


Chart 4: Does exemption 45 CFR 46.101(b)(2) or (b)(3) (for Tests, Surveys, Interviews, Public Behavior Observation) Apply?

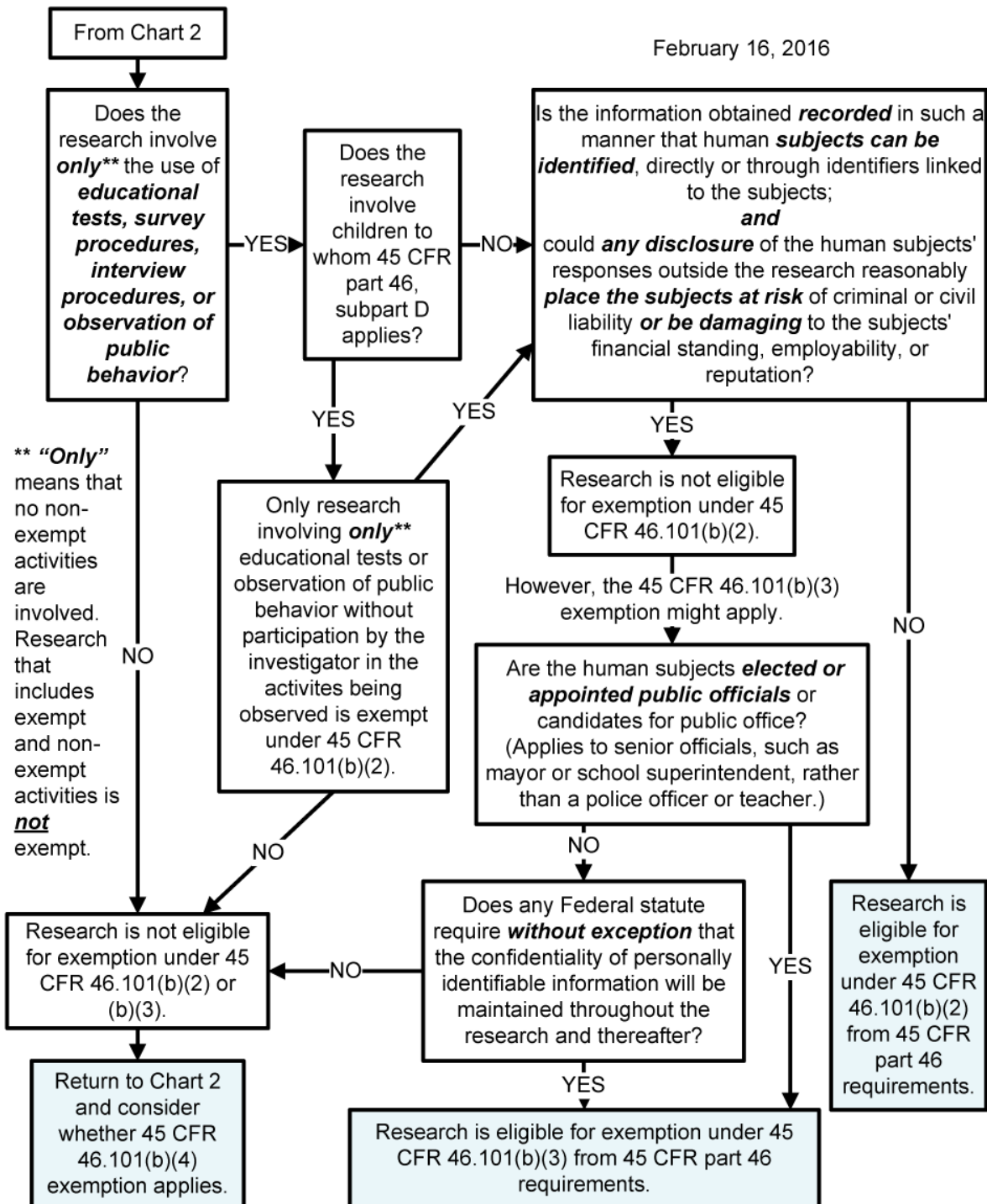
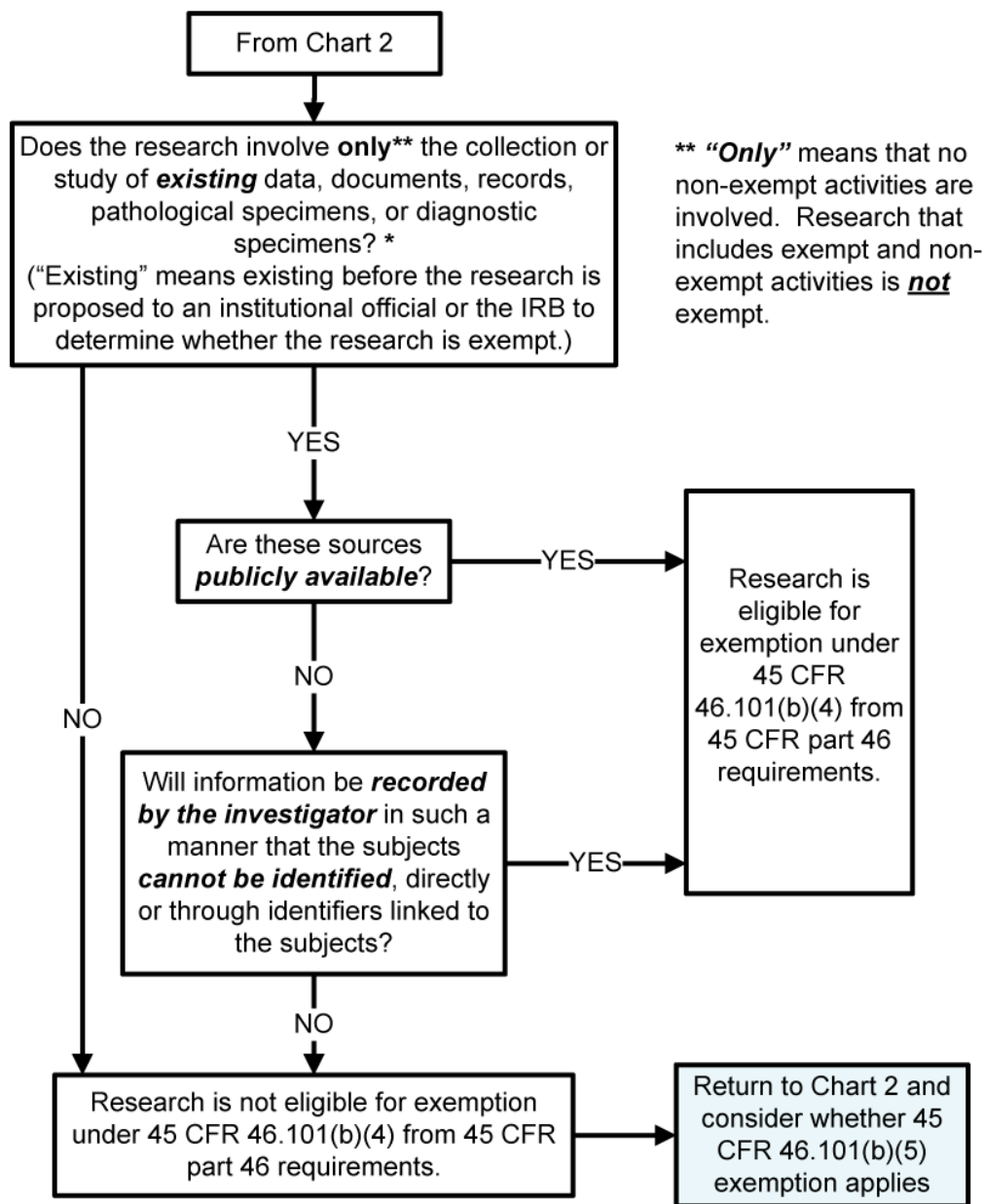


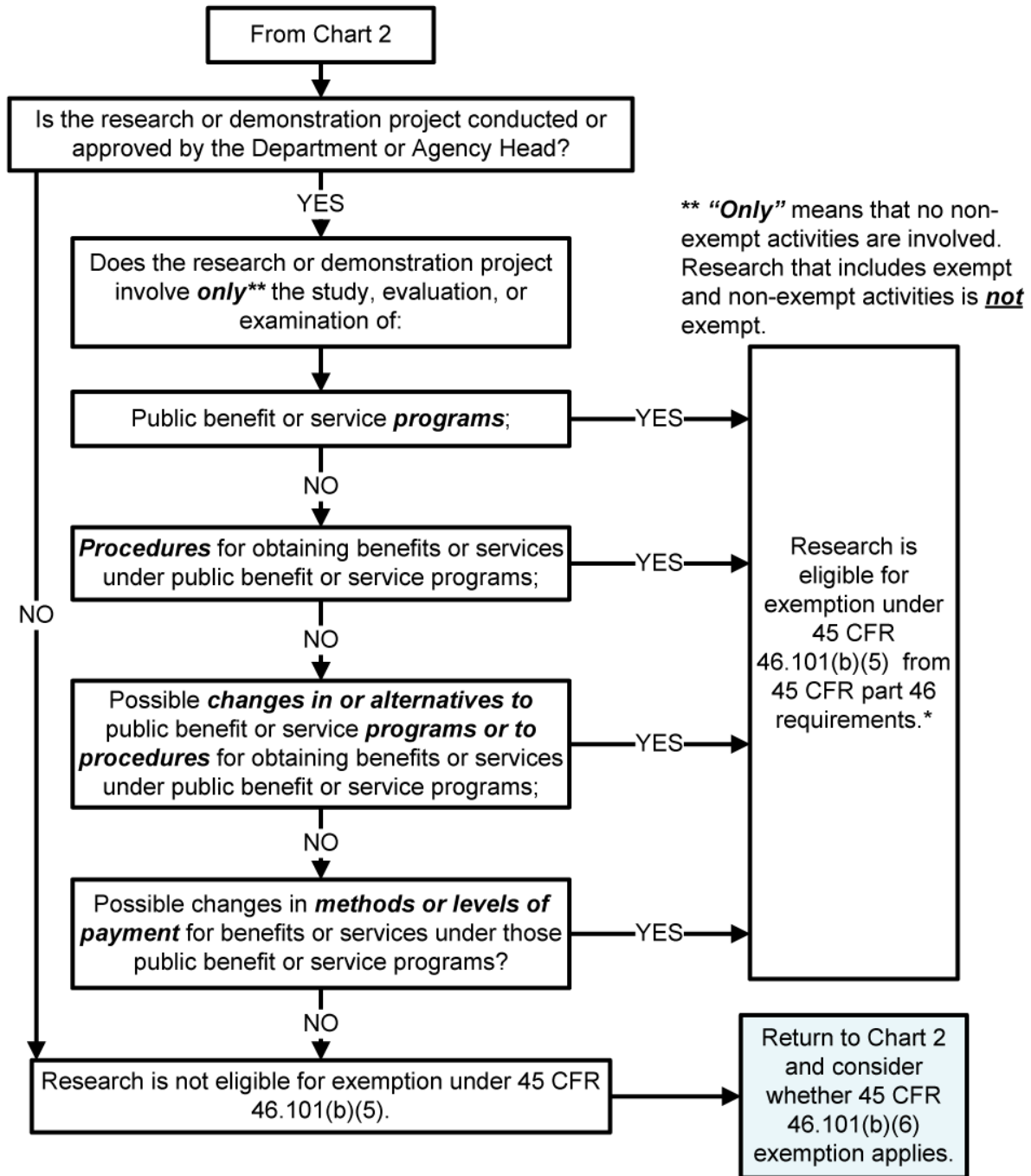
Chart 5: Does Exemption 45 CFR 46.101(b)(4) (for Existing Data, Documents, Records and Specimens) Apply?



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

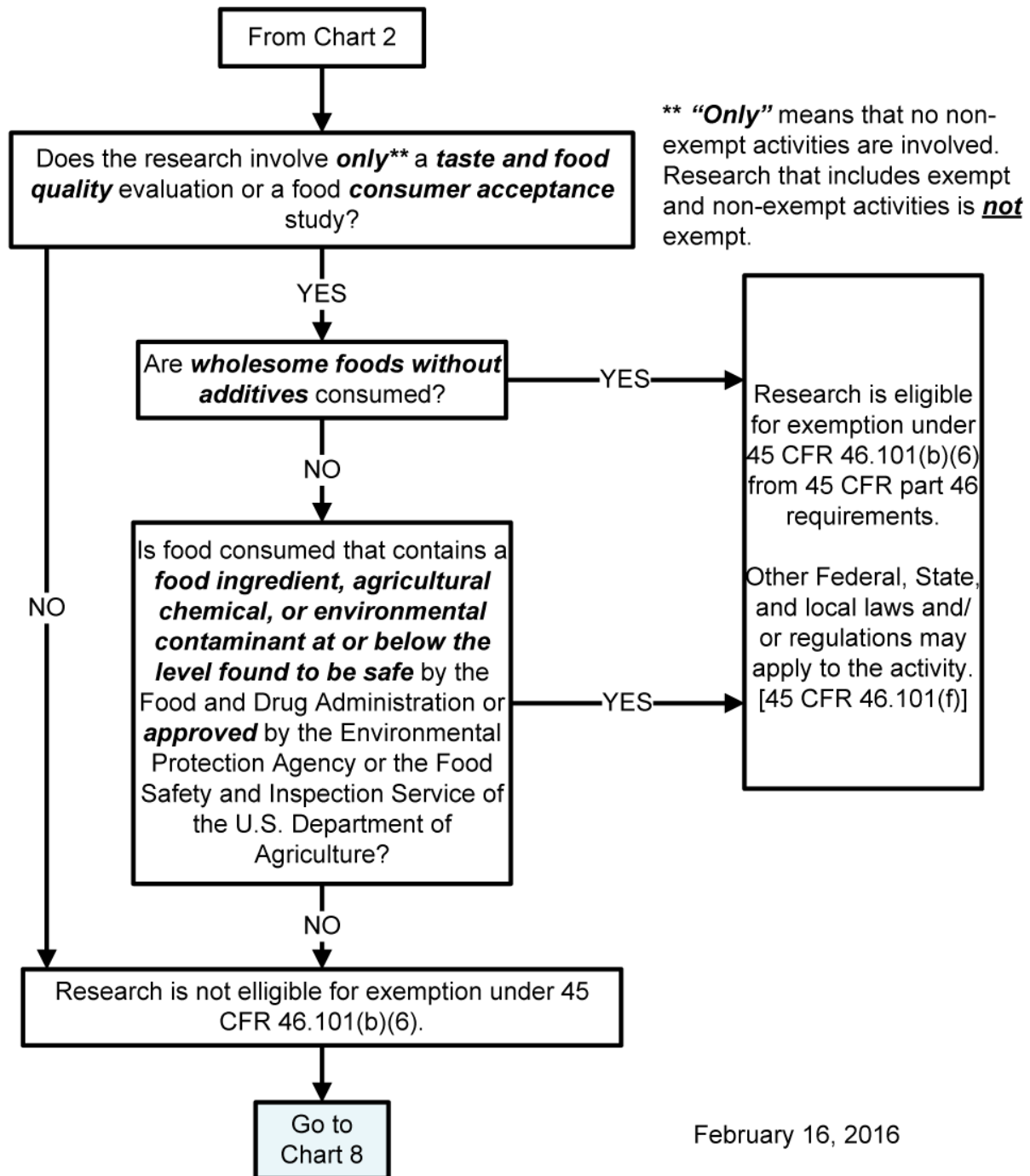
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Chart 6: Does Exemption 45 CFR 46.101(b)(5) (for Public Benefit or Service Programs) Apply?



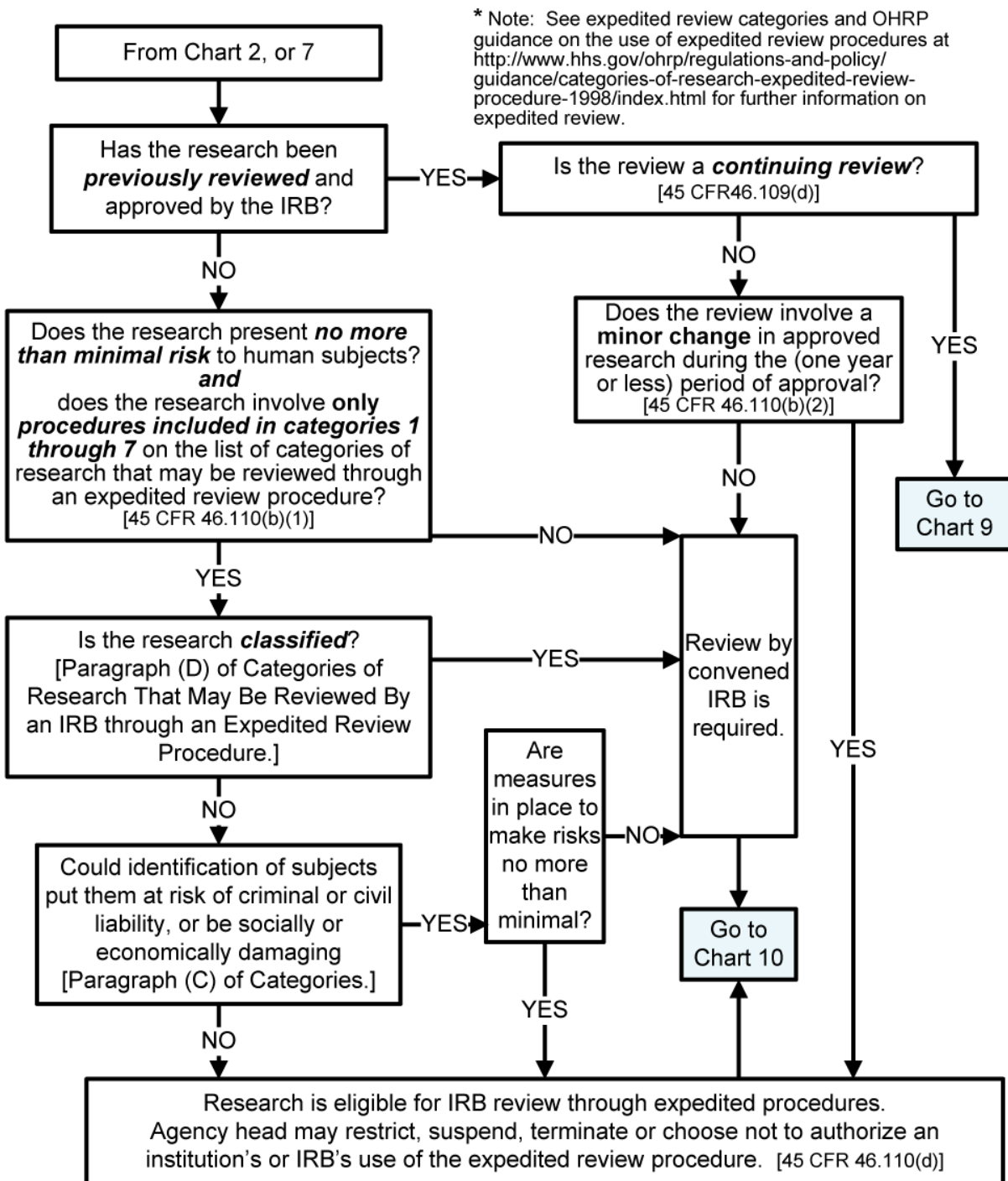
* Note: See OHRP guidance on exemptions at <http://www.hhs.gov/ohrp/regulations-and-policy/guidance/exemptions-for-public-benefit-and-service-programs/index.html> for further description of requirements for this exemption.

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?



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Chart 9: May the IRB Continuing Review Be Done by Expedited Procedures?

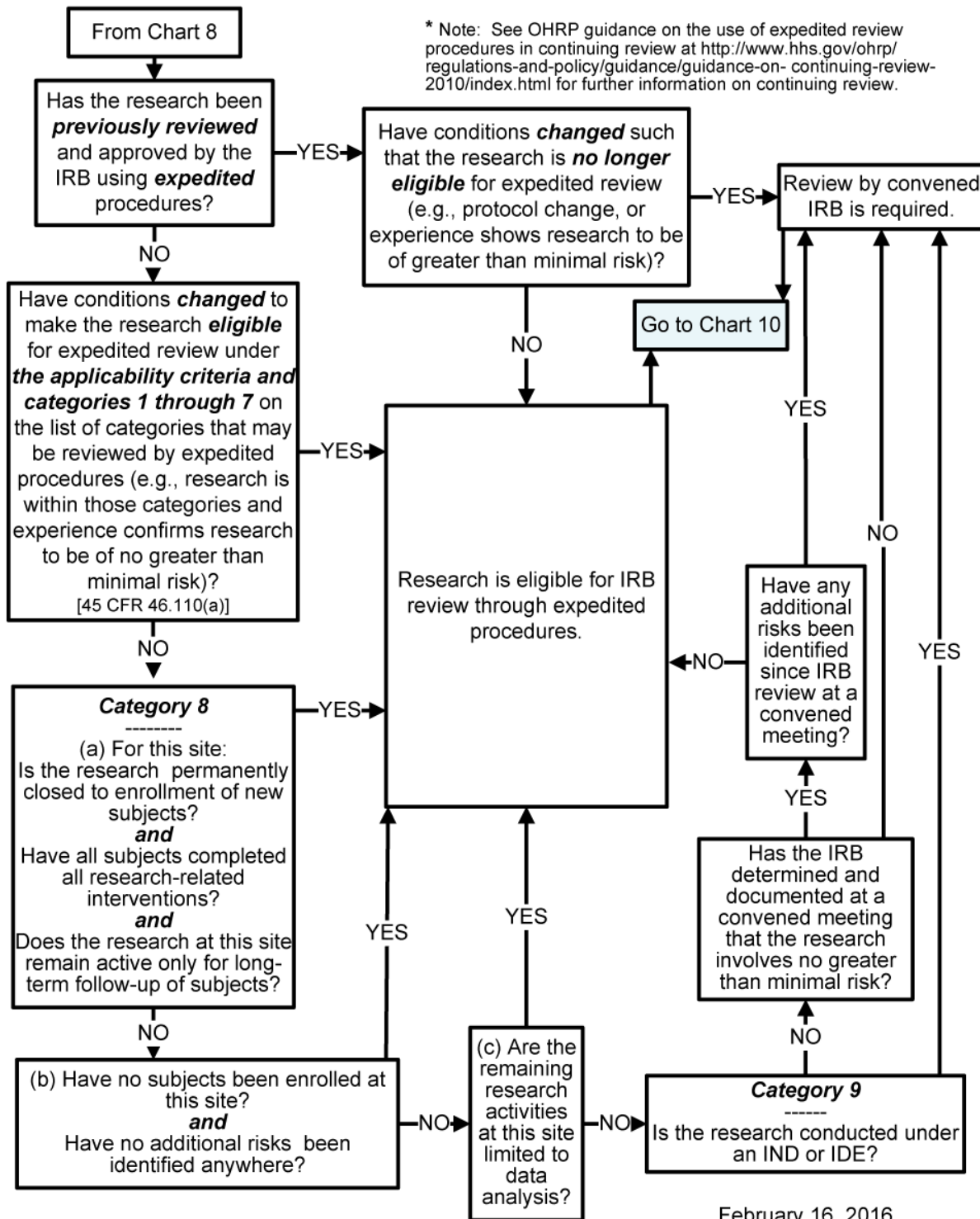
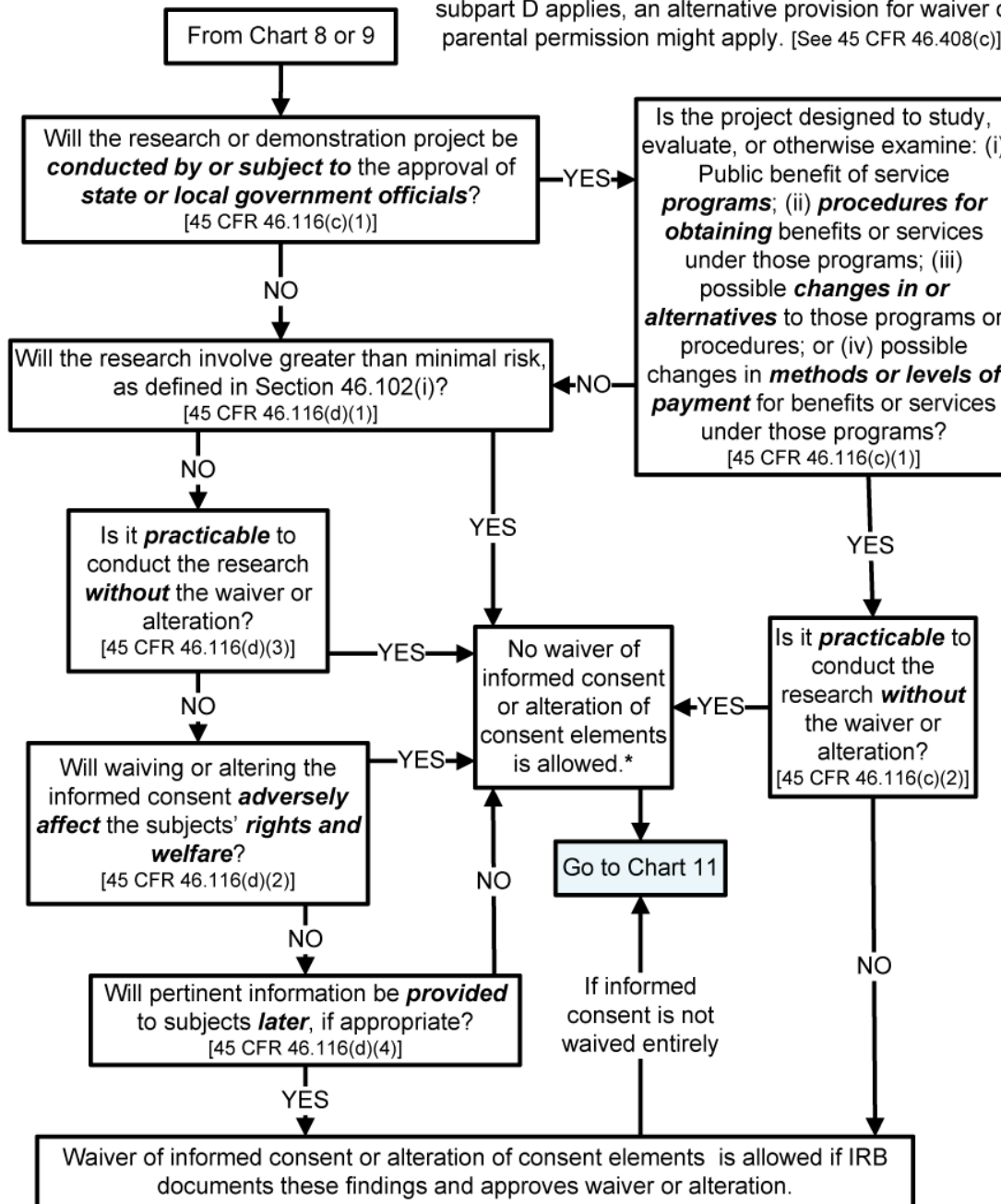


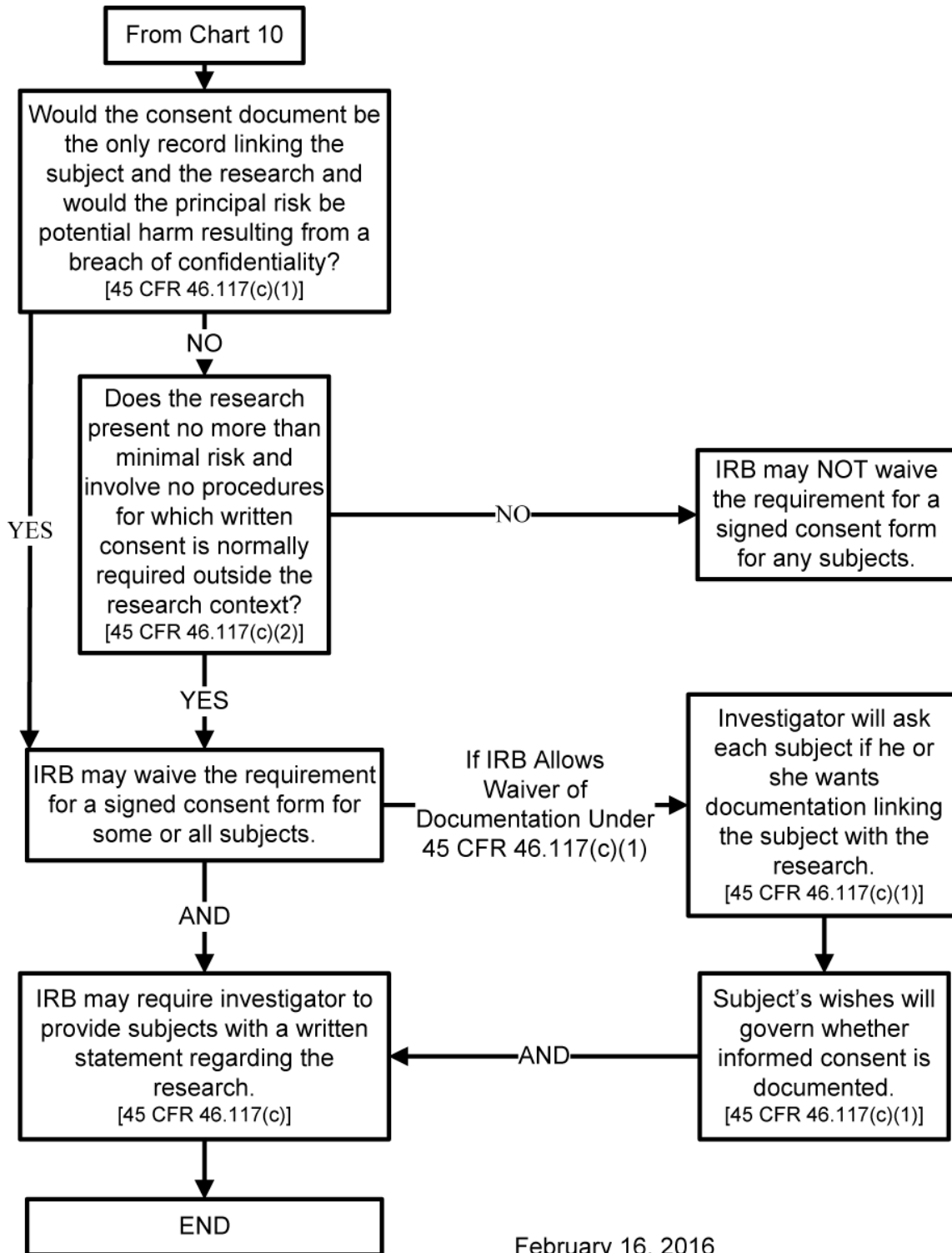
Chart 10: May Informed Consent Be Waived or Consent Elements Be Altered under 45 CFR 46.116(d)?

** (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/regulations-and-policy/guidance/emergency-research-informed-consent-requirements/index.html> for further information on emergency research informed consent waiver.

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



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