Human Subject Regulations Decision Charts

February 16, 2016

The Office for Human Research Protections (OHRP) provides the following graphic aids as a guide for institutional review boards (IRBs), investigators, and others who decide if an activity is research involving human subjects that must be reviewed by an IRB under the requirements of the U.S. Department of Health and Human Services (HHS) regulations at 45 CFR part 46. OHRP welcomes comment on these decision charts. The charts address decisions on the following:

- whether an activity **is research** that must be reviewed by an IRB
- whether the review may be performed by **expedited procedures**, and
- whether **informed consent** or its documentation may be waived.

Considerations

The charts are intended to assist IRBs, institutions, and investigators in their decision-making process and should not be used as substitutes for consulting the regulations. OHRP cautions that the full text of applicable regulatory provisions should be considered in making final decisions.

These charts are necessarily generalizations and may not be specific enough for particular situations. Other guidance documents are available related to specific topics, at OHRP Policy Guidance by Topic. OHRP invites inquiries for additional information.

The charts do not address requirements that may be imposed by other organizations, such as the Food and Drug Administration, National Institutes of Health, other sponsors, or state or local governments.

Chart 1: Is an Activity Research Involving Human Subjects?

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

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, Records and Specimens) Apply?

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

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

Chart 8: May the IRB Review Be Done by Expedited Procedures?

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)?

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

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

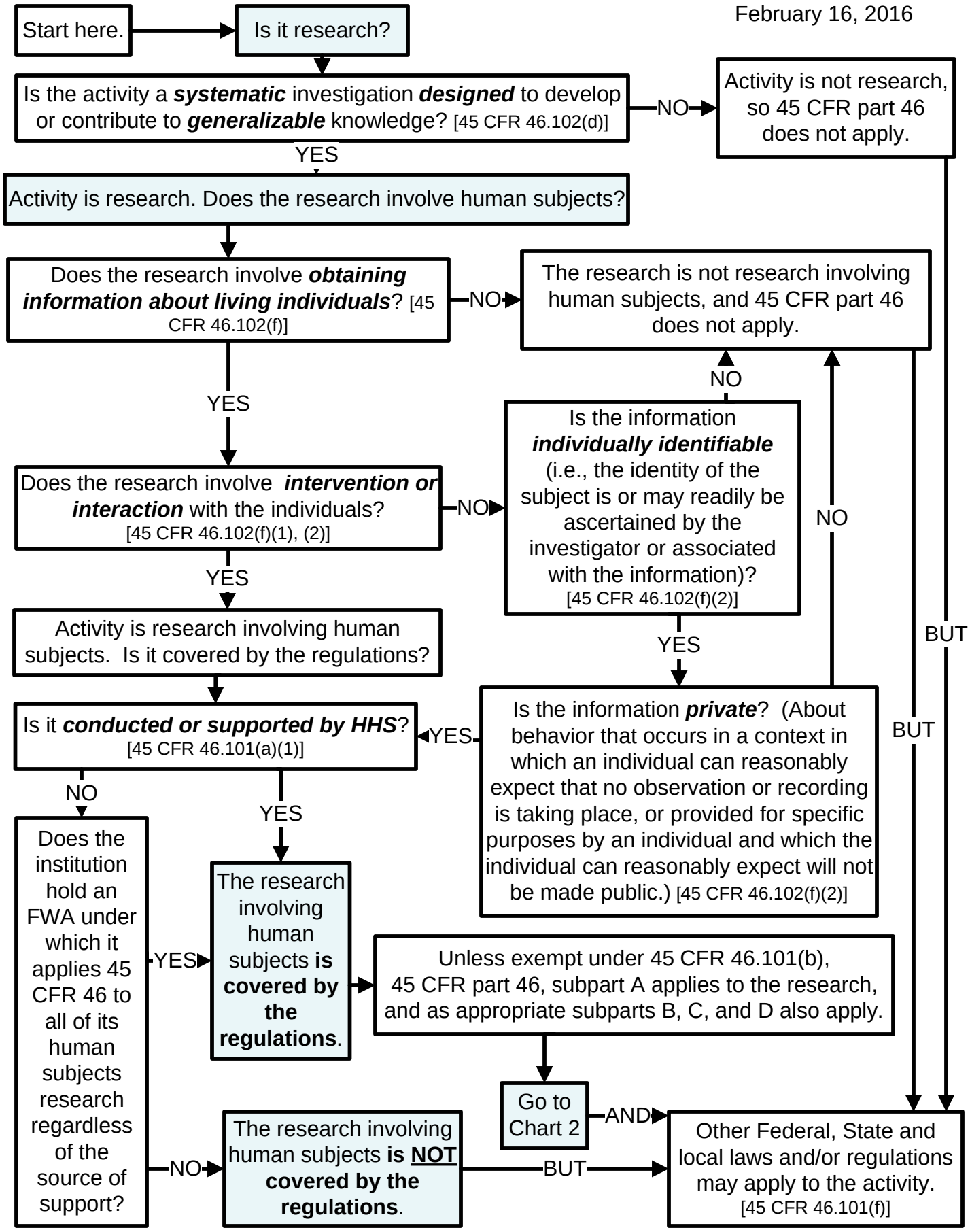

Chart 2: Is the Research Involving Human Subjects Eligible for Exemption Under 45 CFR 46.101(b)?

From Chart 1

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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)]

YES → Go to Chart 8

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. → Go to Chart 3

If not exempt under (b)(1)

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

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

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

If not exempt under (b)(4)

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

YES → Exemption 45 CFR 46.101(b)(5) may apply. → Go to Chart 6

If not exempt under (b)(5)

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

If not exempt under (b)(6)

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.

→ Go to Chart 8

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

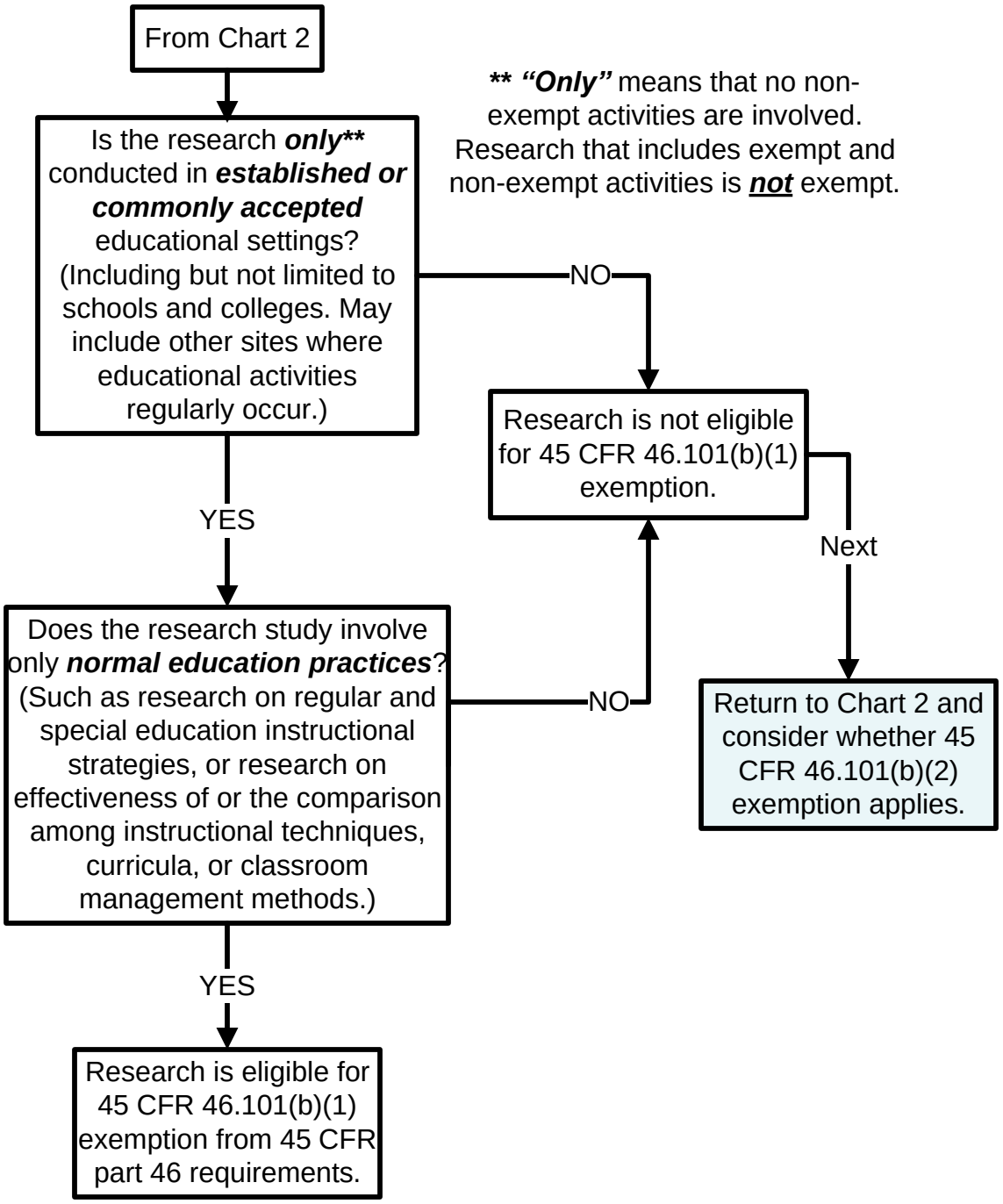

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Chart 4: Does Exemption 45 CFR 46.101(b)(2) or (b)(3) (for Tests, Surveys, Interviews, Public Behavior Observation) Apply?

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From Chart 2

Does the research involve ***only**** the use of ***educational tests, survey procedures, interview procedures, or observation of public behavior***?

YES

Does the research involve children to whom 45 CFR part 46, subpart D applies?

NO

Is the information obtained ***recorded*** in such a manner that human ***subjects can be identified***, directly or through identifiers linked to the subjects;
and
could ***any disclosure*** of the human subjects' responses outside the research reasonably ***place the subjects at risk*** of criminal or civil liability ***or be damaging*** to the subjects' financial standing, employability, or reputation?

YES

Research is not eligible for exemption under 45 CFR 46.101(b)(2).

However, the 45 CFR 46.101(b)(3) exemption might apply.

Are the human subjects ***elected or appointed public officials*** or candidates for public office? (Applies to senior officials, such as mayor or school superintendent, rather than a police officer or teacher.)

NO

Does any Federal statute require ***without exception*** that the confidentiality of personally identifiable information will be maintained throughout the research and thereafter?

YES

Research is eligible for exemption under 45 CFR 46.101(b)(3) from 45 CFR part 46 requirements.

NO

Research is not eligible for exemption under 45 CFR 46.101(b)(2) or (b)(3).

Return to Chart 2 and consider whether 45 CFR 46.101(b)(4) exemption applies.

YES

Research is eligible for exemption under 45 CFR 46.101(b)(2) from 45 CFR part 46 requirements.

NO

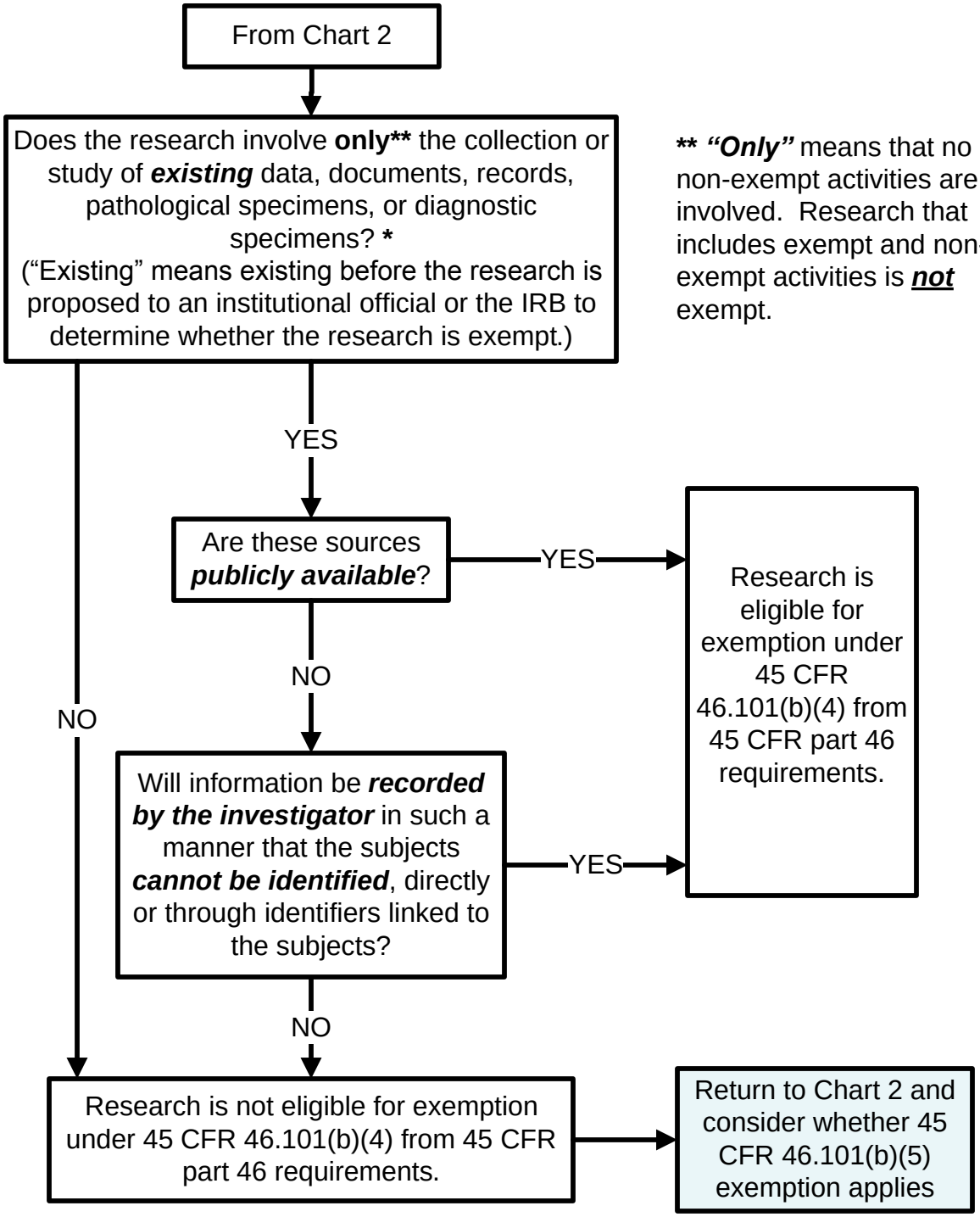
Only research involving ***only**** educational tests or observation of public behavior without participation by the investigator in the activites being observed is exempt under 45 CFR 46.101(b)(2).

YES

NO

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

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



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

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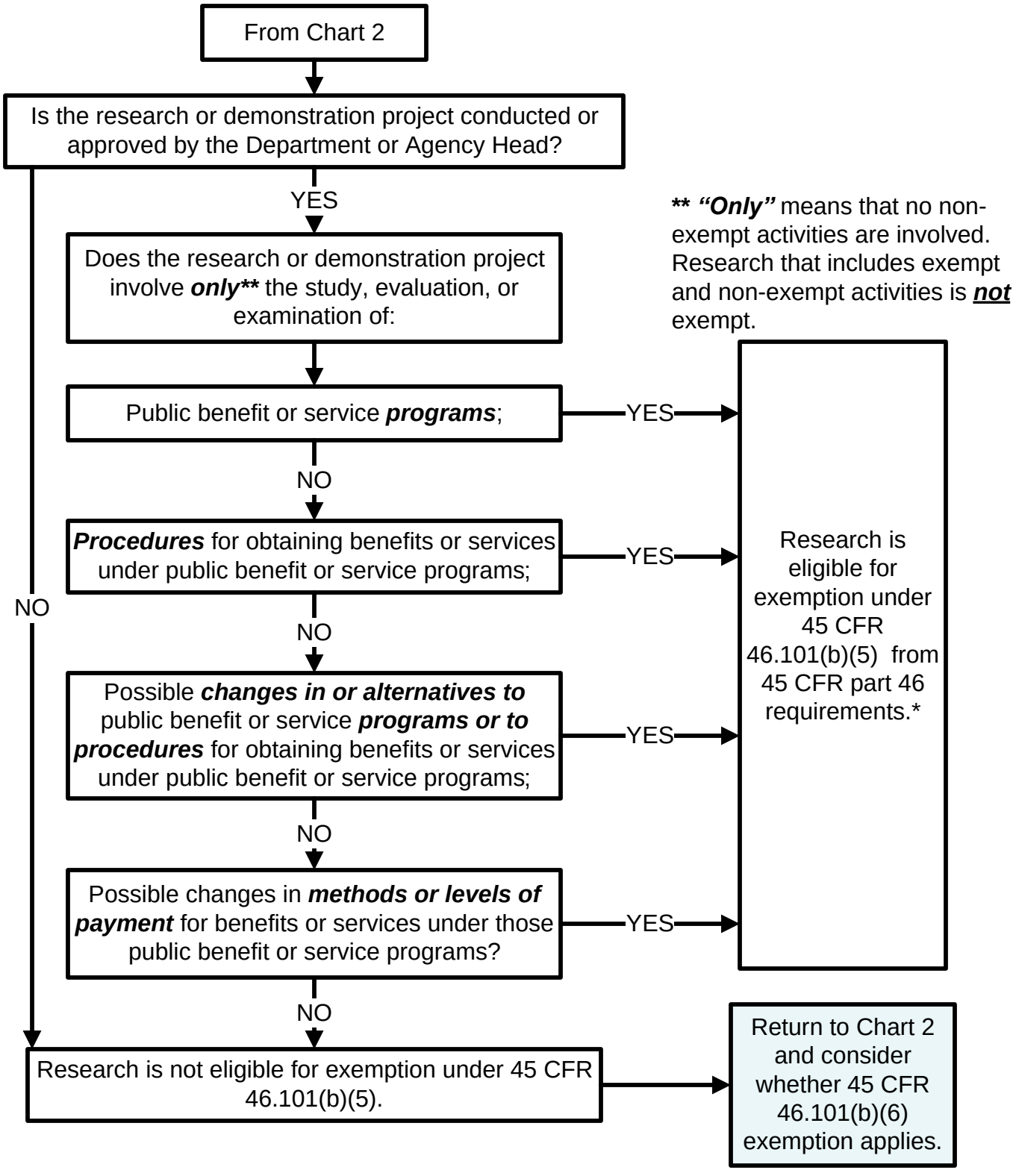
Chart 6: Does Exemption 45 CFR 46.101(b)(5) (for Public Benefit or Service Programs) Apply?



* 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.

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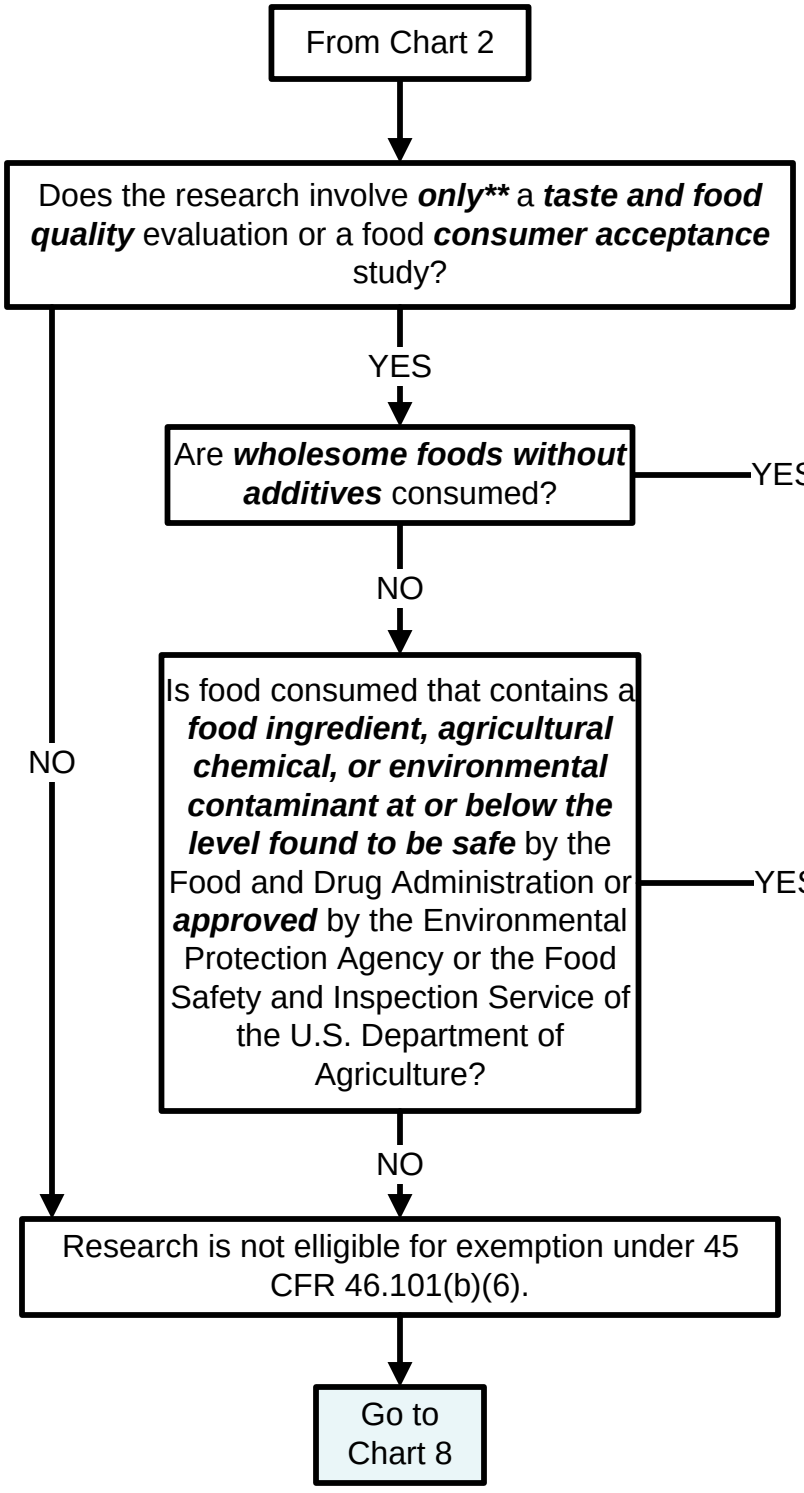
Chart 7: Does Exemption 45 CFR 46.101(b)(6) (for Food Taste and Acceptance Studies) Apply?



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

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

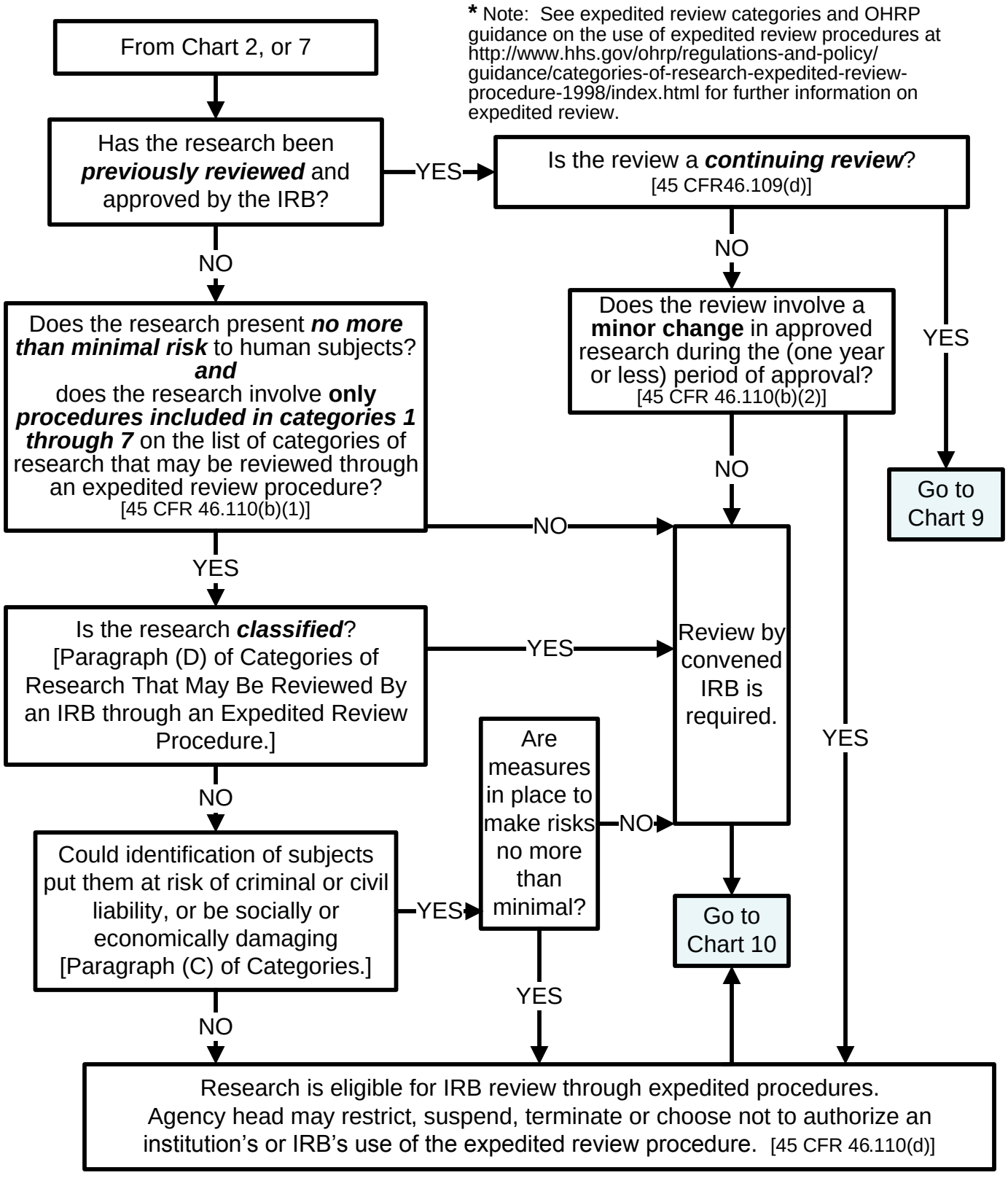

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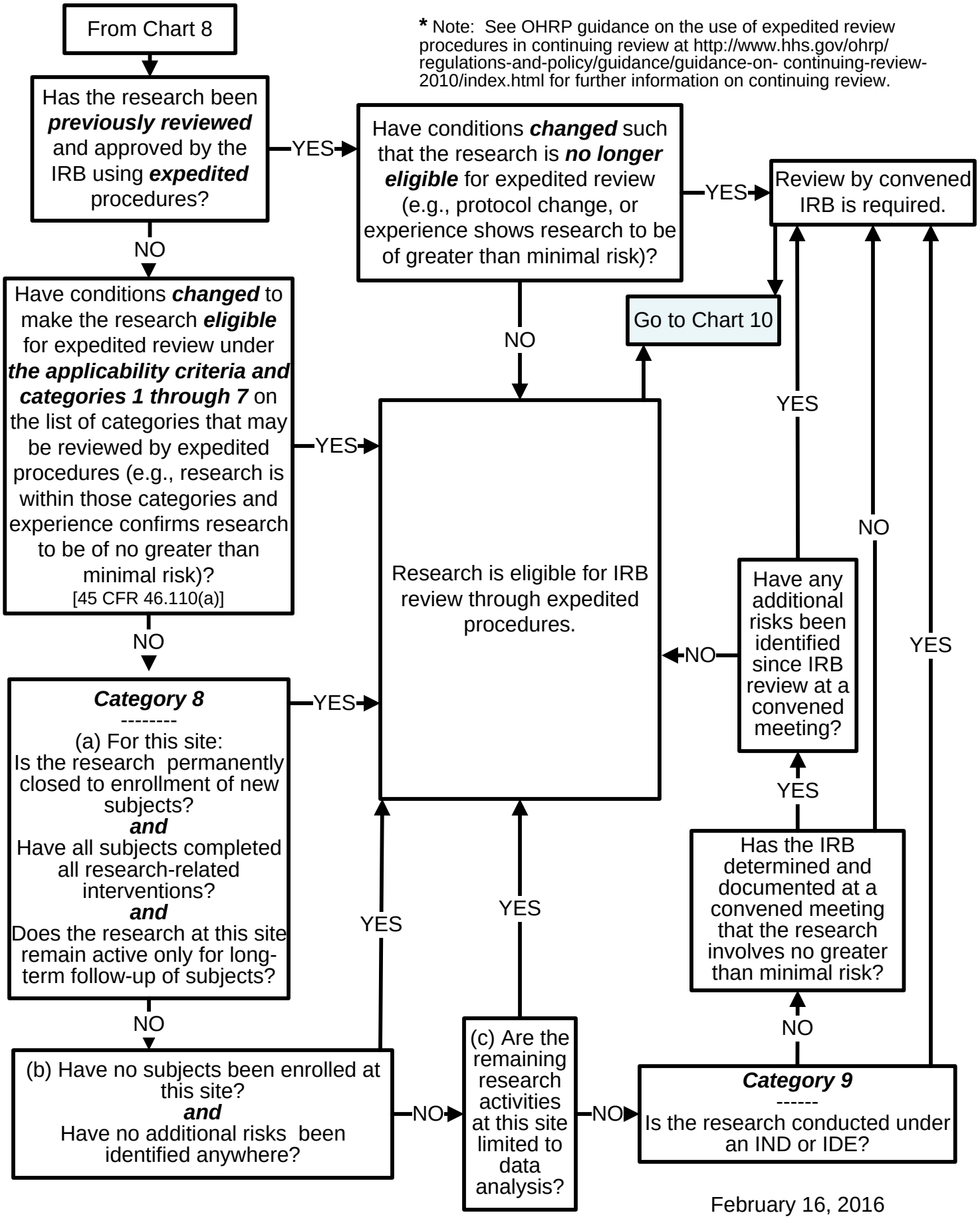
Chart 9: Can Continuing Review be Done by Expedited Procedures Under 45 CFR 46.110?



***** Note: See OHRP guidance on the use of expedited review procedures in continuing review at http://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on- continuing-review-2010/index.html for further information on continuing review.

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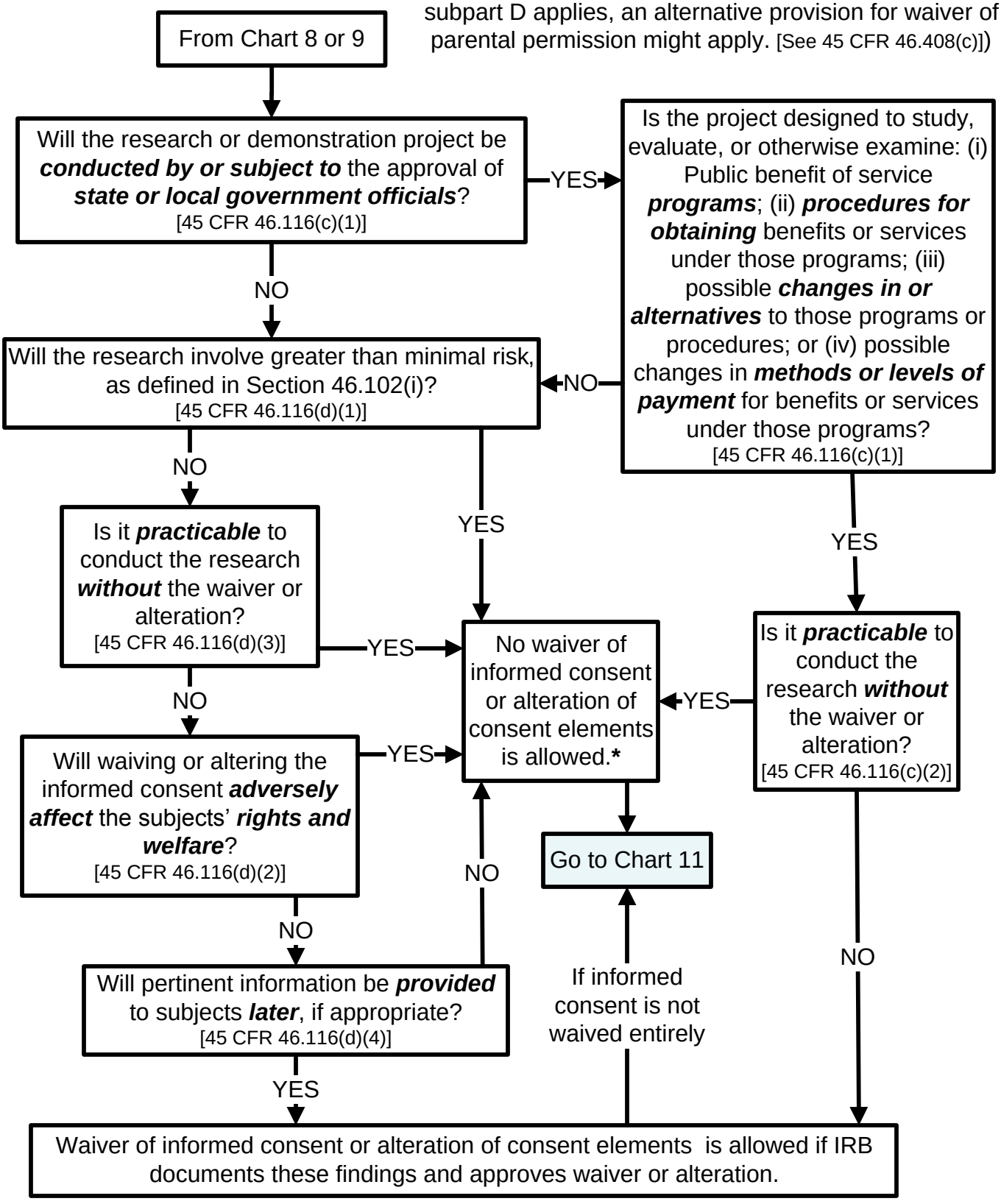
Chart 10: Can Informed Consent Be Waived or Consent Elements Be Altered Under 45 CFR 46.116(c) or (d)?**

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

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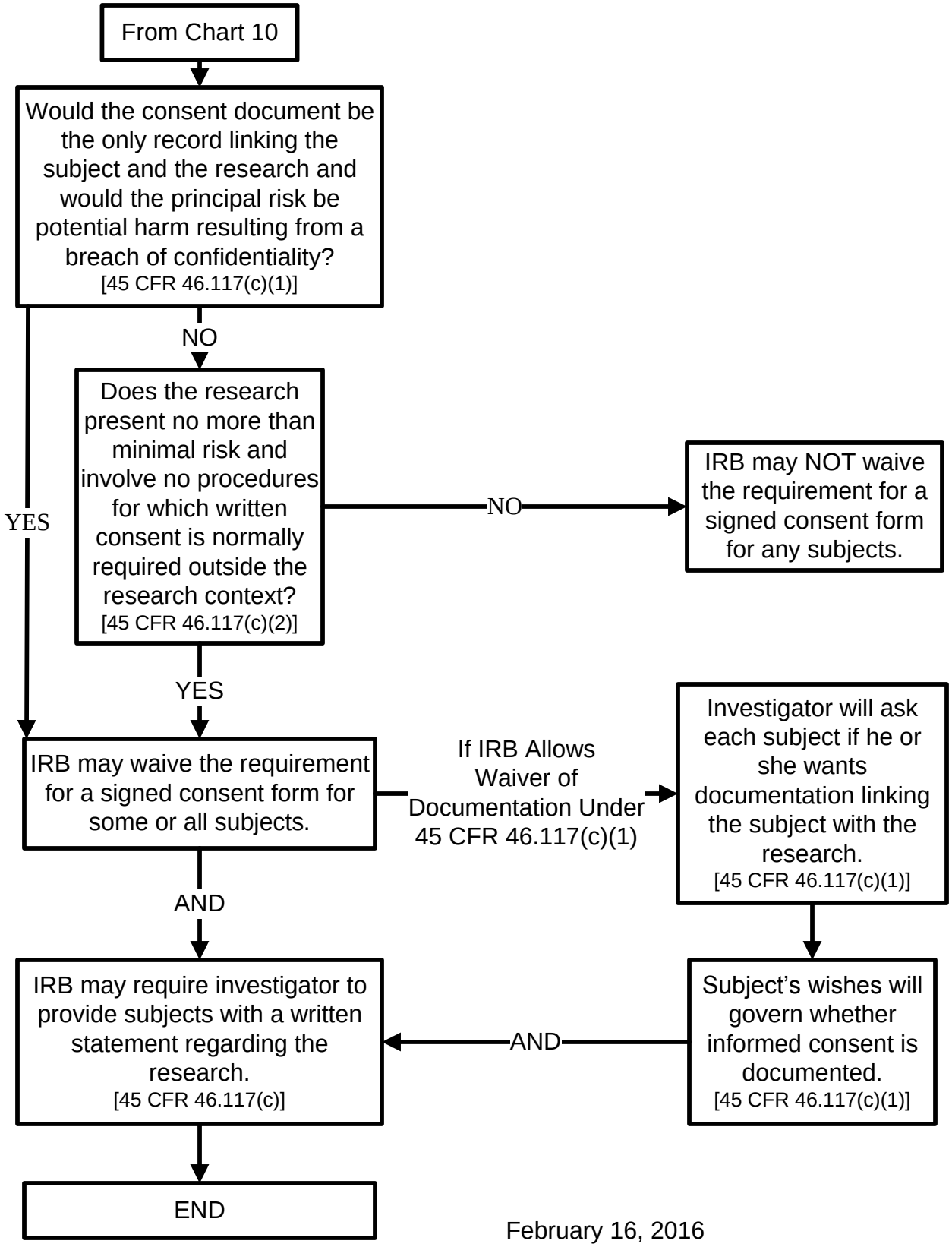
Chart 11: May Documentation of Informed Consent Be Waived Under 45 CFR 46.117(c)?



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