**Guidelines For Determining Whether An Activity Is Research Or Public Health Practice**

In determining whether a project is research or public health practice, and whether IRB review is required, the SAC may use the attached Checklist adapted from one developed by the Council of State and Territorial Epidemiologists[1], and the Decision Charts developed by the US Office of Human Research Protections (OHRP)[2].

The Checklist and Decision Charts present models to help guide public health practitioners through a process to determine whether an activity is public health practice (practice) or human subjects research (research) consistent with the Common Rule and the HIPAA Privacy Rule. There are always difficult examples that do not neatly fit into either category. However, these tools are designed to help resolve a majority of cases to provide consistency in decision-making. The Checklist is more useful for distinguishing between research vs public health practice, and the Decision Charts are more suited for deciding if an activity is research involving human subjects that must be reviewed by an IRB—one or both may be used in different situations. The SAC may consider and use additional information other than this document and these tools to assist in the decision-making process.

To use the Checklist, answer the key Assumptions and Questions in Steps 1-4, proceeding in accordance with your responses, to reach the Conclusions in Step 5. In some cases, this process will not require addressing all of the steps; in other cases, each of the steps may contribute to clarifying the distinction.

To use the Decision Charts, begin with Chart 1, which will then point you to the need for any of the other Charts in the set. Not all Charts will be applicable to every situation.


1. Council of State and Territorial Epidemiologists, *Public Health Practice vs. Research, A Report for Public Health Practitioners Including Cases and Guidance for Making Distinctions*, May 24, 2004.
2. Office of Human Research Protections, Federal Register /Vol. 82, No. 12, Thursday, January 19, 2017.

Checklist adapted from Council of State and Territorial Epidemiologists, Public Health Practice vs. Research, A Report for Public Health Practitioners Including Cases and Guidance for Making Distinctions, May 24, 2004.

| **Steps and Related Assumptions and Questions** | **Yes** | **No** | **Next Action** | |
|---|---|---|---|---|
| | | | **If Yes, then** | **If No, then** |
| **Step 1: Check Key Assumptions** | | | | |
| **Assumption 1.** Does the activity involve the acquisition, use, or disclosure of identifiable health data (i.e., individually-identifiable private information or biospecimens? | | | Go to **Step 2.** | **Stop.** This Checklist does not apply. |
| **Step 2: Assess the Foundations of Public Health Practice** | | | | |
| **Assumption 2.** In general, does the activity involve the collection and analysis of identifiable private information for the purpose of protecting the health of a particular community, where the benefits and risks are primarily designed to accrue to the participating community? | | | Go to **Q 2.A**. | Go to **Step 3**. |
| **Question 2.A.** Is there a *specific* legal authorization (via statute, administrative regulation, or other law) and corresponding governmental duty to use identifiable health data for a public health purpose that underlie the | | | **Stop**. This activity is practice. | Go to **Q 2.B**. |
| **Question 2.B.** Does the activity involve direct performance or oversight by a public health authority (or its authorized partner) and accountability to the public for its performance? | | | Go to **Q 2.C**. | Go to **Step 3**. |
| **Question 2.C.** Does the activity legitimately involve persons who must participate in the activity or did not specifically volunteer to participate (i.e., they did not provide informed consent absent a waiver under | | | **Stop**. This activity is practice. | Go to **Step 3**. |
| **Step 3: Assess the Foundations of Human Subjects Research** | | | | |
| **Assumption 3.A.** In general, does the activity involve the collection and analysis of identifiable private information for the purpose of generating knowledge that will benefit those beyond the community of persons who bear the risks of participation? | | | Go to **Q 3.A**. | The activity is likely practice. Go to **Step 4**. |
| **Question 3.A.** Does the activity involve living individuals? | | | Go to **Q 3.B**. | **Stop**. This is not human subjects research |
| **Question 3.B.** Does the activity involve, in part, identifiable private information? | | | Go to **Q 3.C**. | **Stop**. This is not human subjects research. |
| **Question 3.C.** Does the activity involve persons who voluntarily participate via informed consent or the consent of their guardian, absent a waiver of informed consent under the Common Rule? | | | Go to **Step 4**. | **Stop**. This activity is practice. |
| **Step 4: Consider Enhanced Guidance** | | | | |
| **Question 4.A.** ***General Legal Authority***: Is there *general* legal authorization (via statute, administrative regulation, or other law) and a corresponding governmental duty supporting the use of identifiable private information for a legitimate public health purpose? | | | The activity is likely practice. Go to **Q 4.B. 1-2** | Go to **Q 4.B. 1-2** |

Checklist adapted from Council of State and Territorial Epidemiologists, Public Health Practice vs. Research, A Report for Public Health Practitioners Including Cases and Guidance for Making Distinctions, May 24, 2004.

| **Steps and Related Assumptions and Questions** | **Yes** | **No** | **Next Action** | |
|---|---|---|---|---|
| | | | **If Yes, then** | **If No, then** |
| **Question 4.B.1.** ***Specific Intent***: Is there any intent underlying the activity to test a hypothesis and seek to generalize the findings or acquired knowledge beyond the activity's participants? | | | The activity is likely research. Go to **Q 4.C**. | Go to **Q 4.B.2**. |
| **Question 4.B.2.** ***Specific Intent***: Is the primary intent underlying the activity to assure the conditions in which people can be healthy through public health efforts that are primarily aimed at preventing known or suspected injuries, diseases, or other conditions, or promoting the health of a | | | The activity is likely practice. Go to **Q 4.C**. | Go to **Q 4.C**. |
| **Question 4.C.** ***Responsibility***: Is responsibility for the health, safety, or welfare of the participants vested or assigned to an identified person, like a principal investigator? | | | The activity is likely research. Go to **Q 4.D 1-2** | Go to **Q 4.D.1.** |
| **Question 4.D.1.** ***Participant Benefits***: Is the activity designed to provide some benefit to the participants or their population as a whole? | | | The activity is likely practice. Go to **Q 4.E**. | Go to **Q 4.D.2**. |
| **Question 4.D.2.** ***Participant Benefits***: Does the activity involve additional risks imposed on participants in order to make the results generalizable beyond the participants themselves? | | | The activity is likely research. Go to **Q 4.E**. | Go to **Q 4.E**. |
| **Question 4.E.** ***Experimentation***: Is the activity designed to introduce non-standard or experimental elements or methods to the research subjects or the analysis of their identifiable health data? | | | The activity is likely research. Go to **Q 4.F**. | Go to **Q 4.F**. |
| **Question 4.F.** ***Subject Selection***: Are the participants in the activity selected randomly so that the results of the activity can be generalized to a larger population? | | | **Stop**. The activity is likely research. | **Stop**. The activity is likely practice. |
| **Step 5: Conclusions** | | | | |
| **Conclusion 5.A.** ***Public Health Practice***: If your responses affirm that your activity (or some part thereof) is or is likely public health practice, the activity is not subject to the Common Rule. However, it must still be conducted consistent with principles of law and ethics designed to protect individuals and their privacy while furthering the public's health. In addition, while the HIPAA Privacy Act allows sharing of identifiable health data without written authorization for public health purposes, note that the Rule does not require data sharing. Authorizations for disclosures from covered entities under the Rule derive from other public health laws or policies. | | | | |
| **Conclusion 5.B.** ***Human Subject Research***: If your responses affirm that your activity (or some part thereof) is or is likely human subjects research, the Common Rule may apply, subject to an exemption. In addition, the activity may be entitled to expedited review under the Common Rule. **Proceed to Decision Charts as needed**. | | | | |

# Human Subject Regulations Decision Charts

(as provided by the Office of Human Research Protection)

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**

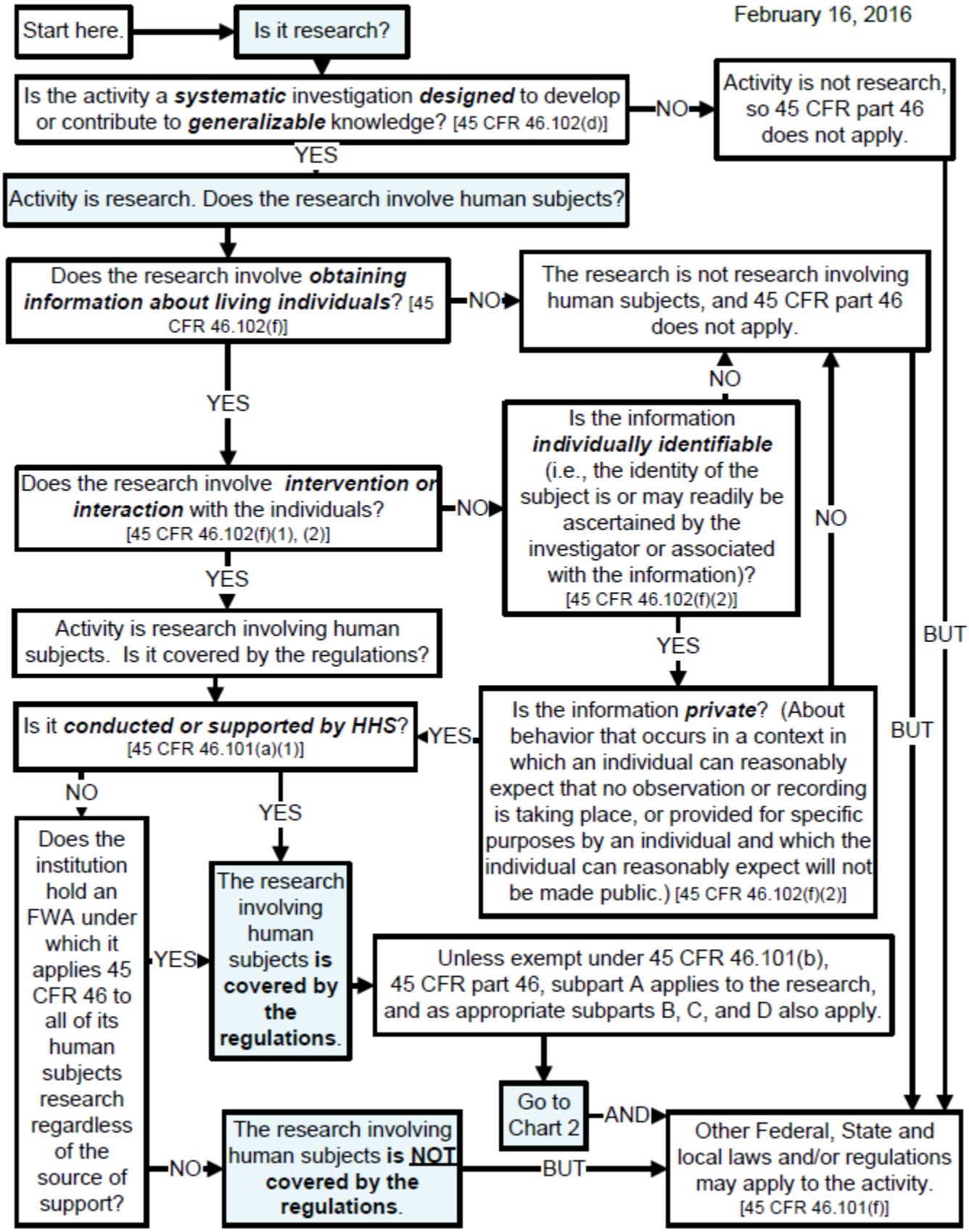
The charts are intended to assist IRBs, institutions, and investigators in their decision-making process and should not be used as substitutes for consulting the regulations. OHRP cautions that the full text of applicable regulatory provisions should be considered in making final decisions.

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.

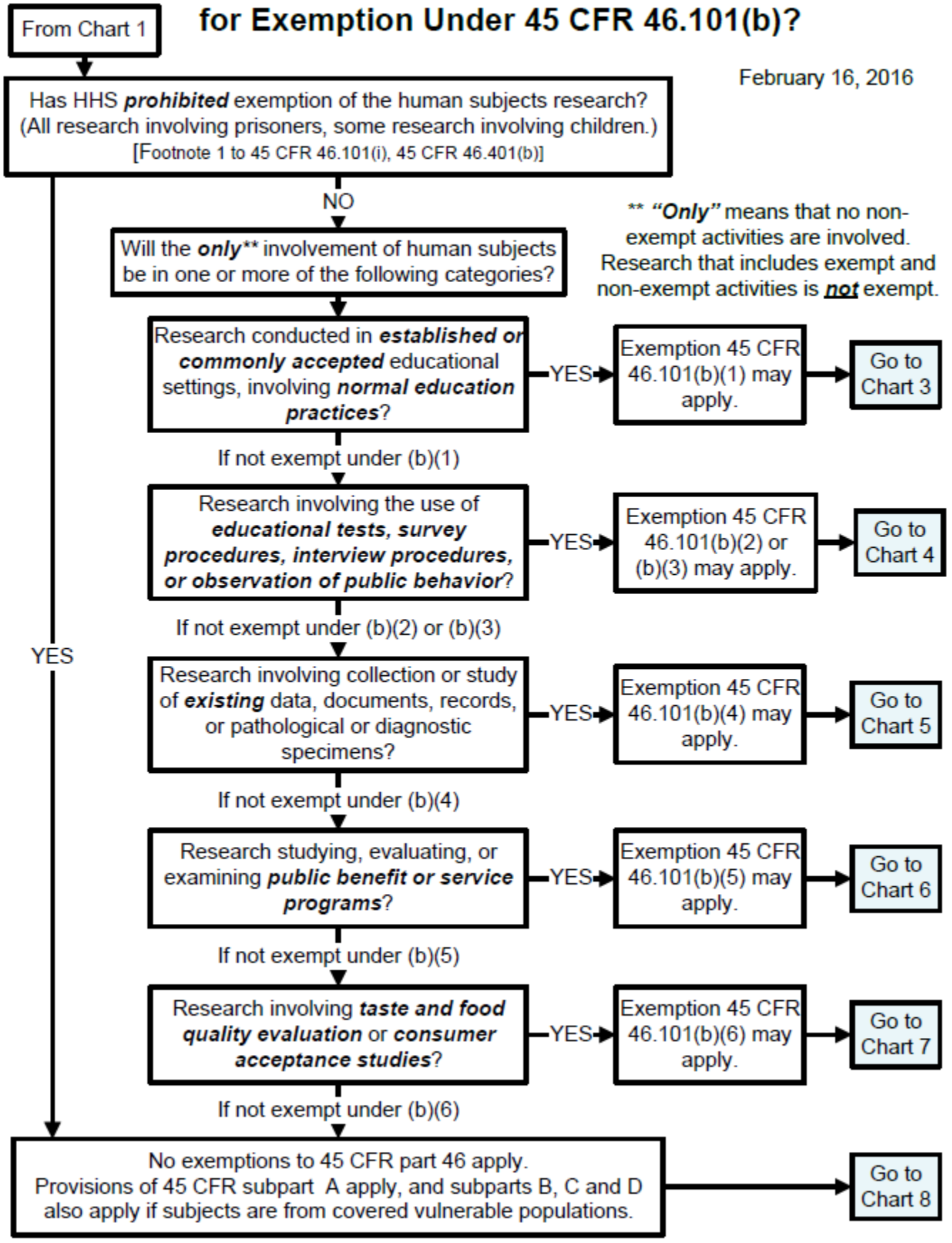
The charts do not address requirements that may be imposed by other organizations, such as the Food and Drug Administration, National Institutes of Health, other sponsors, or state or local governments.

- 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)?

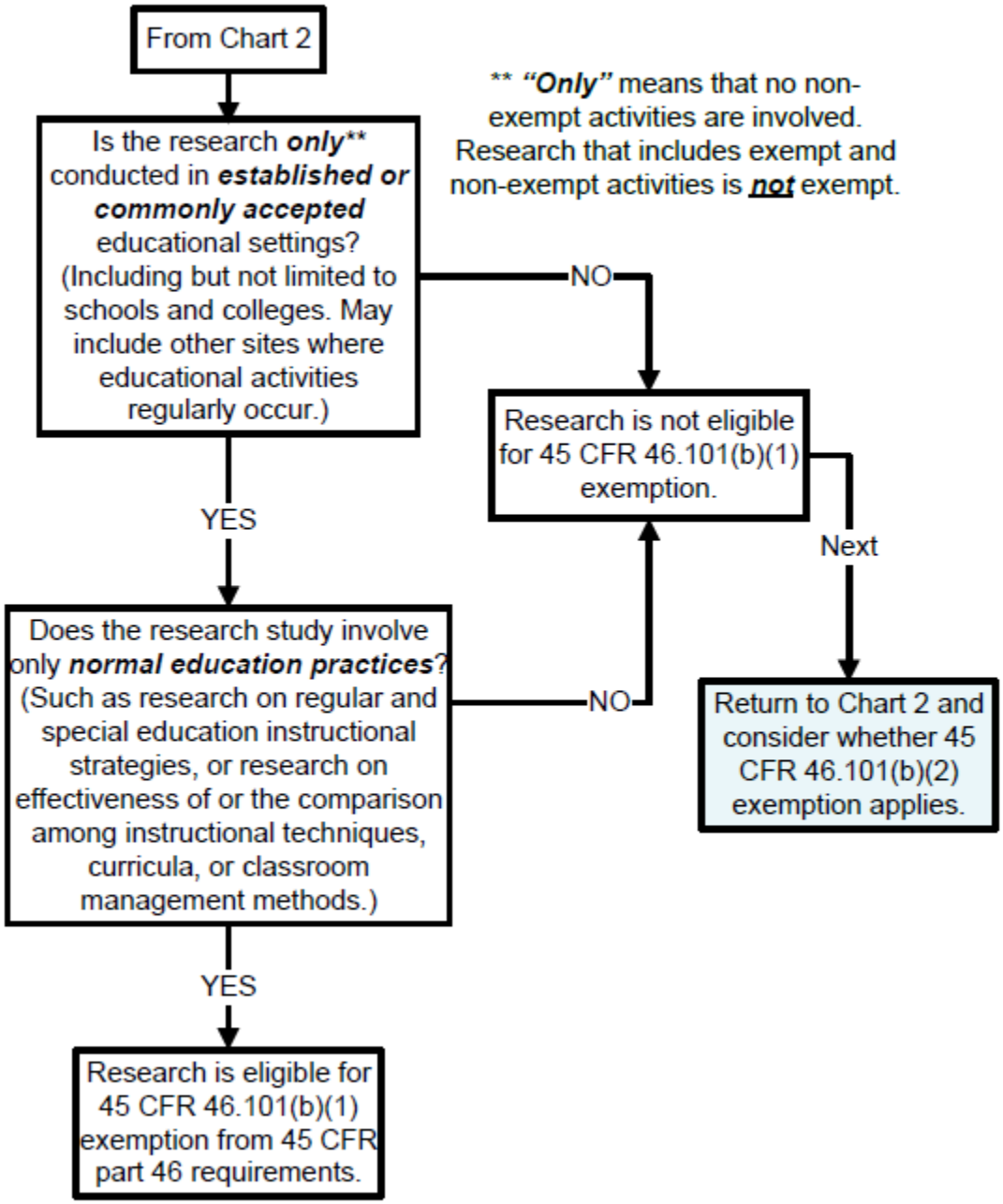
# Chart 1: Is an Activity Research Involving Human Subjects Covered by 45 CFR part 46?



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



# 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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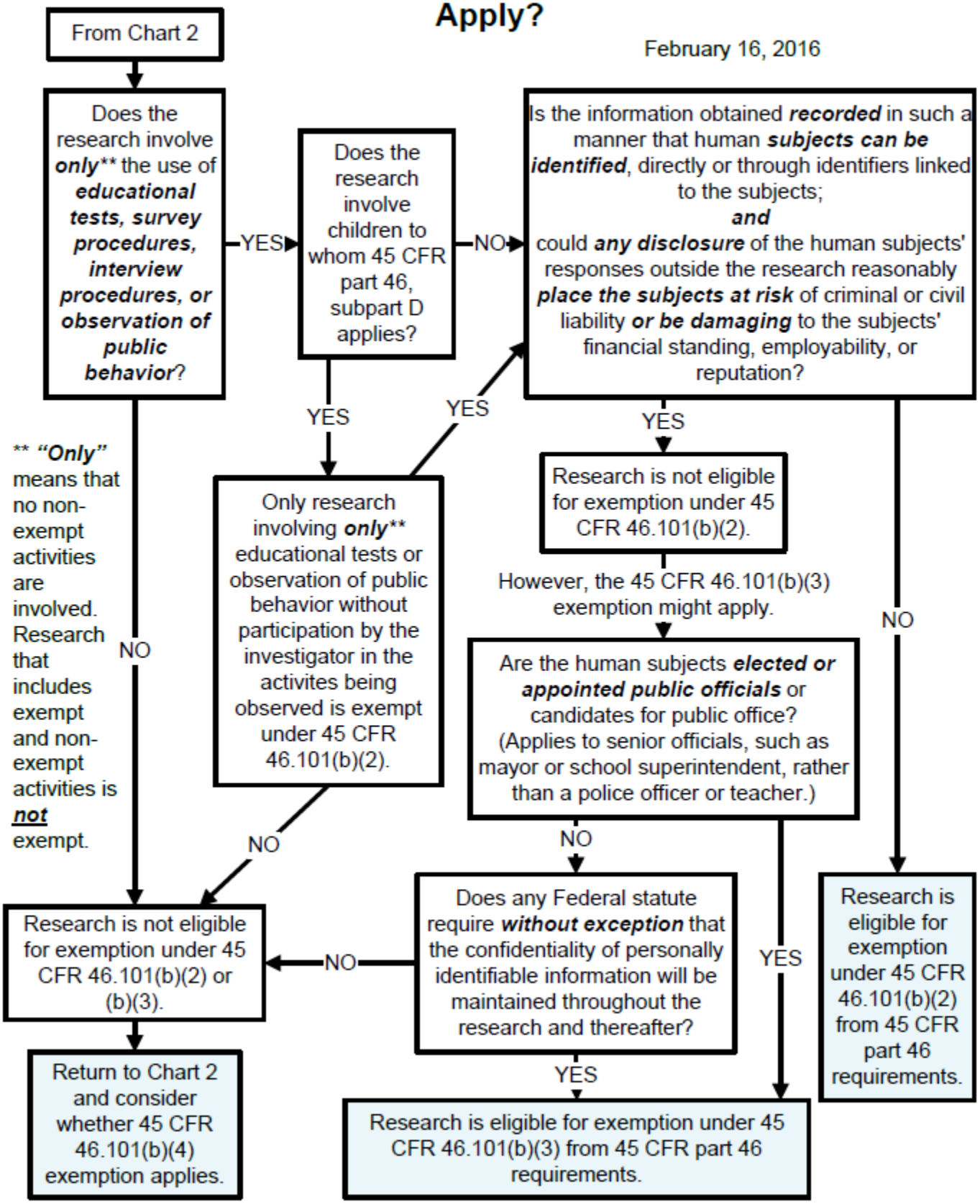
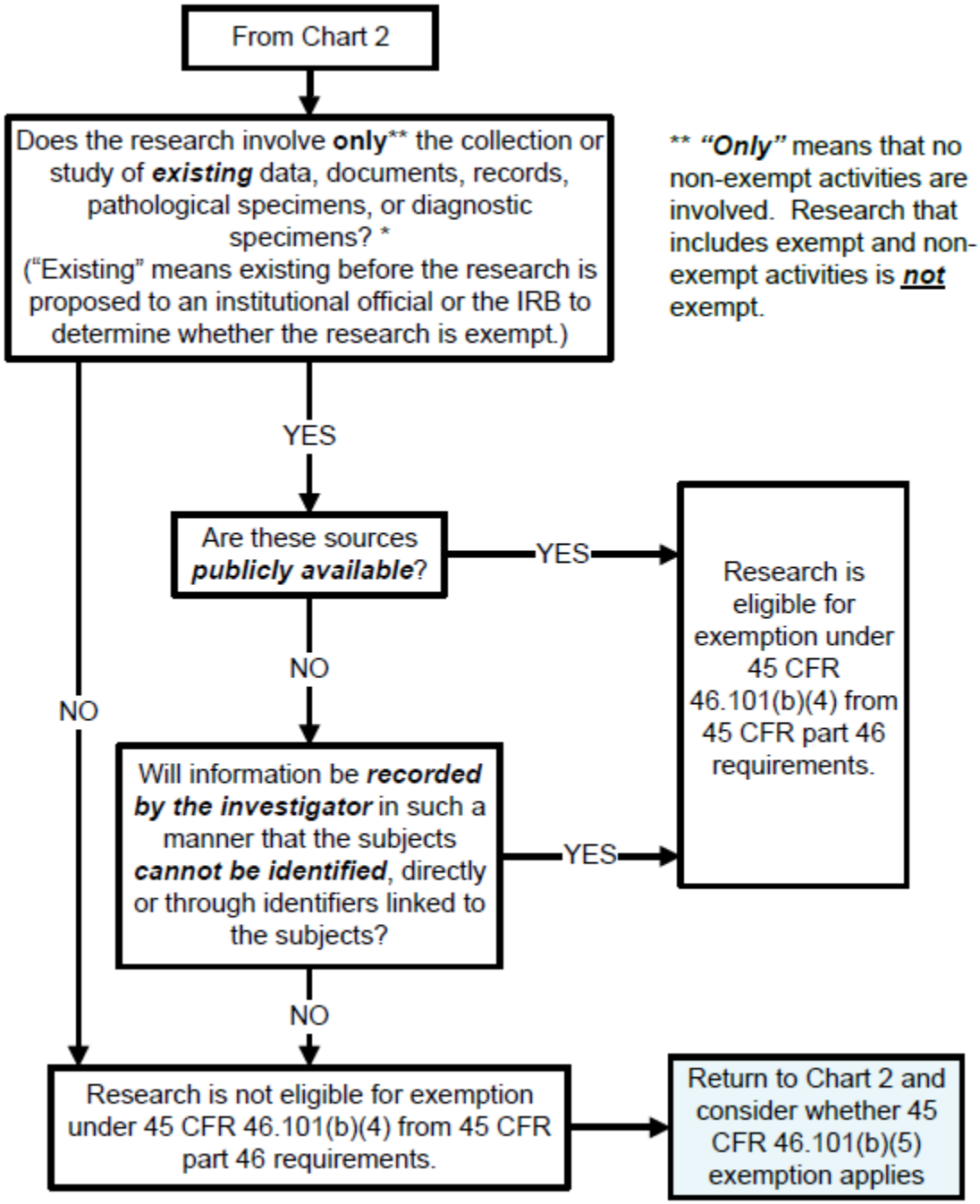


# Chart 5: Does Exemption 45 CFR 46.101(b)(4) (for Existing Data Documents and Specimens) Apply?




* Note: See OHRP guidance on research use of stored data or tissues and on stem cells at http://www.hhs.gov/ohrp/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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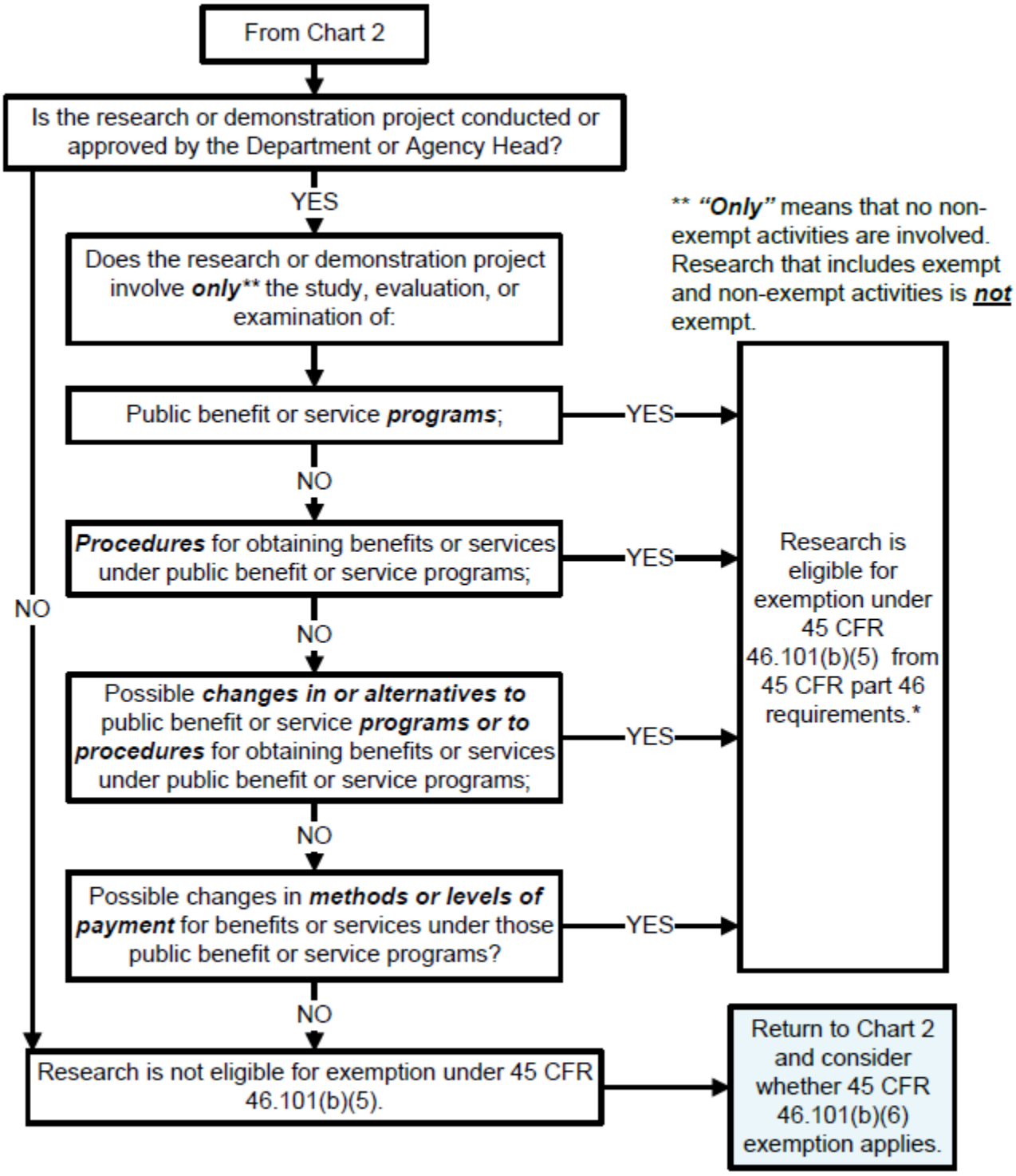
# Chart 6: Does Exemption 45 CFR 46.101(b)(5) (for Public Benefit or Service Programs) Apply?




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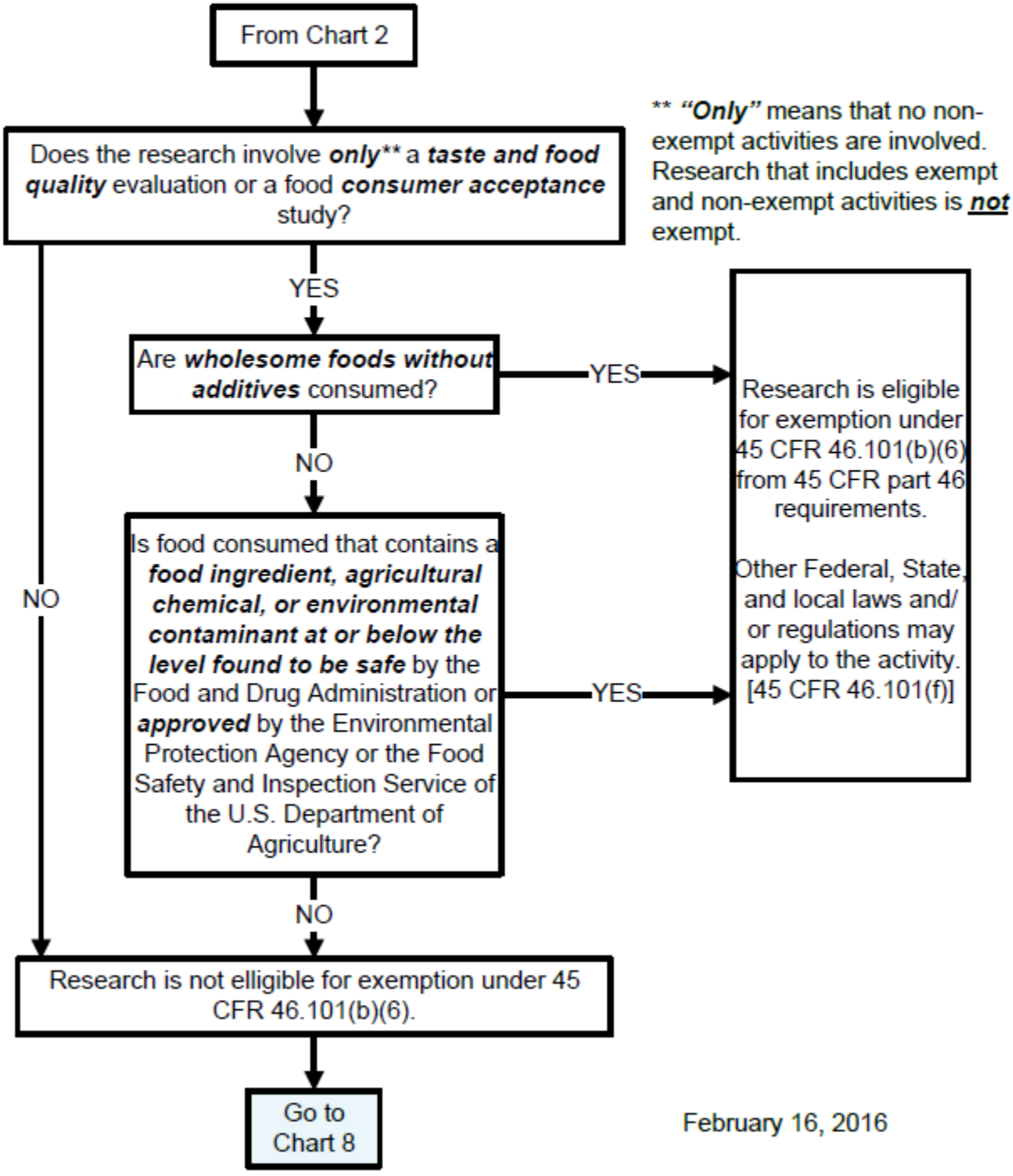
# Chart 7: Does Exemption 45 CFR 46.101(b)(6) (for Food Taste and Acceptance Studies) Apply?

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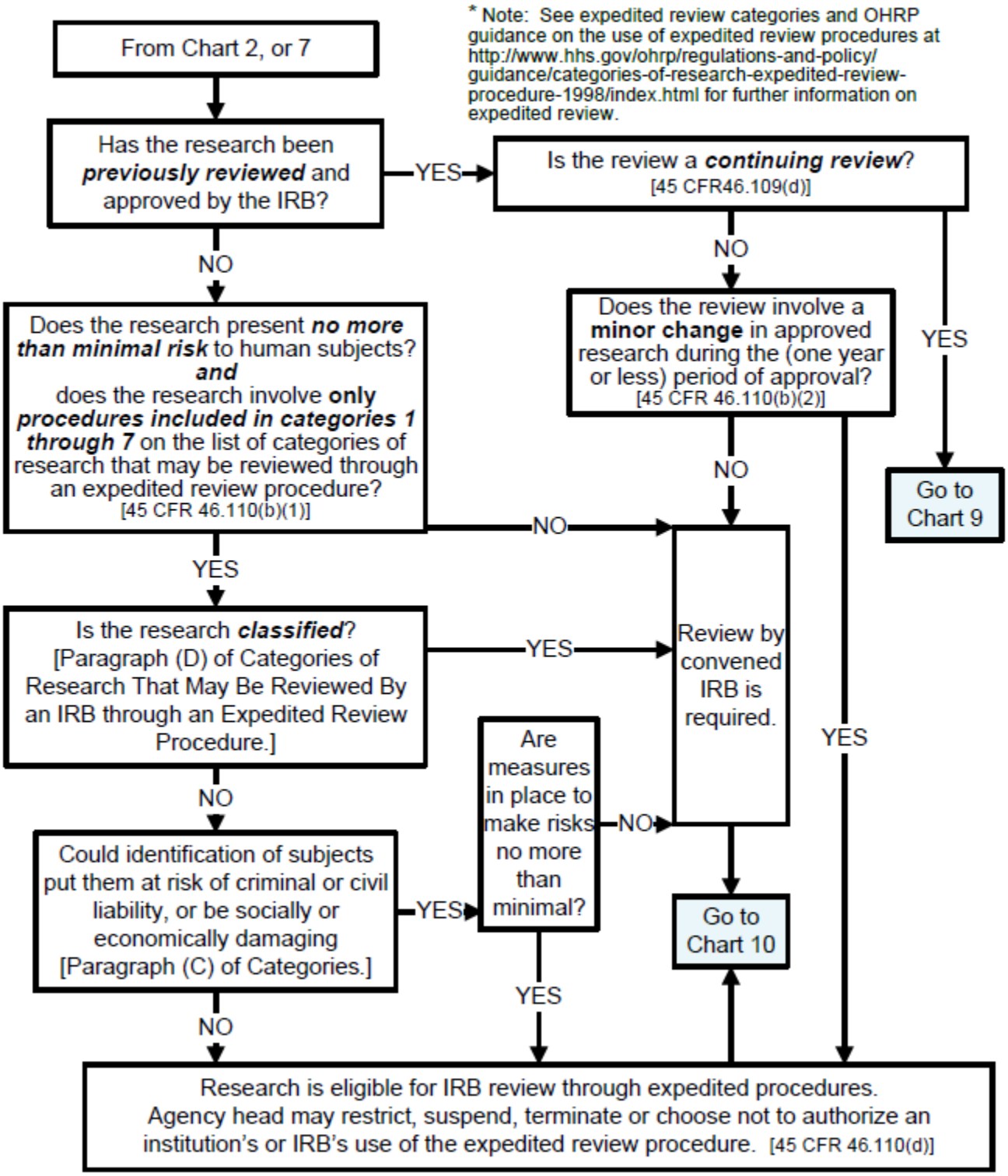
# Chart 8: May the IRB Review Be Done by Expedited Procedures Under 45 CFR 46.110?*

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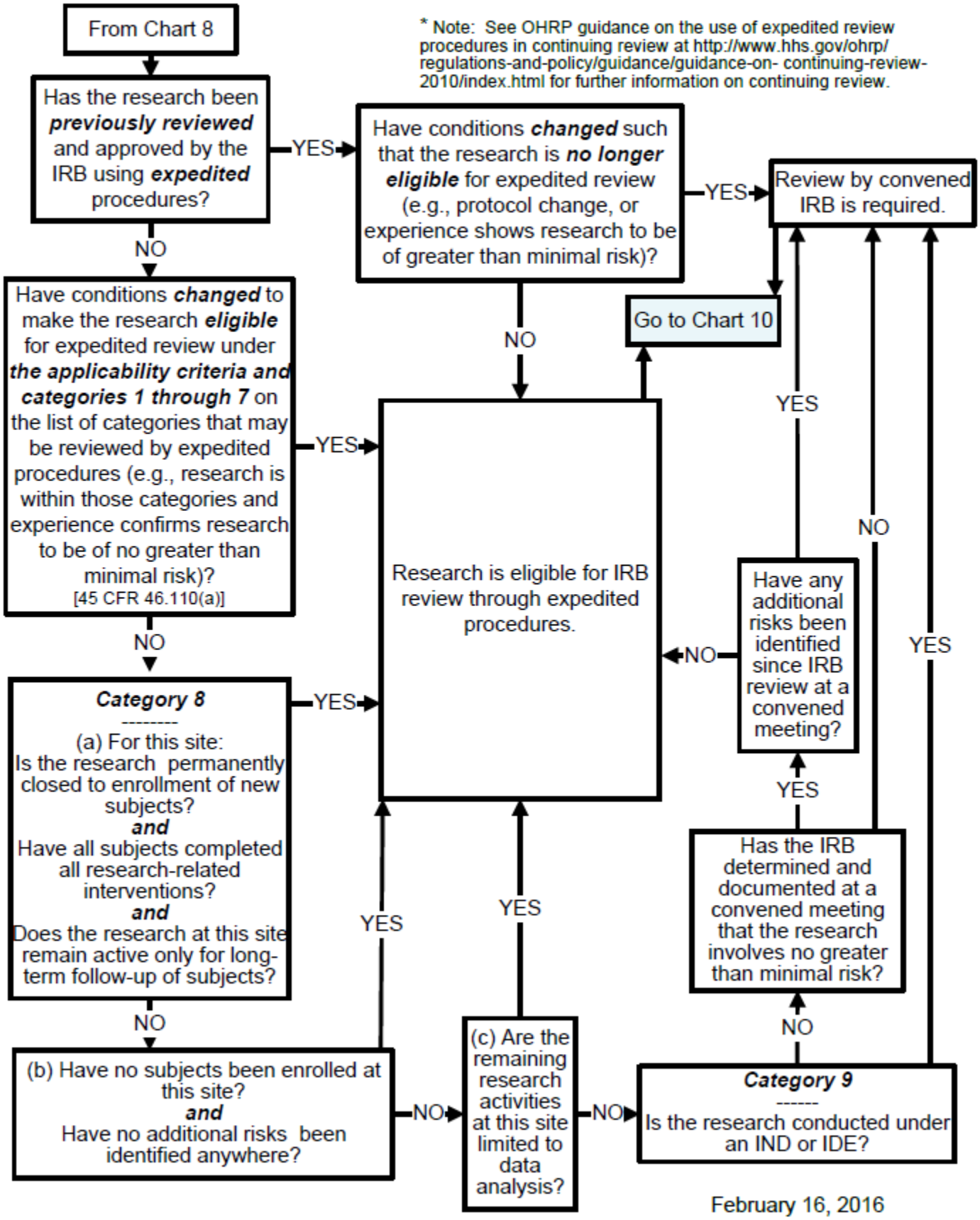
# Chart 9: Can Continuing Review be Done by Expedited Procedures Under 45 CFR 46.110?




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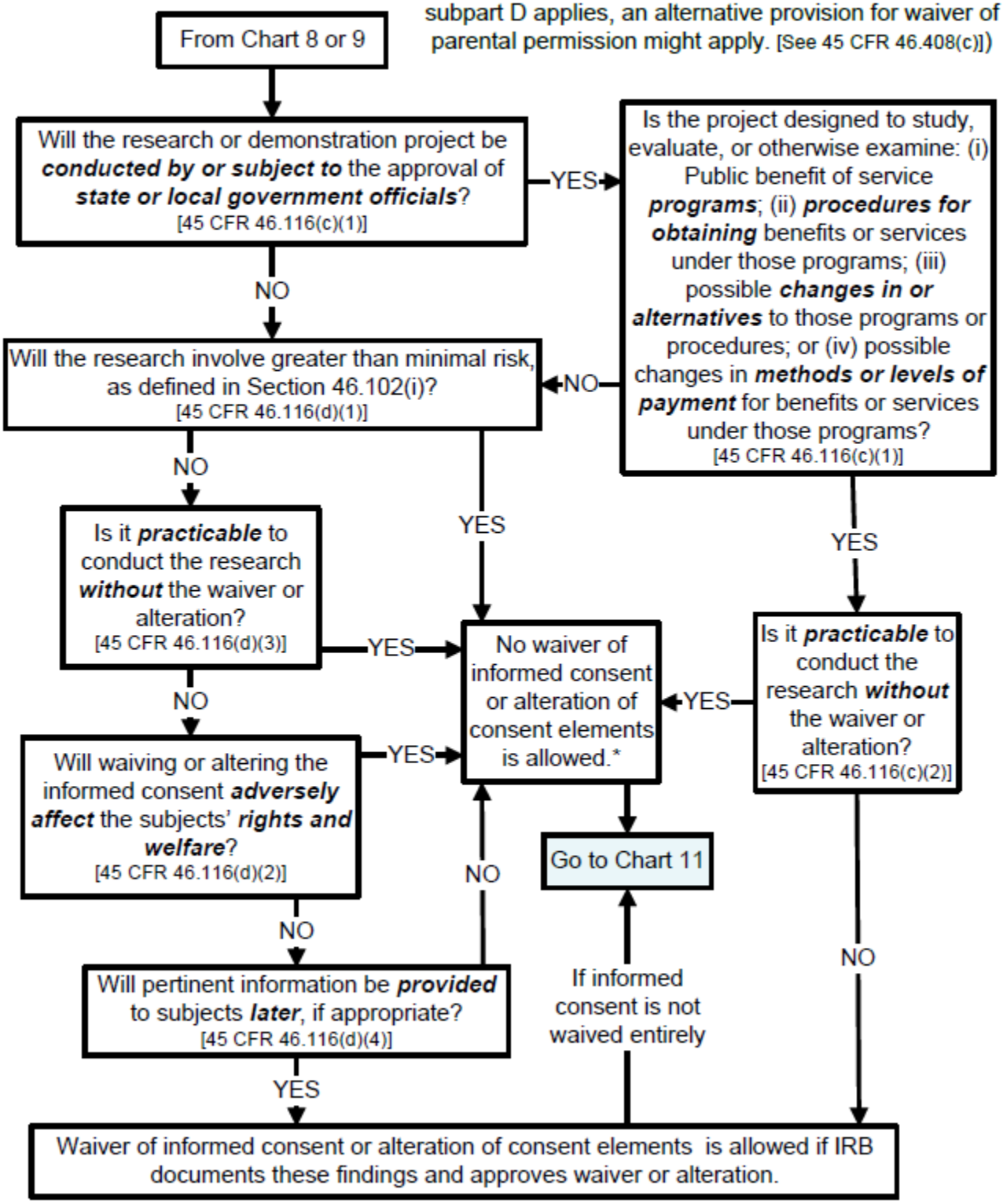
# Chart 10: Can Informed Consent Be Waived or Consent Elements Be Altered Under 45 CFR 46.116(c) or (d)?**

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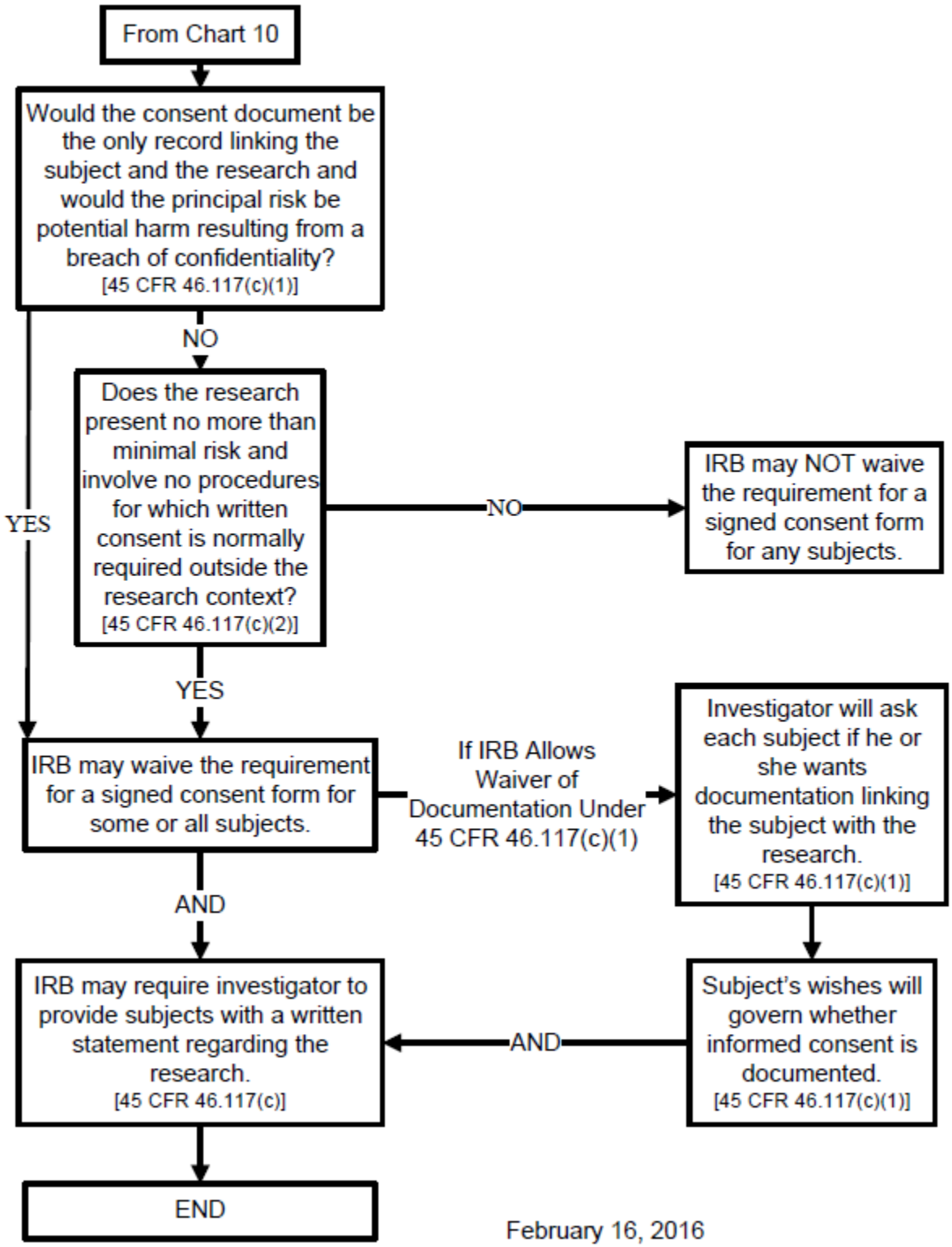
# Chart 11: May Documentation of Informed Consent Be Waived Under 45 CFR 46.117(c)?

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