Request for Exempt from IRB Review Form

PART I - STUDY PROTOCOL INFORMATION	
Reference Number:	
UVIRB Code:	
Study Protocol Title:	Click here to enter text.
PART II - CONTACT INFORMATION	
Proponent:	<Family Name, Name, Middle Name>
Other Authors:	<Family Name, Name, Middle Name>
College	Click here to enter text.
Department	Click here to enter text.
Course	Click here to enter text.

PART III - REQUEST INFORMATION

The IRB Chair, or his or her representative, shall determine the proposal's exemption from review. Exempt from Review is the term used to denote that a protocol does not need to undergo either full or expedited review after a preliminary assessment by a designated member of the IRB. "Exempt from Review" is a decision made by the IRB. While UV-IRB is ultimately responsible for deciding if research qualifies for exemption, investigators are asked to make an initial determination of the appropriate exemption category. Please select all the categories that apply from the list below.

Note: Research projects involving prisoners or the collection of biological samples cannot be granted exemption.

☐	Category 1 - Protocols that neither involve human participants nor identifiable human tissue, biological samples, and data (e.g., meta-analysis protocols) shall be exempted from ethical review.
☐	Category 2 - Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as: regular education instructional strategies, or effectiveness or comparison of instructional techniques, curricula, or classroom management methods. Provided that the following do not involve more than minimal risks or harms.
☐	*Category 3 - Research involving one or more of the following, provided that the following do not involve more than minimal risks or harms: 1. Educational tests (cognitive, diagnostic, aptitude, achievement): - If the information is recorded in a manner that individuals cannot be identified (directly or through identifiers linked to the individual), OR - If the information may be recorded in a manner that individuals can be identified (directly or through identifiers linked to the individual), but disclosure of the information could NOT reasonably place the participants at risk of criminal or civil liability or be damaging to their financial standing, employability, or reputation.** 2. Survey or interview procedures (this exemption category does not apply to research activities with minors/children): - If the information is recorded in a manner that individuals cannot be identified (directly or through identifiers linked to the individual), OR - If the information may be recorded in a manner that individuals can be identified (directly or through identifiers linked to the individual), but disclosure of the information could NOT reasonably place the participants at risk of criminal or civil liability or be damaging to their financial standing, employability, or reputation.** 3. Observation of public behavior:

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	For minors/children: Observation of public behavior of minors is eligible for exemption only if the researcher does not participate in the activities being observed. For non-minors: Generally considered exempt from IRB review as follows: - If the information is recorded in a manner that individuals cannot be identified (directly or through identifiers linked to the individual), OR - If the information may be recorded in a manner that individuals can be identified (directly or through identifiers linked to the individual), but disclosure of the information could NOT reasonably place the participants at risk of criminal or civil liability or be damaging to their financial standing, employability, or reputation.**
**Exemption category #3 does not apply to research with children, unless the research is exclusively limited to activities described in 3.1 (educational tests) and/or 3.3 (observation of public behavior and the investigators do not participate in the study or manipulate the activities being observed).* ***Risks of criminal or civil liability, or of damage to financial standing, employability, or reputation can be dependent on the context of the research and are determined by the IRB staff based on experience, past precedent and bench marked best practices. The IRB staff welcomes the input of investigators in determining the possibility of such risks, but if there is reasonable doubt about whether or not criteria b. applies, the research is not exempt.*	
☐	Category 4 - Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior, but is not eligible for the above exemption (3), can be exempted if the research participants are elected or appointed public officials or candidates for public office, or federal statute requires that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter. Provided that the following do not involve more than minimal risks or harms.
☐	Category 5 - Research involving the collection or study of existing (i.e., existing before the request for exemption is submitted to UV-IRB to determine whether the research is exempt) data, documents, records, pathological specimens, or diagnostic specimens: 1. If these sources are publicly available; OR 2. If the sources are not publicly available, but the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.***
****Example: A PI who receives restricted access data, but stores the data in a secure environment may be eligible for exemption under this category if s/he is not recording identifiable private information into her/his own research records, or is not merging datasets that may lead to identification of individuals. However, PIs should be advised that the owner of the dataset or funding agencies may have their own policies requiring IRB review.*	
☐	Category 6 - Research and demonstration projects that are conducted by or subject to the approval of government agencies, and are designed to study, evaluate, or otherwise examine public benefit or service programs, procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs.
☐	Category 7 - Taste and food quality evaluation and consumer acceptance studies: 1. If wholesome foods without additives are consumed, OR 2. If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Management or the Food Safety Control System of the Department of Agriculture.

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☐	Category 8 - Protocols for institutional quality assurance purposes, evaluation of public service programs, public health surveillance, educational evaluation activities, and consumer acceptability tests.

PART IV - STUDY DESIGN, METHODS AND PROCEDURES

Type of project/study: *Please select ALL of the categories of work that apply to this proposed project.*

☐ Technical Studies such as Design, Innovation and Invention *(STOP here, Do not Proceed to next Items)*
☐ Operations Research and Quality Assurance Research *(STOP here, Do not Proceed to next Items)*
☐ Active collection of data (not human biological materials or physiological data)
☐ Use of existing data (not human biological materials)
☐ Use of existing human biological materials
☐ Food Technology and Tasting *(STOP here, Do not Proceed to next Items provided that it do not involve more than minimal risks or harms as stipulated in the conditions of Category 7):*
  ☐ Are there additives? *(If YES, needs further assessment)*
  ☐ Are there ingredients safe for consumption? *(If YES, attach FDA proof, else needs further assessment)*

Please provide a lay summary of the study, including the purpose and the research questions and hypothesis to be evaluated:
Click here to enter text.

Please describe briefly how this study will contribute to existing knowledge in the field:
Click here to enter text.

Active collection of data (not human biological materials or biomedical procedures).
Please select ALL the methods of data collection that will be employed in this study (select all that apply)
☐ In person interviews
☐ Paper surveys
☐ Telephone surveys
☐ Internet surveys (including online and email based data collection)
☐ Use of Social Networking Sites
☐ Data collected using other communication/electronic devices (e.g., cell phones, pagers and texting devices)
☐ Observation
☐ Cognitive or behavioral measures, including daily diaries *(Note: if surveys will also be administered, please select the appropriate option above.)*
☐ Focus groups
☐ Audio/Video recording
☐ Anthropometric measures (e.g., height, weight, waist circumference, etc.)
☐ Self-health monitoring (e.g., pedometers, food diaries, etc.)
☐ Other activities or interventions, specify: Click here to enter text.

Please provide details of all the procedures selected above (*If none are selected, enter N/A)*:
Click here to enter text.

Please indicate all the geographical locations where data will be collected:
Click here to enter text.

Please select ALL the specific locations where data will be collected *(select all that apply)*:
☐ Participants' homes
☐ Elementary, secondary or high school, specify Click here to enter text.
☐ University of the Visayas campuses, specify campus Click here to enter text.
☐ Other university campuses, specify Click here to enter text.
☐ Hospitals, specify Click here to enter text.
☐ Community clinics, specify Click here to enter text.
☐ Prisons/halfway houses, specify Click here to enter text.

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☐ Nursing homes, specify Click here to enter text.
☐ Prison, correctional facility, detention center, penitentiary or remand centre, specify Click here to enter text.
☐ Mental health facility, specify Click here to enter text.
☐ Other locations not indicated above, specify Click here to enter text.

PART V - PARTICIPANTS, RECRUITMENT AND COMPENSATION ☐ Not applicable

Please indicate the estimated number of participants you plan to recruit:
Click here to enter text.

Please provide the age range of the participants:
Click here to enter text.

Please select all the categories of participants that will be included in your study:
☐ Healthy adult volunteers
☐ Children under 18
☐ Employees of the investigating group
☐ University of the Visayas students
☐ University of the Visayas employees
☐ None of the above, specify Click here to enter text.

Please select all of the tools that you plan to use to recruit your participants:
☐ Flyers
☐ Notices
☐ Mailers *(specify corresponding mailing address)*: Click here to enter text.
☐ Online Advertisements *(specify sites)*: Click here to enter text.
☐ Email *(specify corresponding email address)*: Click here to enter text.
☐ Use of Internet social media or online networking sites *(specify sites)*: Click here to enter text.
☐ TV, radio, print advertisements *(specify stations/newspaper/magazine)*: Click here to enter text.
☐ Face to face public intercept
☐ Presentations at meetings
☐ Other *(Please describe)*: Click here to enter text.

Please describe each recruitment method to be used:
Click here to enter text.

Describe the inclusion or exclusion criteria for participants as applicable in this study:
Click here to enter text.

Will participants be compensated for their participation?
☐ Yes, how? Click here to enter text.
☐ No, why not? Click here to enter text.

Please describe the tasks that the participants will be asked to perform for each phase of the study:
Click here to enter text.

Please provide an estimate of the time commitment from each participant for each phase of the study:
Click here to enter text.

PART VI - PRIVACY AND CONFIDENTIALITY ☐ Not applicable

Will you or any member of your research team collect or have access to any of the personal identifiers listed below? *Select all that apply.*
☐ Name ☐ Date of birth ☐ Mailing or email address ☐ Phone or fax numbers ☐ IP address
☐ Social Security number ☐ Medical records ☐ License, certificate or Vehicle ID ☐ Biometric identifiers
☐ Photos/images/audio recording ☐ Signatures, handwriting samples
☐ Any unique identifier not mentioned above: Click here to enter text.
☐ No member of the research team will have access to any personal identifiers. *This option is valid only if none of the*

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other options in this question are selected.
PART VII - INFORMED CONSENT PROCESS ☐ Not applicable
Please indicate the informed consent process(es) and/or document(s) to be used in the study. ☐ Are the 15 elements present? *(If YES, attach the ICF; If NO, modify the ICF [ask template from IRB officer].*
Check all that apply. Provide copies of documents, as applicable. ☐ Informed Consent – form ☐ Informed Consent – oral script/online/unsigned ☐ Process Consent – form ☐ Process Consent – oral script/online/unsigned ☐ Assent (participants under 18) – form ☐ Assent – oral script/online/unsigned ☐ Parental Permission – form ☐ Parental Permission – oral script/online/unsigned ☐ Translated Consent/Assent – form(s), script(s), etc. ☐ Debriefing script ☐ Other – please explain: Click here to enter text.
Describe the consent process. Explain when and where consent will be obtained: Click here to enter text.
PART VIII – SIGNATURE OF PRINCIPAL INVESTOGATOR
This page is to be signed by the principal investigator. If the principal investigator is an undergraduate or graduate student, the faculty supervisor must also sign in the lower box.
Principal Investigator: *I certify that the information I provide in this application is correct and complete. I also pledge that I will not change any of the procedures, forms, or protocols used in this study without first seeking review and approval from the Institutional Review Board for Human Participants.*
☐ Attestation of Principal Investigator
Date Signed: Click here to enter a date. <Family Name, Name, Middle Name> Signature over printed name of Principal Investigator
For undergraduate or graduate student: Date Signed: Click here to enter a date. <Family Name, Name, Middle Name> Signature over printed name of Faculty Adviser

RECOMMENDED ACTION
☐ EXEMPTED FOR ETHICAL AND TECHNICAL REVIEW ☐ EXEMPTED FOR ETHICAL REVIEW BUT NOT EXEMPTED FOR TECHNICAL REVIEW* ☐ EXPEDITED ☐ FULL BOARD
**When the technical and scientific merit is not sound, the assessor may opt not to exempt the study for technical review. As mandated by the 2017 National Ethical Guidelines (page 28, section D, paragraph 2), UV-IRB should consider both the scientific and ethical aspects of the proposed research even when the IRB is distinct from the technical review committee. For student researches, PI and advisers are advised to ensure that the technical and scientific soundness are in place, and that the recommendations of the technical review committee and consultants are considered and integrated in the protocol. It is further advised, that the Research Protocol Assessment Forms issued by UV-IRB are considered during the crafting and evaluation of the proposal.*

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JUSTIFICATION FOR RECOMMENDED ACTION:
PRIMARY REVIEWER: _____ (Print Name & Signature) (Date)

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The University of the Visayas Institutional Review Board adopts the following graphic aids from the Office for Human Research Protections (OHRP) to provide 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 in reference to the regulations at 45 CFR part 46. However, the final decision in the determination of exempt shall follow the 2017 National Ethical Guidelines issued by the Philippine Health Research Ethics Board under the Philippine National Health Research System. The charts address decisions on the following:

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

The charts are intended to assist UV-IRB and investigators in their decision-making process and should not be used as substitutes for consulting the regulations. UV-IRB and investigators shall be cautioned 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 specified by the 2017 National Ethical Guidelines. The charts do not address requirements that may be imposed by other organizations and shall peruse, interpret and observe the compliance to the national regulations.

- 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)?

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

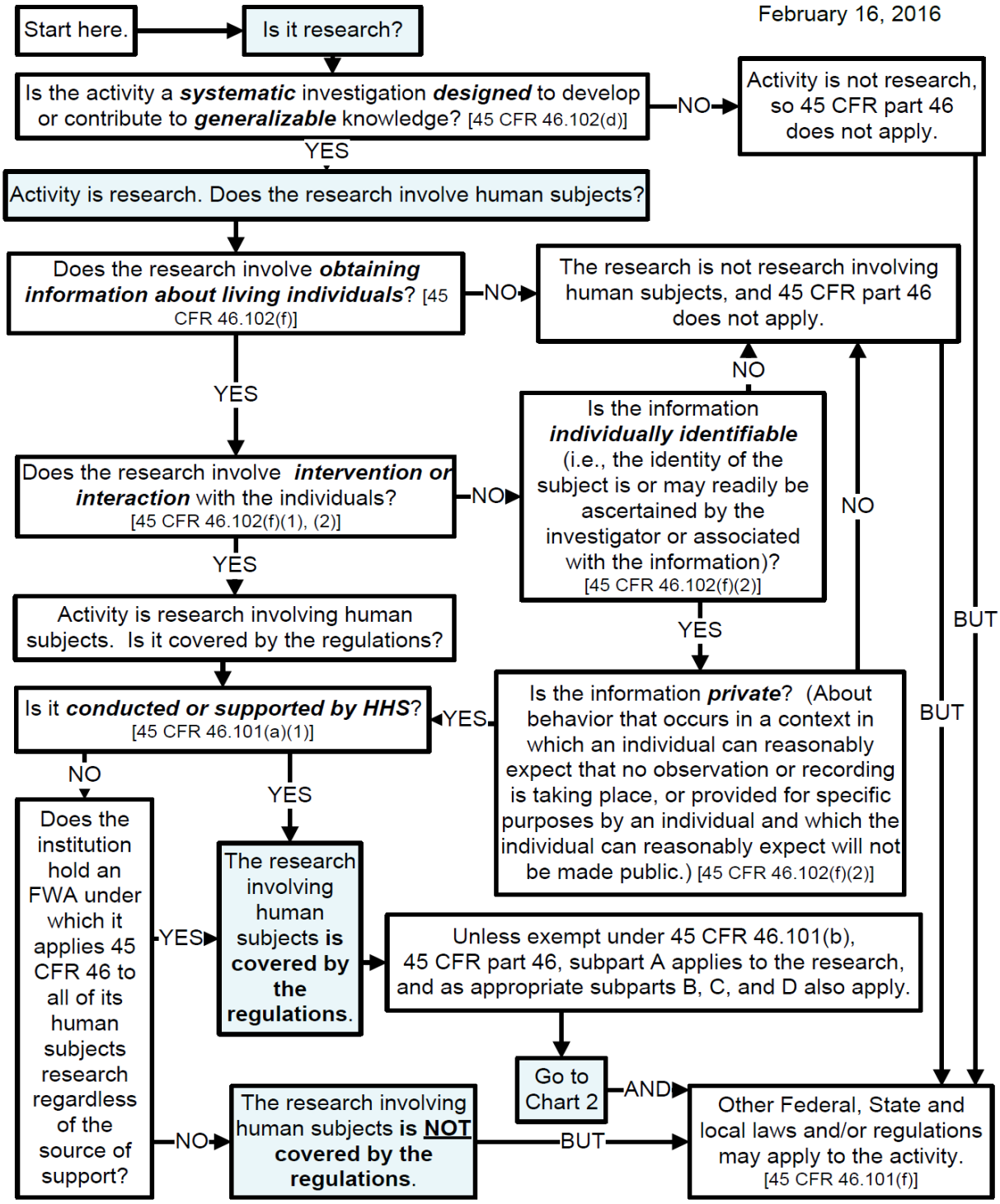

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Chart 2: Is the Research Involving Human Subjects Eligible for Exemption Under 45 CFR 46.101(b)?

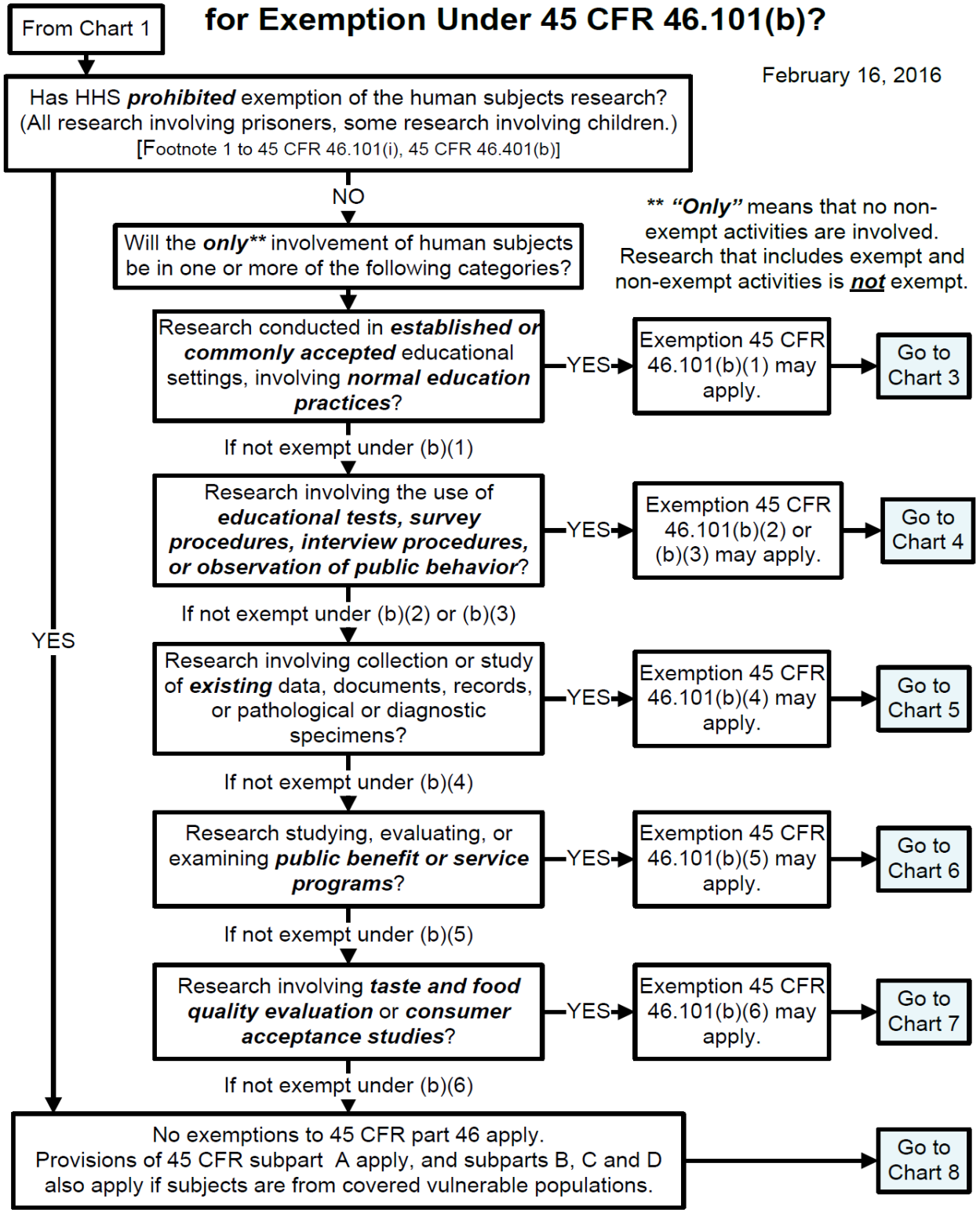

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Chart 3: Does Exemption 45 CFR 46.101(b)(1) (for Educational Settings) Apply?

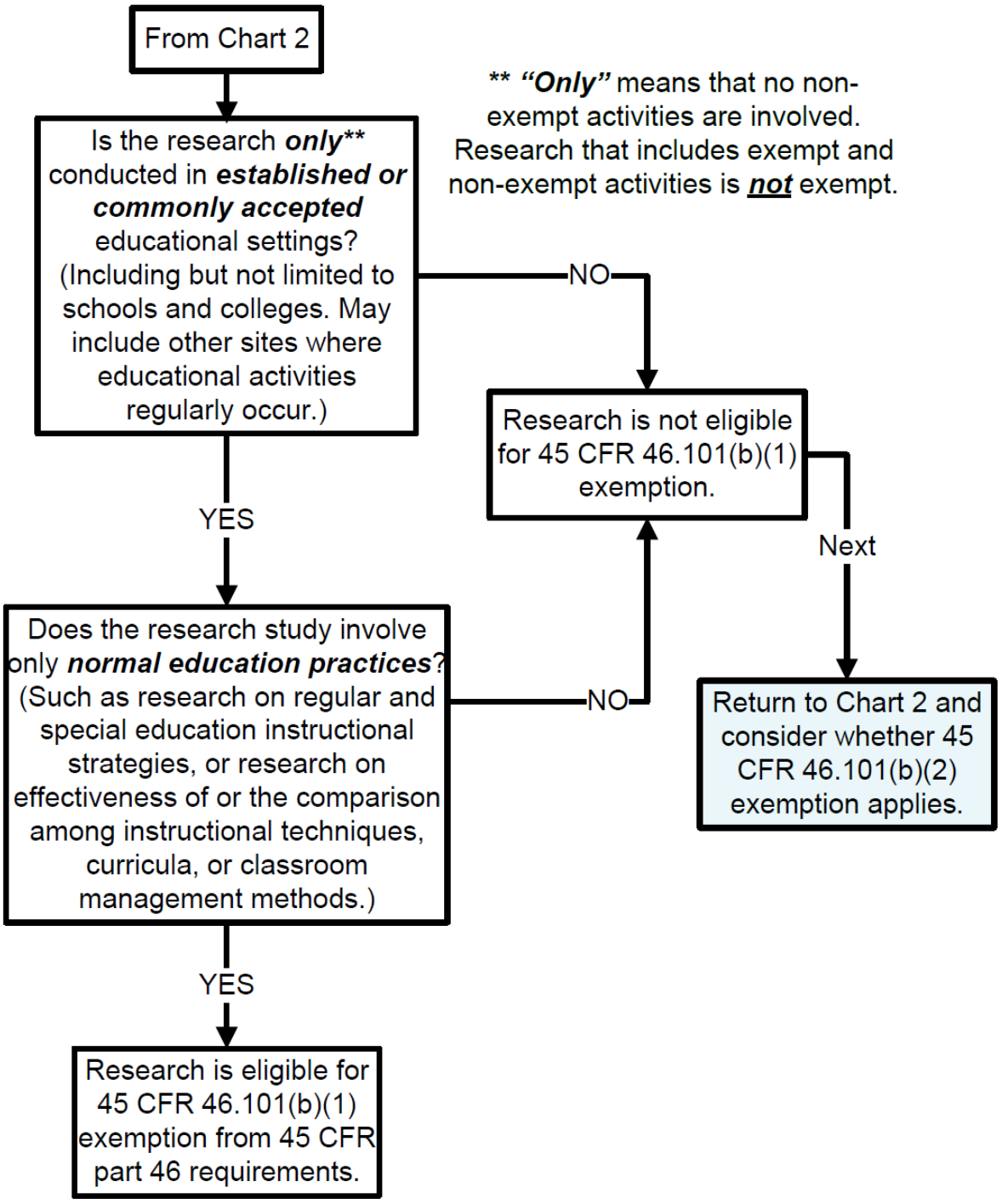

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Chart 4: Does Exemption 45 CFR 46.101(b)(2) or (b)(3) (for Tests, Surveys, Interviews, Public Behavior Observation) Apply?

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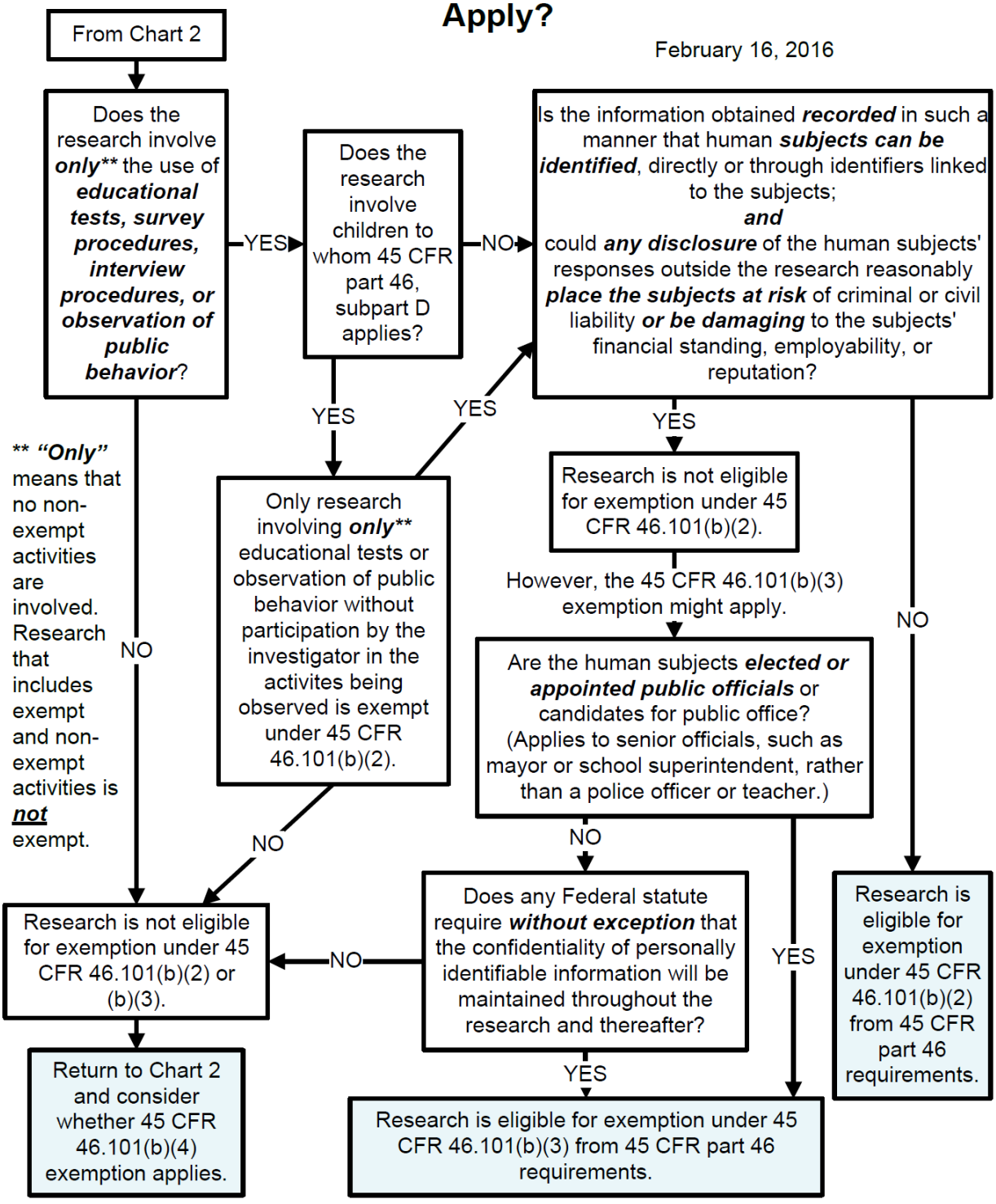

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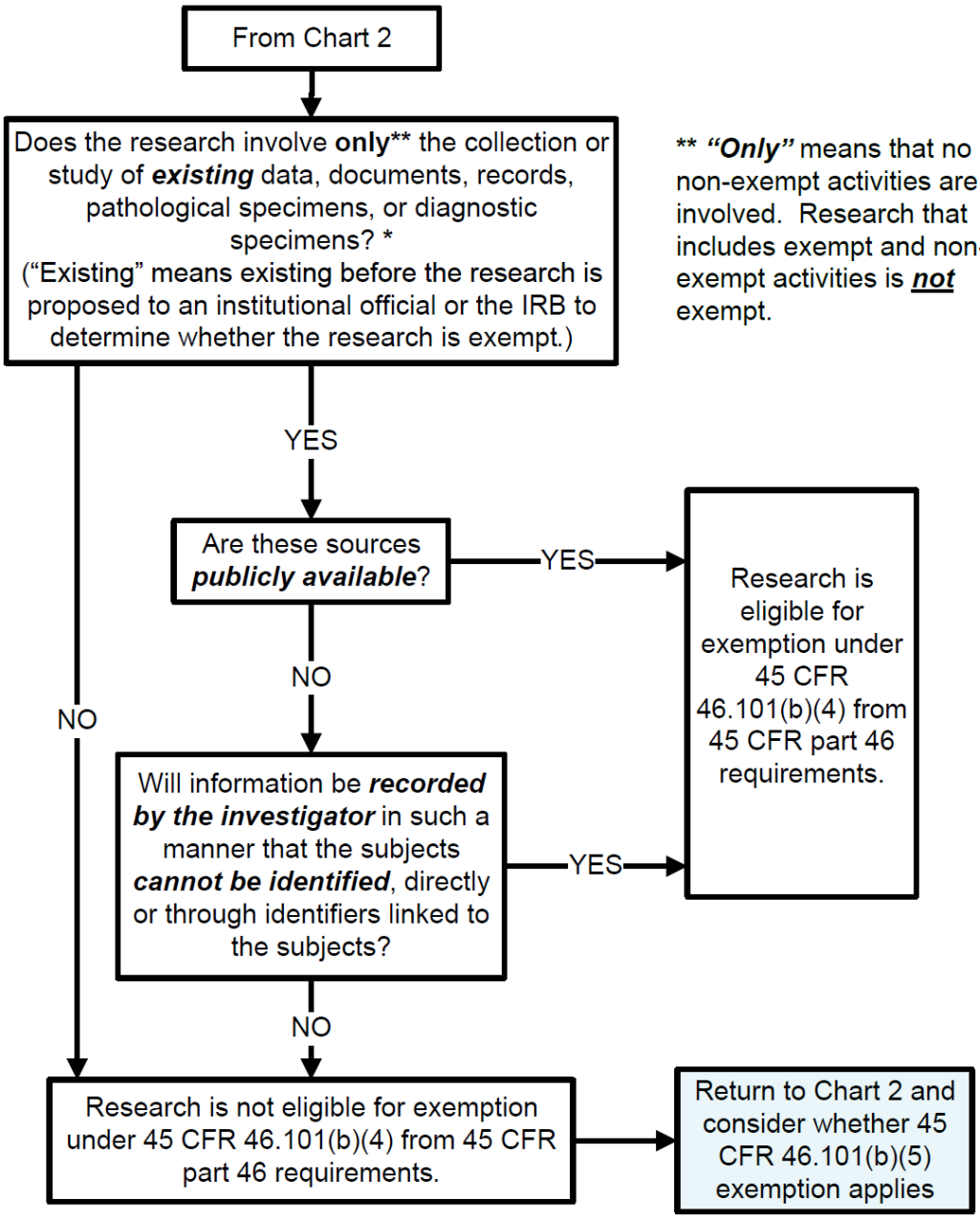
Chart 5: Does Exemption 45 CFR 46.101(b)(4) (for Existing Data Documents and Specimens) Apply?



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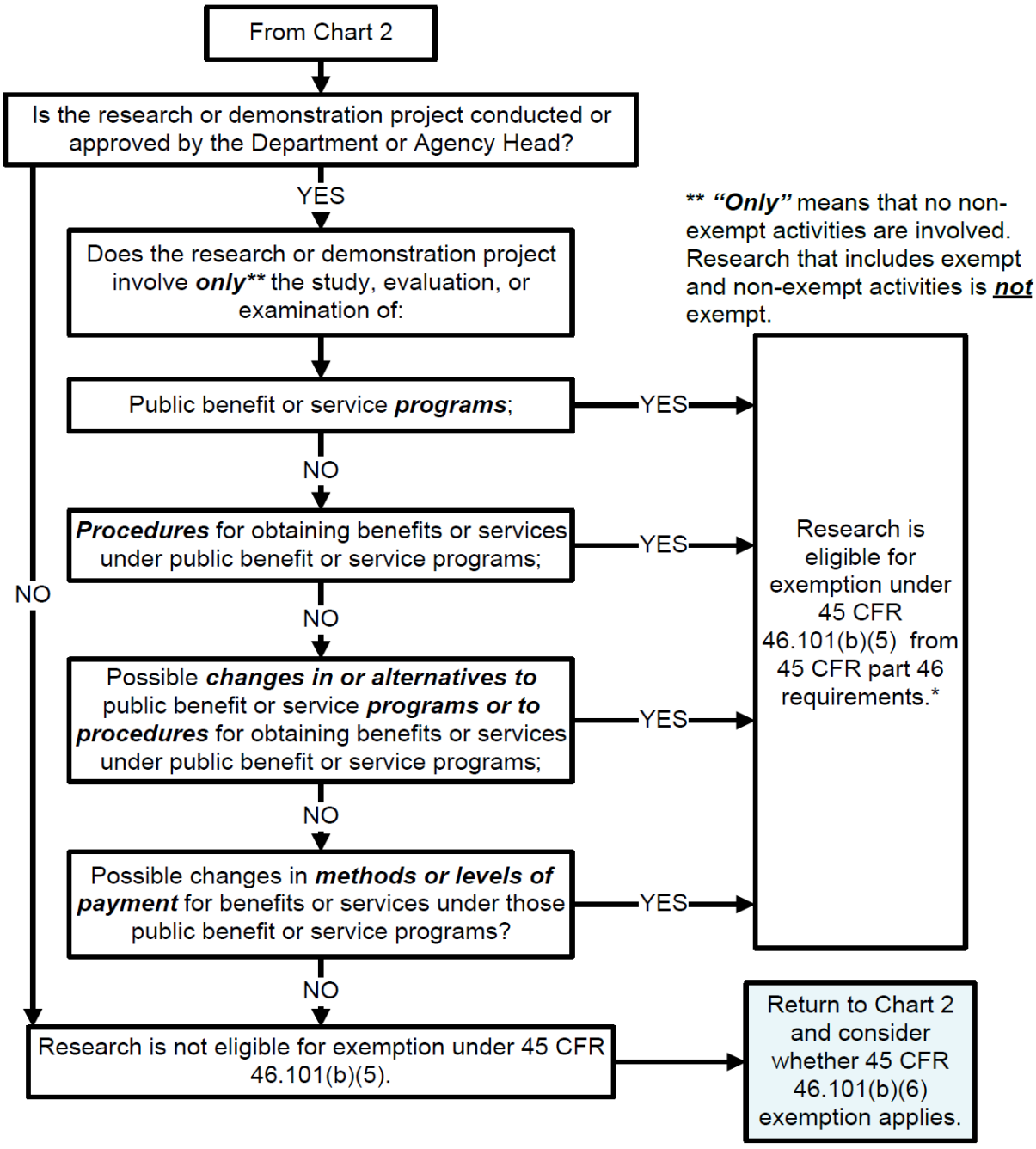
Chart 6: Does Exemption 45 CFR 46.101(b)(5) (for Public Benefit or Service Programs) Apply?



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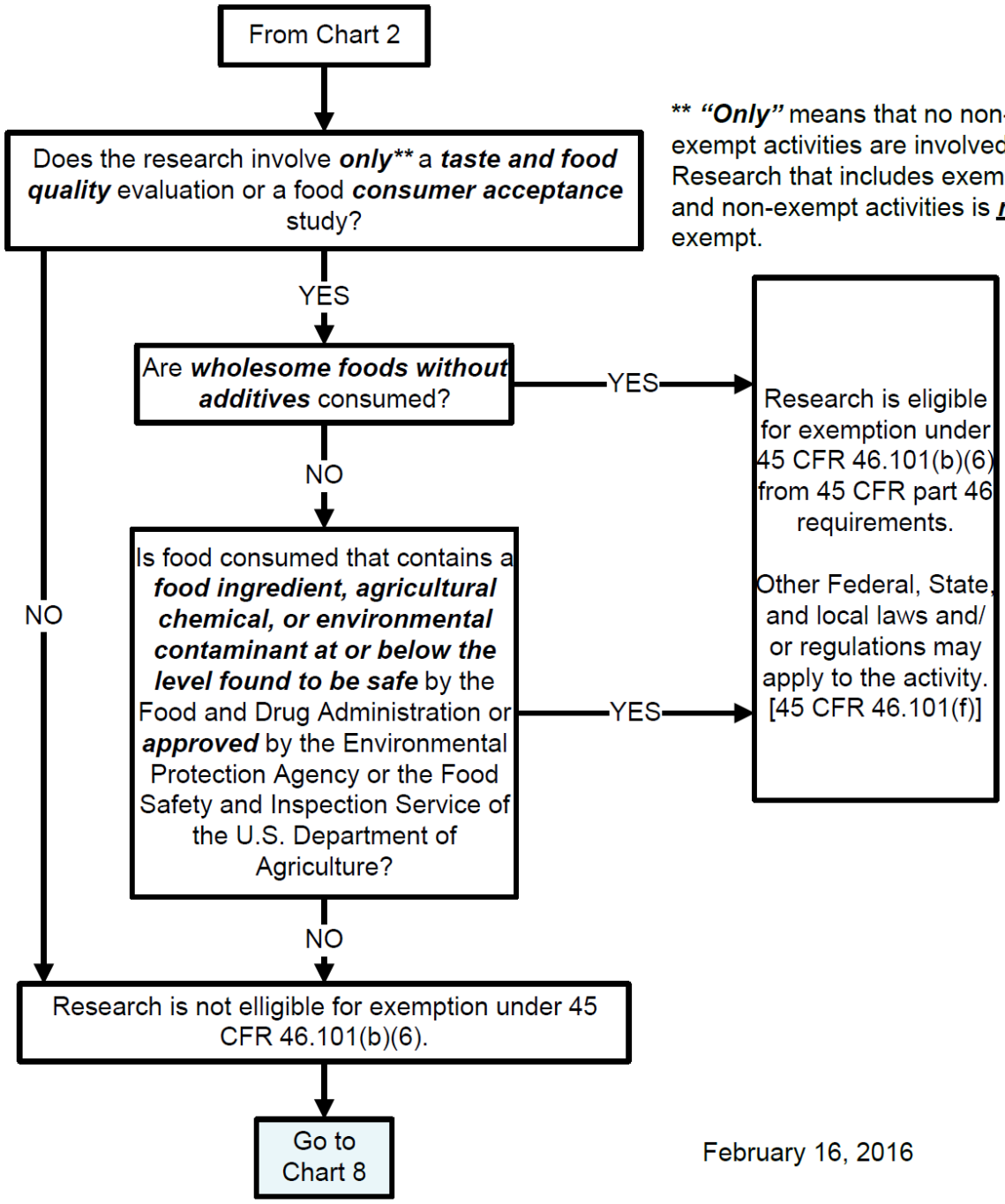
Chart 7: Does Exemption 45 CFR 46.101(b)(6) (for Food Taste and Acceptance Studies) Apply?



** *"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?*

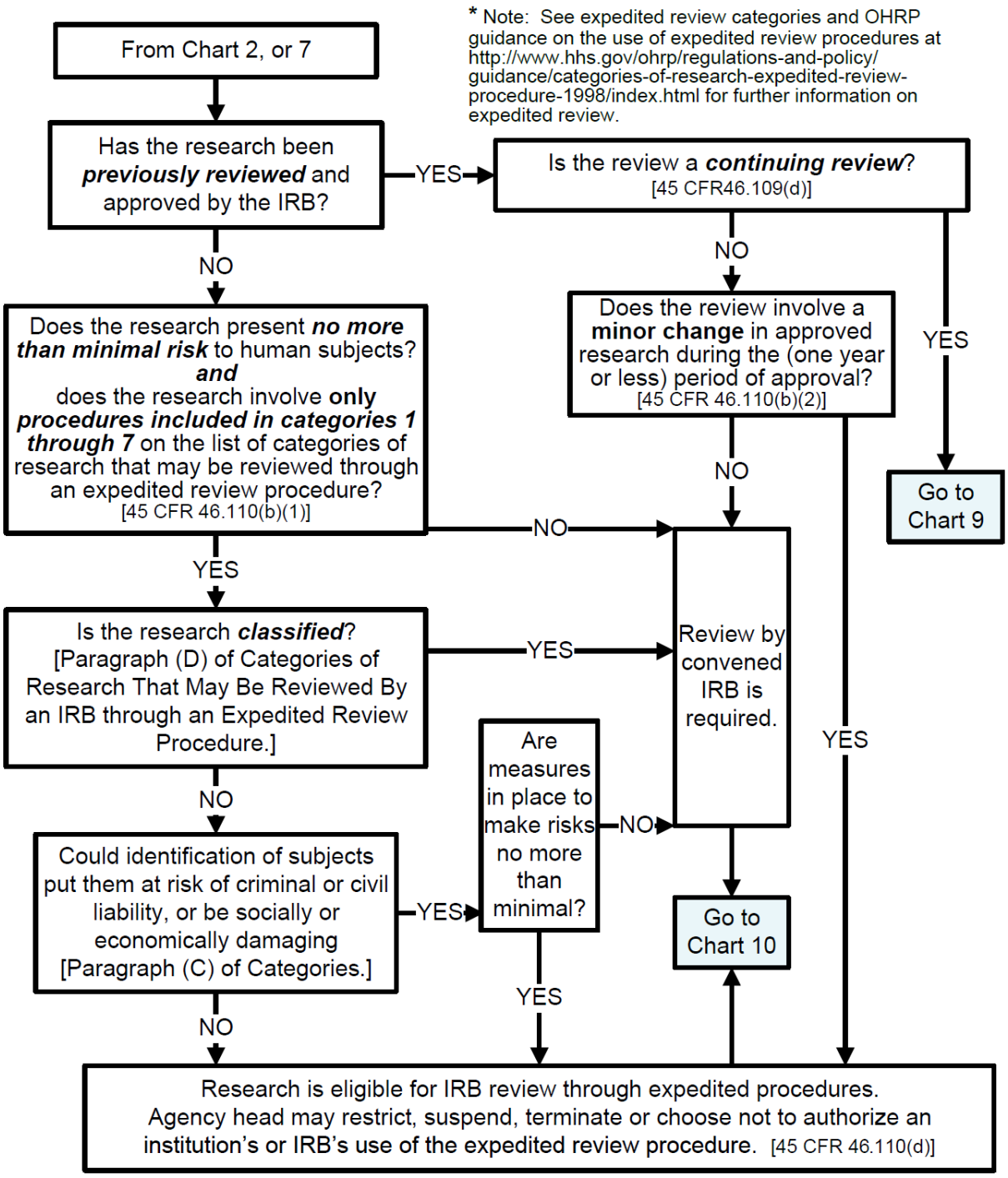

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Chart 9: Can Continuing Review be Done by Expedited Procedures Under 45 CFR 46.110?

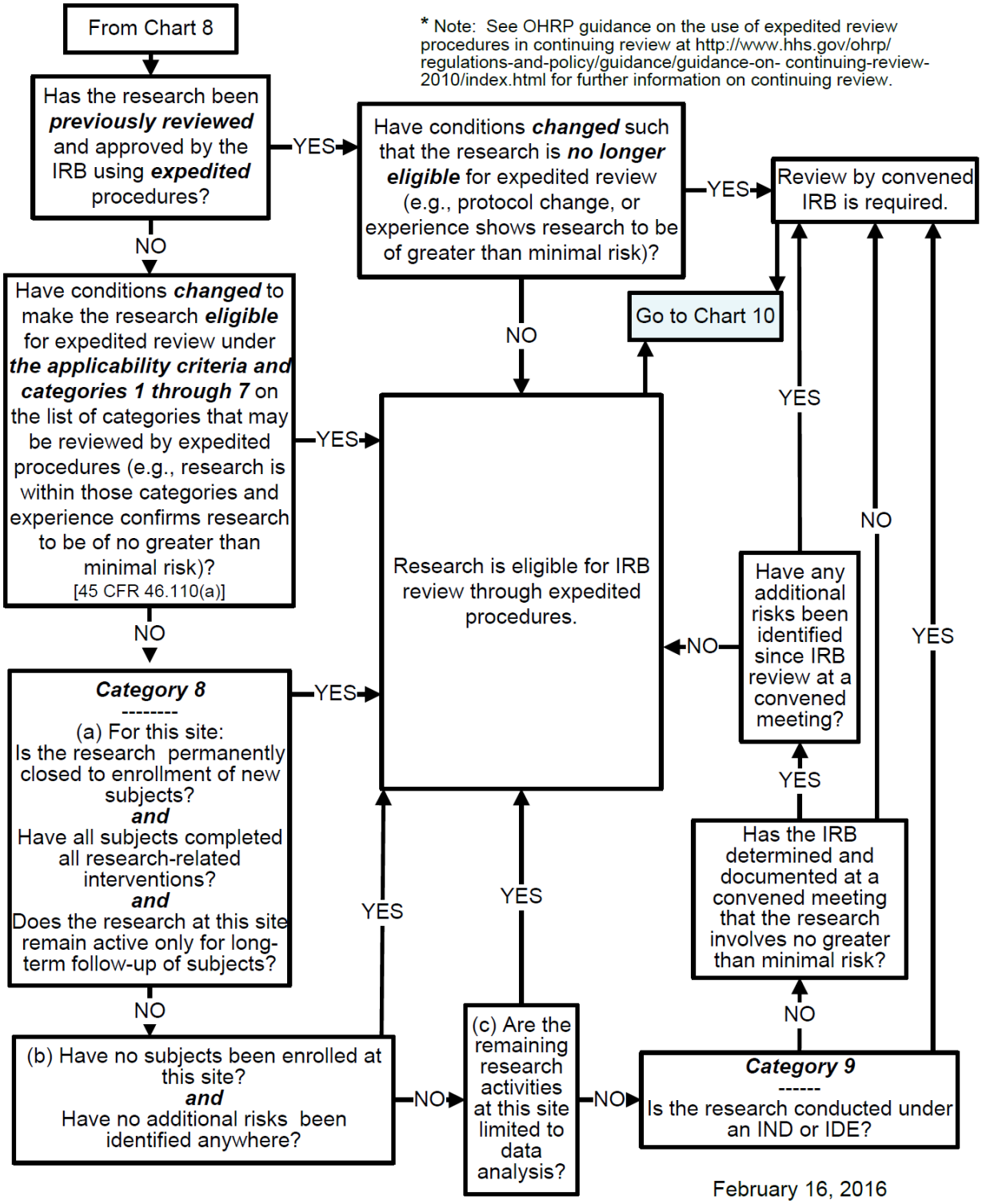

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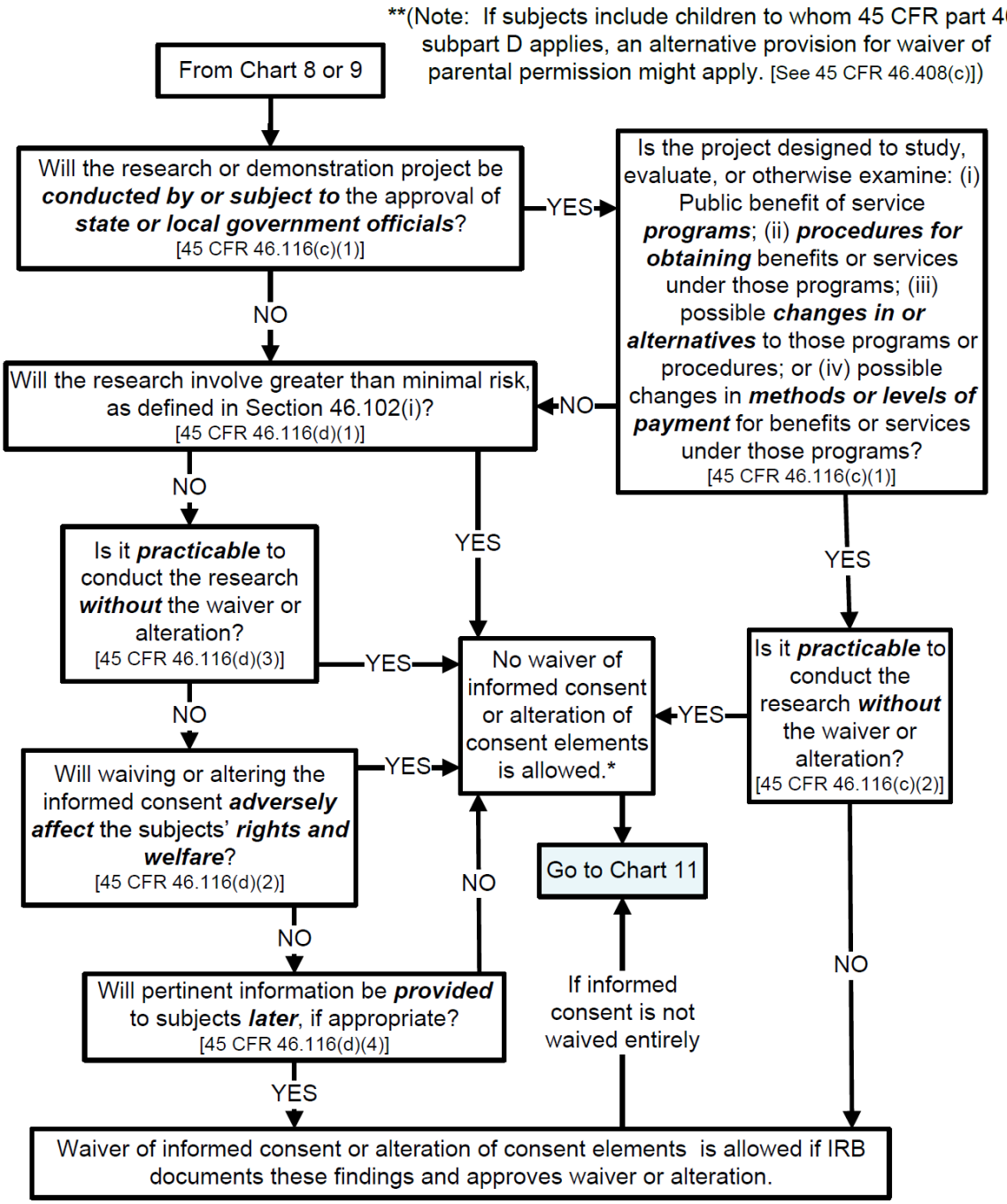
Chart 10: Can Informed Consent Be Waived or Consent Elements Be Altered Under 45 CFR 46.116(c) or (d)?**



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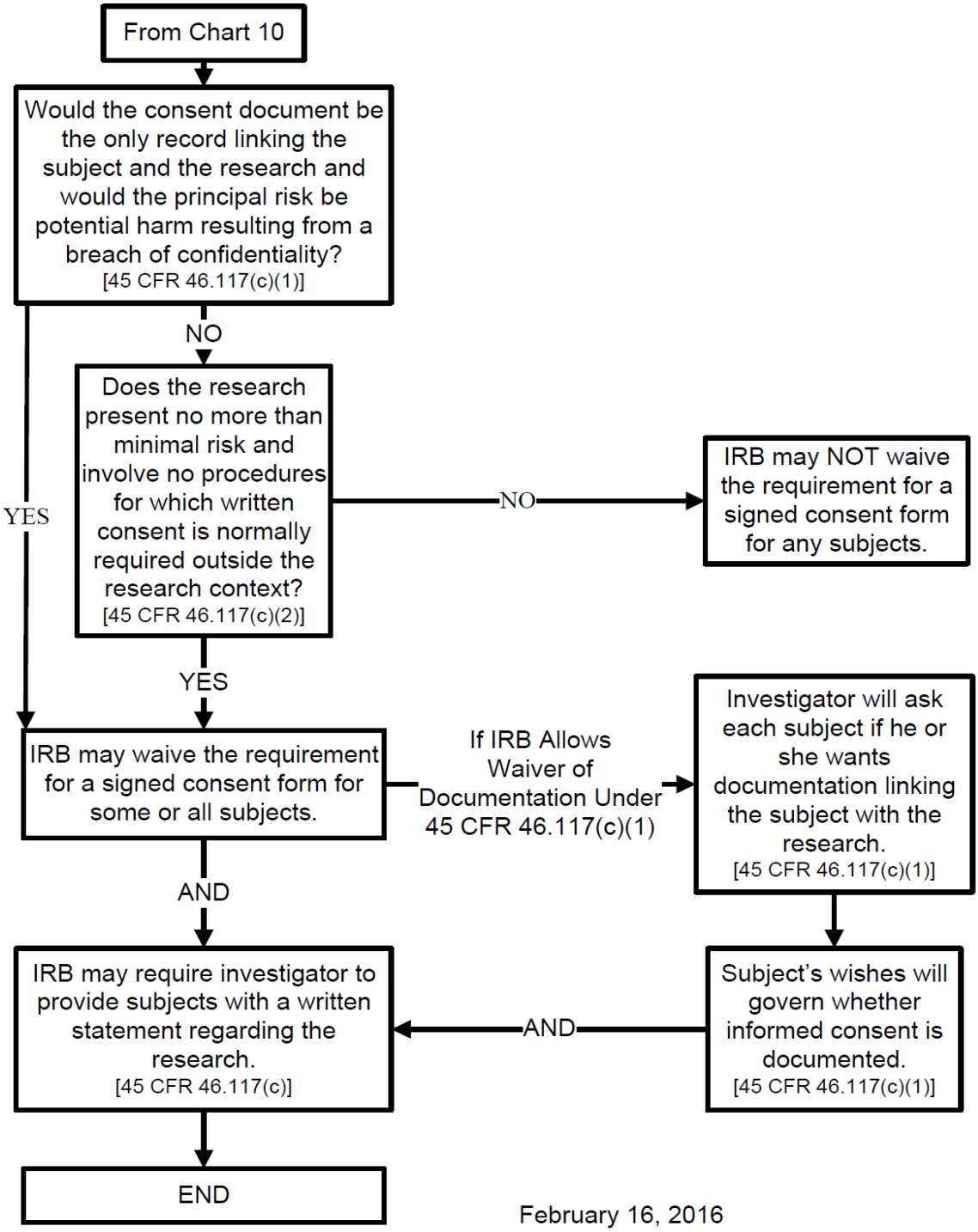
Chart 11: May Documentation of Informed Consent Be Waived Under 45 CFR 46.117(c)?



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