IRB Guidebook 2021-2022

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Overview

The IRB Guidebook is an instruction tool for Roosevelt University IRB Committee members to use while serving of the Institutional Review Board (IRB). The Guidebook is based on the policies of the Roosevelt University IRB as applied to faculty, staff and student researchers. As per RU policy, this document is subject to change, as committee, federal, and state policies change.

Federal regulation (Title 45, Code of Federal Regulations, Part 46) requires that all institutions receiving federal funds which conduct research using living humans as subjects establish operate an Institutional Review Board (IRB). The purpose of the IRB is to ensure the protection of these human subjects. IRBs are guided by the ethical principles embodied in The Belmont Report and by additional local standards and expectations. Roosevelt University has a policy (Policies for the Protection of Human Subjects) that establishes our institution's IRB. This policy provides both background and direction for the mission of the Roosevelt University IRB. This document, the IRB Guidebook of Procedures for the Protection of Human Research Subjects, describes how the Institutional Review Board at Roosevelt University will accomplish its mission.

Committee membership

IRB committee members include both expertise and representation in both scientific and non-scientific fields of study and/or knowledge. The minimum requirement for IRB Members is a total of five members. The Committee is currently made up of one unaffiliated community member, one student member and seven Roosevelt faculty members. The current IRB requires at least four faculty members and one unaffiliated community member present to make quorum and proceed with the meeting. The IRB consists of two IRB members who serve as alternate members, in the event a voting member cannot attend a meeting in person or via zoom.

Requirements for IRB Membership

- Valid and current certification of research ethics training (CITI training)
- Current full time? faculty member of Roosevelt faculty, recommended to serve on IRB by college dean and/or department chair and approved by Associate Provost of Research and Faculty Success.
- Availability to meet with IRB members monthly throughout the year either in person or via zoom.
- Willingness to serve on the IRB for a 3-year appointment.

Instructions for onboarding

Any faculty member interested to serve on the IRB in order to fulfill their service requirement must first contact their department chair or dean. When there are open positions on the IRB a call is sent to all deans and department chairs. Deans and/or department chairs will make a call

for interest by a method that works best for their college/department/unit. At this time, deans and department chairs will provide the name(s) of faculty members to IRB administrators whom they feel are best suited to serve on the IRB. A statement of interest to the dean or department chair or dean does not assure committee membership.

The IRB Chair and Associate Provost for Research and Faculty Success, in consultation with the IRB Administrator have final approval regarding new and continuing board members. There are considerations that must be made on behalf of researchers that the IRB Chair, AP for Faculty Research and Success and the IRB Administrator are privy to, namely board composition with regard to department representation, gender and ethnic diversity, and areas of expertise. If at all possible, the IRB Chair and administrator work to make sure that the board reflects the diversity of the student and faculty body, to the largest extent possible.

Once a request to join the IRB has been approved, the new member will receive a letter of confirmation from the AP for Faculty Research and Success, stating the term for service (3 years), the expectations of each member, and a schedule for meetings for the fiscal year. If the new member is not yet familiar with the online IRB submission system, a meeting with the IRB Administrator will be arranged to assist the new IRB member with navigating IRB Manager online submission platform. Part of the training will include how to access IRB applications, review them using the IRB checklist, and provide feedback as a primary or secondary reviewer.

New appointees will be assigned CITI training for IRB members and shall complete this training within one (two?) months of their appointment.

Instructions Expectations for participation in IRB meetings

Meetings are scheduled to be held in the same room for the entire year, beginning in fall (first meeting in September) and ending in the following summer (last meeting in August). The IRB Administrator, IRB Chair or Vice Chair will call the meeting to order once there is a quorum with a community member present. A meeting cannot commence unless a community member is actually present in person or via teleconference. The graduate assistant (when present) will take minutes that will be made available for viewing in IRB Manager immediately following the meeting. The notes will reflect all of the discussion related to each reviewed application, new business, and any other announcements or training conducted as part of the meeting. Voting on each reviewed application will be captured via IRB Manager and can be reviewed in the meeting tab by IRB members.

The convened IRB Committee only reviews studies requiring approval by the full board. Studies requiring approval by the full board include the following:

- Studies involving vulnerable populations (children, parolees, prisoners, and individuals with limited capacity to make determination to participation in a research study due to mental, physical or environmental conditions)
- Clinical trials
- Studies brought to the full board on the discretion of the IRB Administrator or IRB Chair due to problems with protocols that are of grave concern. Only a convened IRB has the authority to grant disapproval of a study.

IRB members may be notified to review expedited level studies outside of convened committee meetings at the discretion of the IRB Administrator and IRB Chair. The IRB Chair may assign an expedited review to an IRB committee member. Such reviews are not dependent on monthly review cycles and can be reviewed within 1-2 weeks of the application submission.

IRB Review Checklist - Each member will have access to their IRB Review Checklist for each application and can use the checklist as reference during the meetings. The checklist sets a baseline standard for all IRB application to be reviewed equitably. Items that do not meet the standard set by the IRB Review Checklist may receive at least conditional approval or no approval, depending on the severity of the concern. The IRB can pose questions to the study PI that will be communicated by the graduate assistant to the study PI in the official correspondence regarding the committee decision. The convened IRB may also decide to invite the study PI to the next IRB meeting, if the IRB deems it appropriate to do so.

There are three options for approval for each study that the committee must vote and approve to be most adequate:

- Approval – the study may commence as submitted
- Conditional approval – the study may receive approval if the study PI is responsive to concerns of the IRB
- No approval – the study will not be approved as submitted

Conditional approval may require the study PI to submit changes to the full board at the next meeting or submit changes to the IRB Administrator and receive approval upon submission of those changes. Studies that receive conditional approval typically have minor changes required as determined by IRB members that can be reviewed upon submittal by the IRB Administrator without full borad review. Studies that involve protected poulations are not appropriate for conditional approvals. The IRB Committee determines which conditional approval is most appropriate, depending on the severity of the presenting concern. At the vote on the application, these conditions are discussed, included in the vote and are also reflected in the meeting minutes. When the decision is communicated to the principal investigator, these conditions are included in the letter sent.

There are two outcomes for studies that are not approved by the IRB. A study may be fully rejected by the committee which will require resubmittal of a new application or appeal by the principal investigator. Studies that are not fully rejected but require changes with full board approval do not need to be submitted as a new application, however the PI must make changes and submit updated application/documents by the submission dedline of the next scheduled IRB meeting to be reviewed again by the full IRB.

One IRB member will be assigned as the primary reviewer for each application. During the meeting the assigned reviewr will present the application along with their checklist and any comments and concerns regarding the application. Once the application has been presented by the primary reviewer, comments will be opened up to the entire committee.

Post meeting processing – Each member must fill out and submit their IRB Review Checklist via IRB Manager to document their responses to each study either before the scheduled meeting

or within 48 hours of the concluded meeting. Any pending issues with regard to studies will be communicated to the IRB as part of post-meeting processing.

Faculty advisors and Study PI who are members of the IRB and present during meetings. Faculty advisors who are directly responsible for supporting a student as advisor or dissertation chair must recuse her/themselves/himself from voting on a study. Additional information that may inform study details may be shared. If the person serves on a dissertation committee and is not the faculty advisor or the dissertation chair, the committee member may participate in voting. If the committee member is a study PI or co-investigator for a study under review, they cannot vote on the study under review.

Navigating IRB Manager

Each IRB committee member has a designation as a member of the IRB within IRB Manager. This affords each member privileges to review past board meetings, receive and review IRB applications, and submit notation on each IRB application, which can be used during review of applications during convened committee meetings. IRB Manager can be accessed at this **link** using your Roosevelt username and password – no use of personal emails are allowed.

Quality assurance monitoring and reporting

At the end of each academic year the IRB Office will administer a survey to the IRB Committee and a separate survey to faculty, student and staff researchers. The survey for the IRB Committee will determine the extent to which the current practices established for the IRB (meeting structure and process, IRB Manager navigation, professional development opportunities, committee composition, regulatory compliance) are all carried out to the overall satisfaction of the IRB. The survey will be used to target and make changes to areas of improvement, as appropriate.

The survey of the research community to learn about the issues and questions of most concern to them, to learn what information is most useful to them, how they find the online submission system to be user-friendly, accessible, and to solicit feedback regarding their submission experience. The survey will also help the IRB Committee and IRB Office to understand how IRB Manager end users perceive their concerns are being addressed.

IRB Office support

IRB Committee members and the research community of Roosevelt can receive support for IRB Manager navigation and all other research-related inquiries by contacting the IRB Office at research@roosevelt.edu or (312) 341-2449. The office has one dedicated graduate assistant that may be allocated in a supportive role. The graduate assistant is available to provide support to the IRB for 9 hours per week. The office hours are Tuesdays 11 – 2pm at the IRB Office, or via zoom.

Instructions for resignation from the IRB

Each committee member who receives a letter of confirmation of their service to the IRB must also tender their resignation on letter head to be delivered via email to the attention of the IRB Chair and Senior Vice Provost for Academic Affairs. For RU faculty, the resignation must include an effective date and documentation of notification (cc on the letter) to their respective

department chair and dean. We kindly request that enough notice is given in order to maintain the required minimum number of committee members and to establish a quorum at the next full board meeting.

Decision Charts for IRB Committee

The following pages contain decision charts that can be used at your discretion while reviewing IRB applications.

Human Subject Regulations Decision Charts

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. The IRB Chair and IRB Office, and if necessary, in consultation with the OHRP, may advise on a particular case.

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: Does your study require Limited IRB Review?
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)?

Does your study require Limited IRB Review?

What is limited IRB review?
Limited IRB review is increased oversight by the IRB for low-risk research to ensure that either:

- The identifiable private information or biospecimens collected have the appropriate data security and privacy protections in place to reduce the chance of inappropriate disclosure; or
- Broad consent was obtained for the use of stored identifiable data or biospecimens.

***Explanation of the requirements for limited review can be found in the guidance on limited IRB on Inside Roosevelt.**

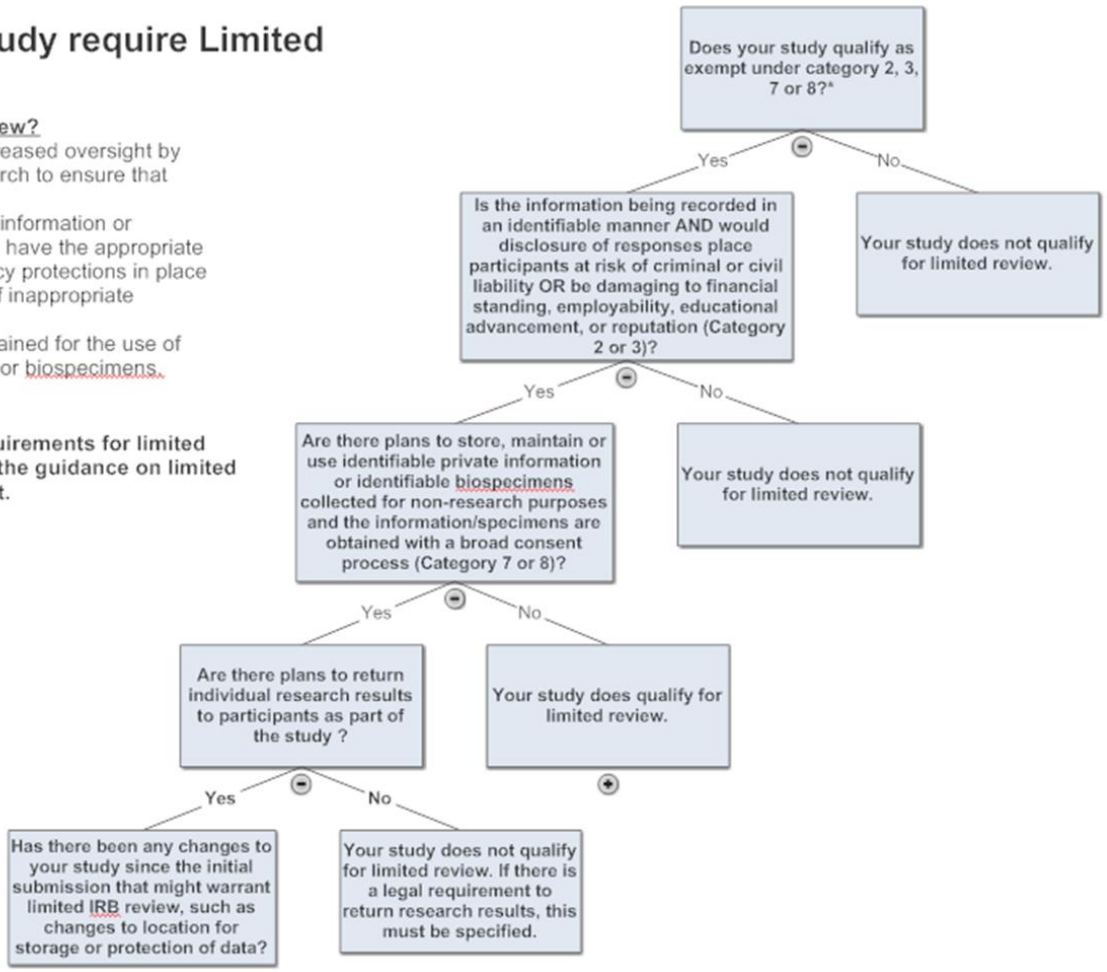

Chart 1: Is an Activity Research Involving Human Subjects Covered by 45 CFR part 46?

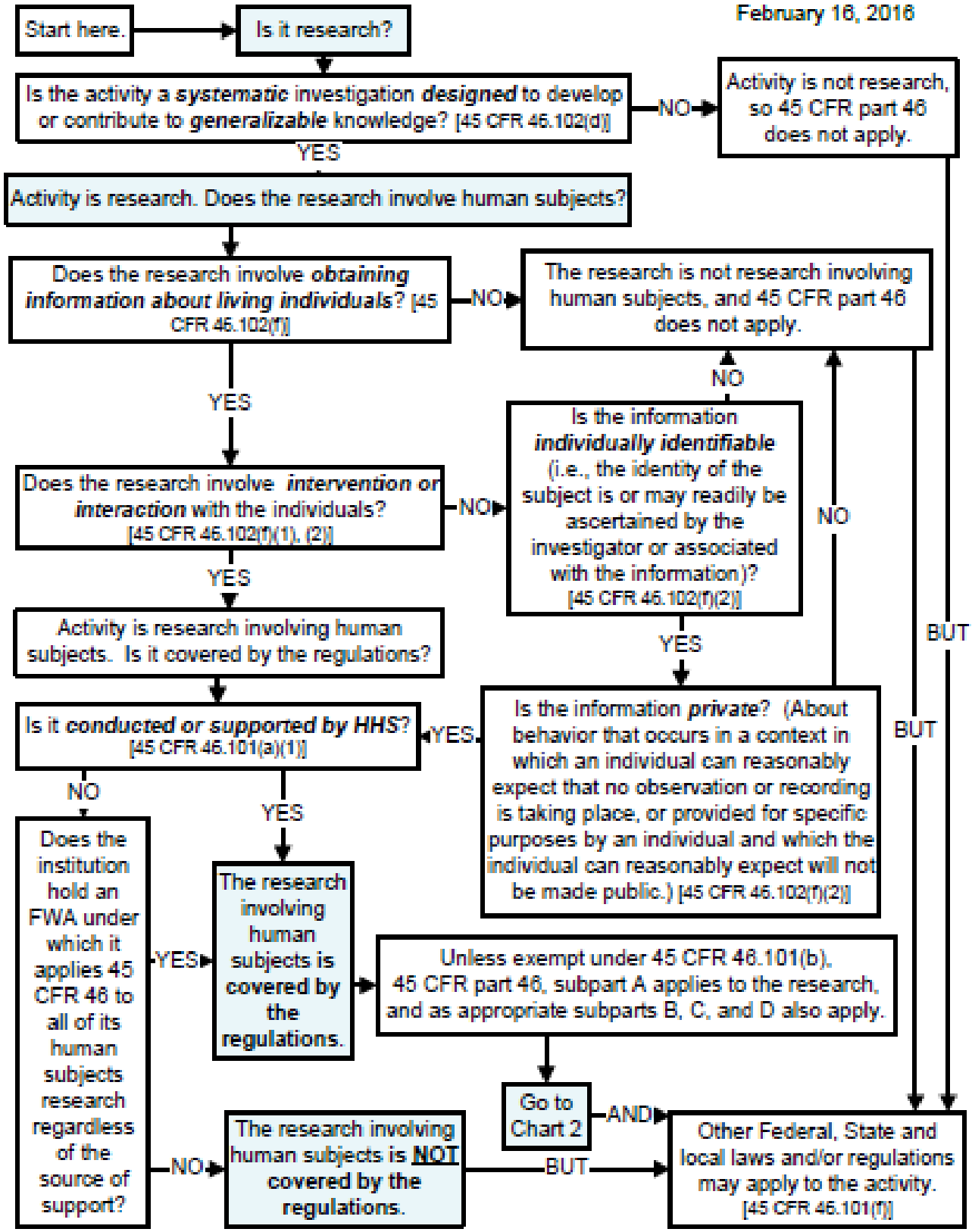

Chart 2: Is the Research Involving Human Subjects Eligible for Exemption Under 45 CFR 46.101(b)?

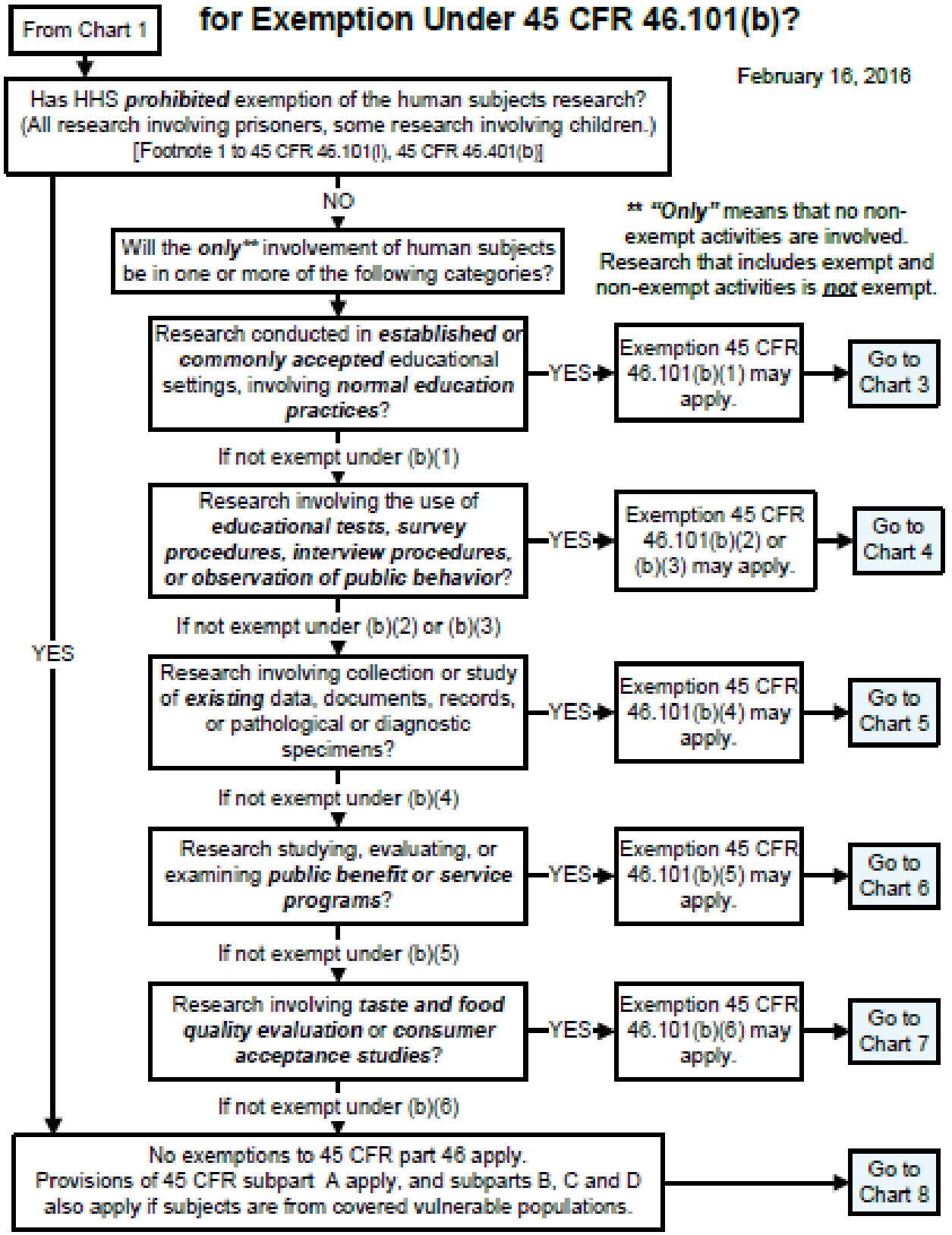

Chart 3: Does Exemption 45 CFR 46.101(b)(1) (for Educational Settings) Apply?

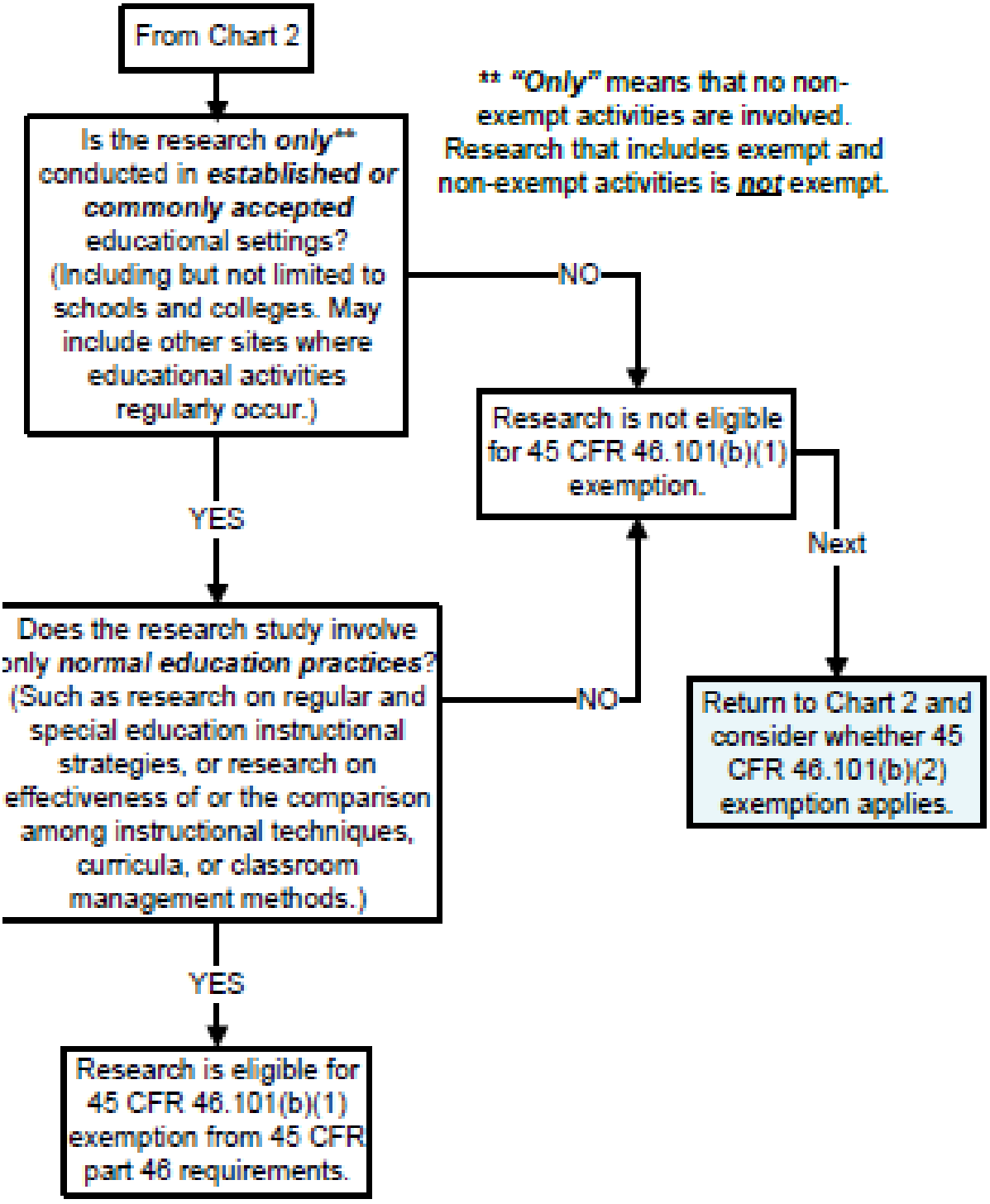

Chart 4: Does Exemption 45 CFR 46.101(b)(2) or (b)(3) (for Tests, Surveys, Interviews, Public Behavior Observation) Apply?

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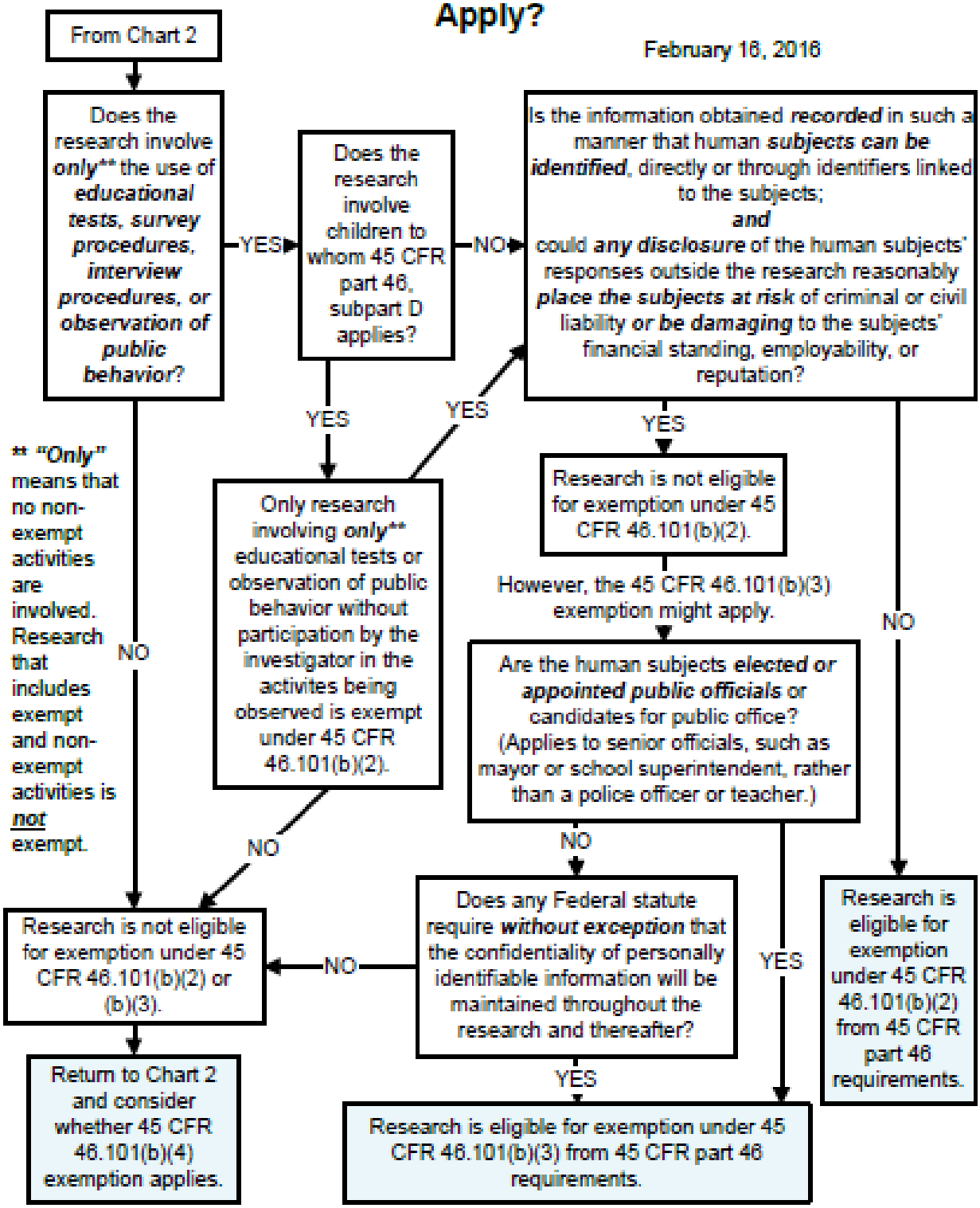


Chart 5: Does Exemption 45 CFR 46.101(b)(4) (for Existing Data Documents and Specimens) Apply?

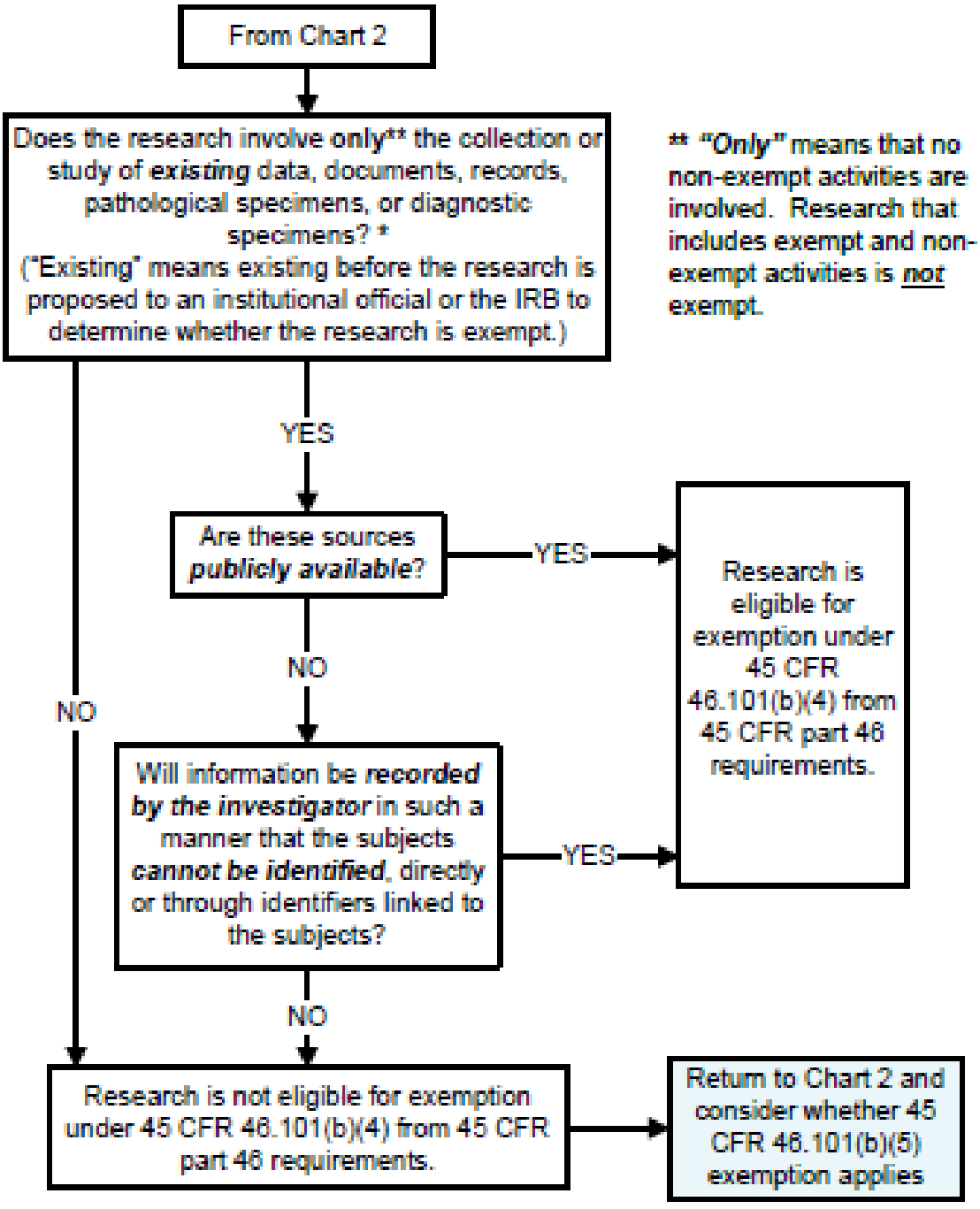
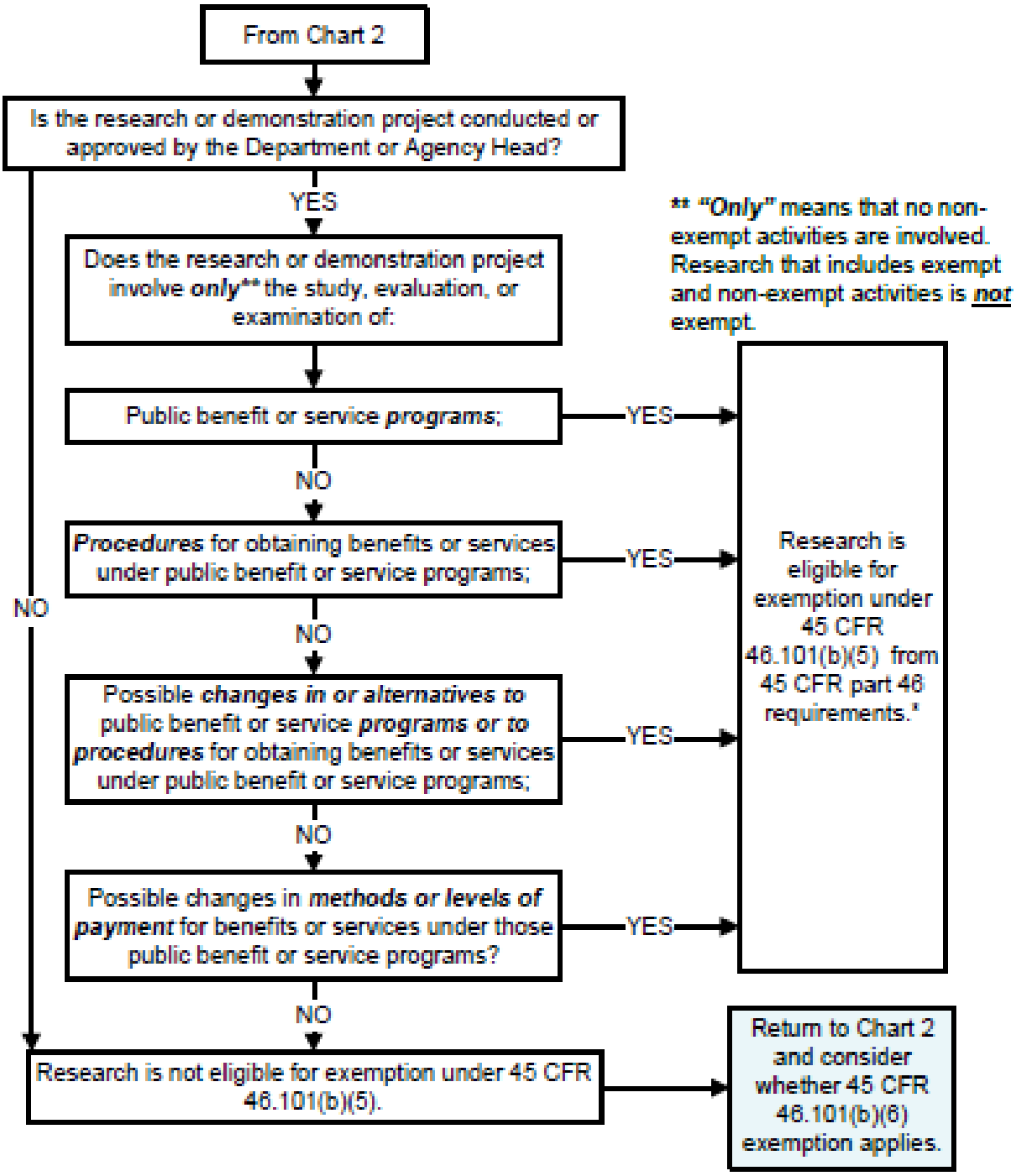


Chart 6: Does Exemption 45 CFR 46.101(b)(5) (for Public Benefit or Service Programs) Apply?



* 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?

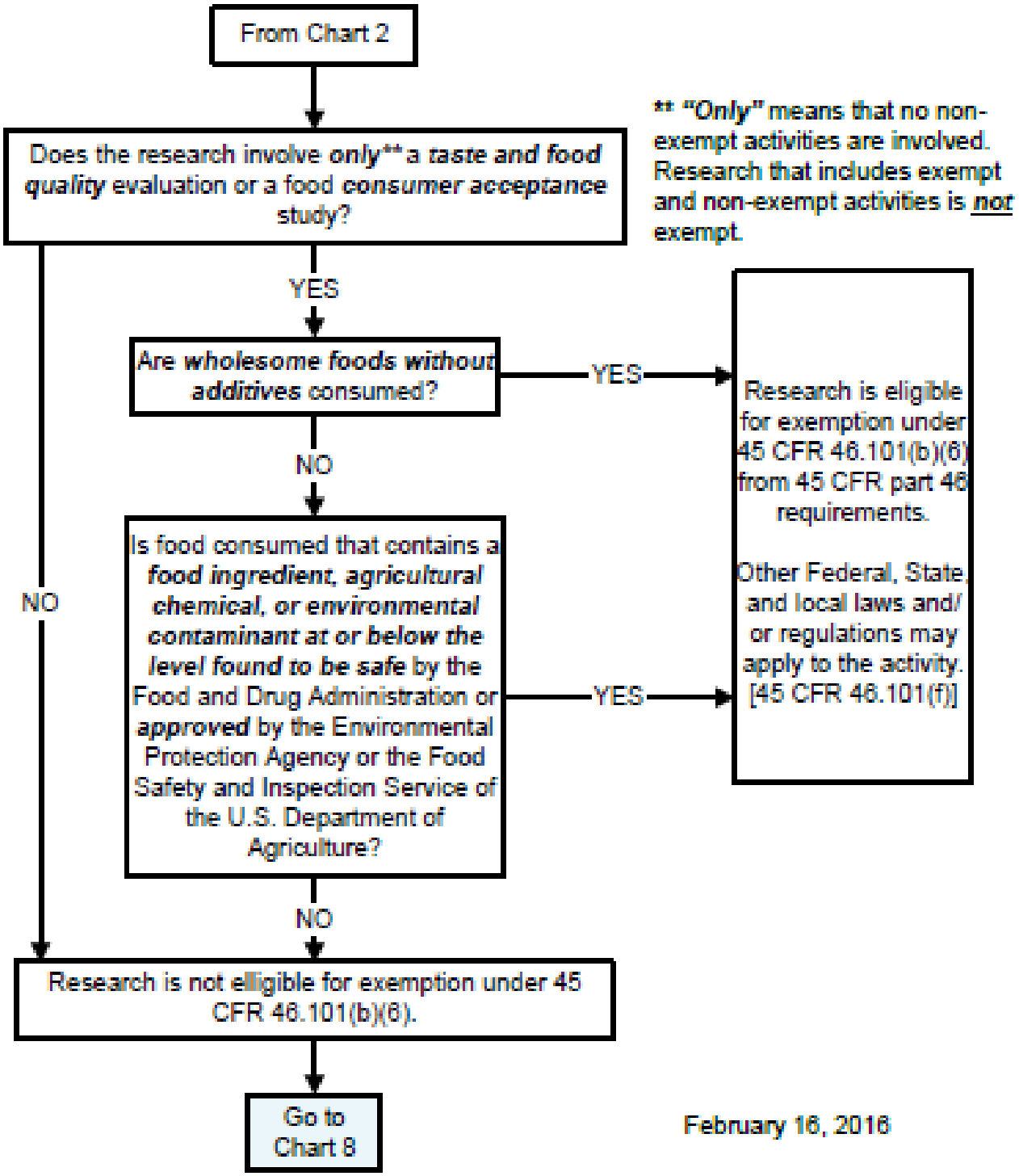


Chart 8: May the IRB Review Be Done by Expedited Procedures Under 45 CFR 46.110?*

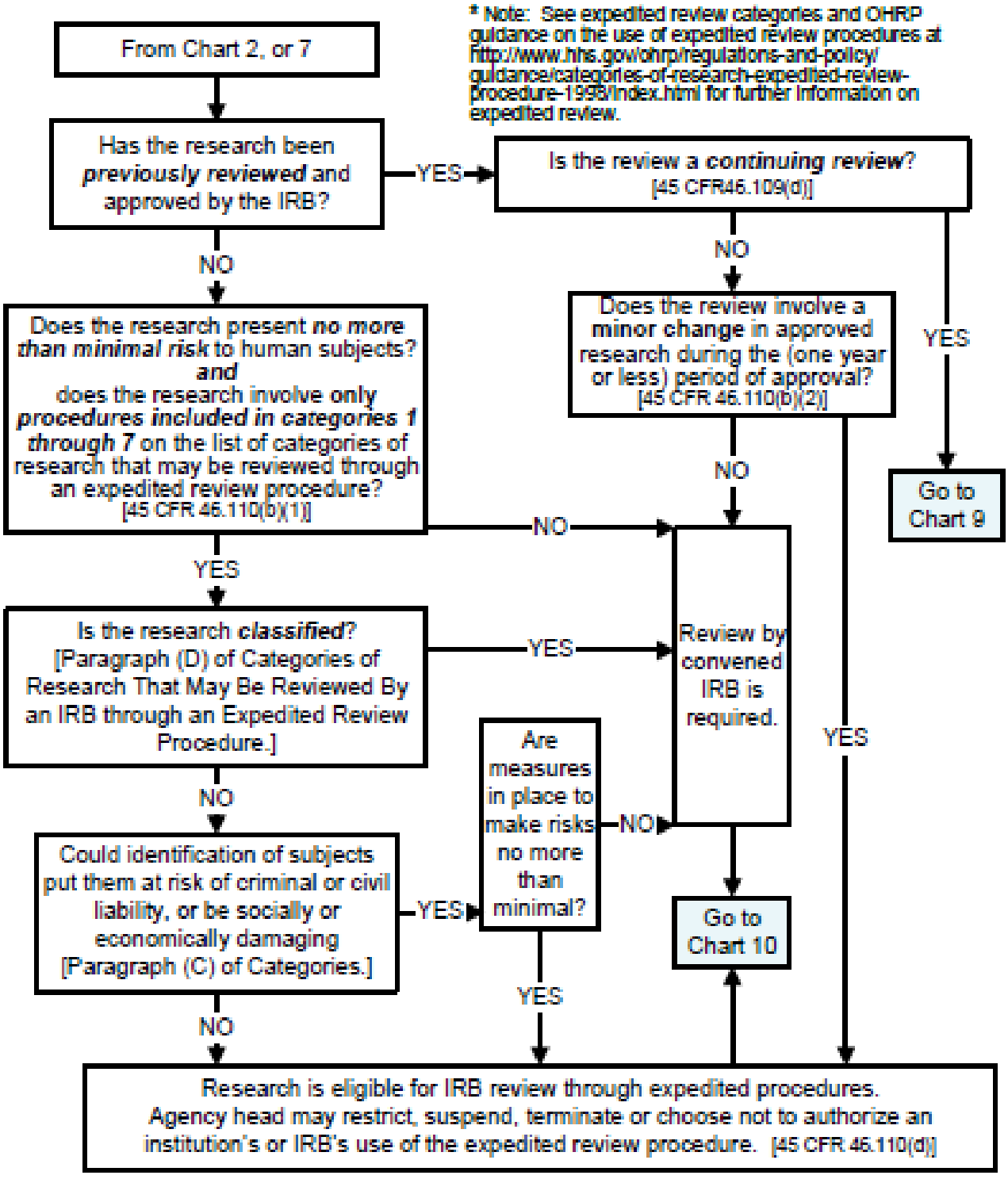


Chart 9: Can Continuing Review be Done by Expedited Procedures Under 45 CFR 46.110?

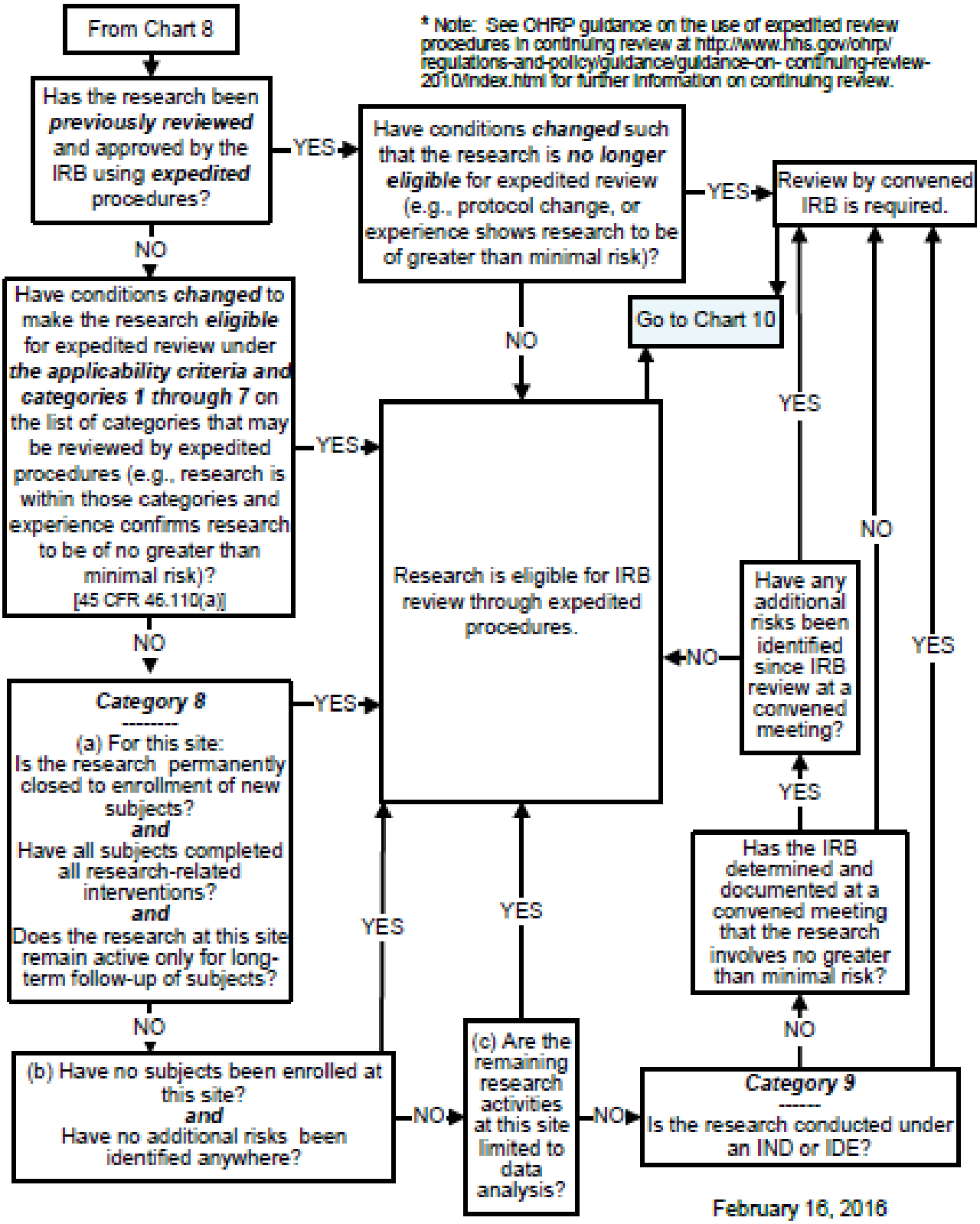
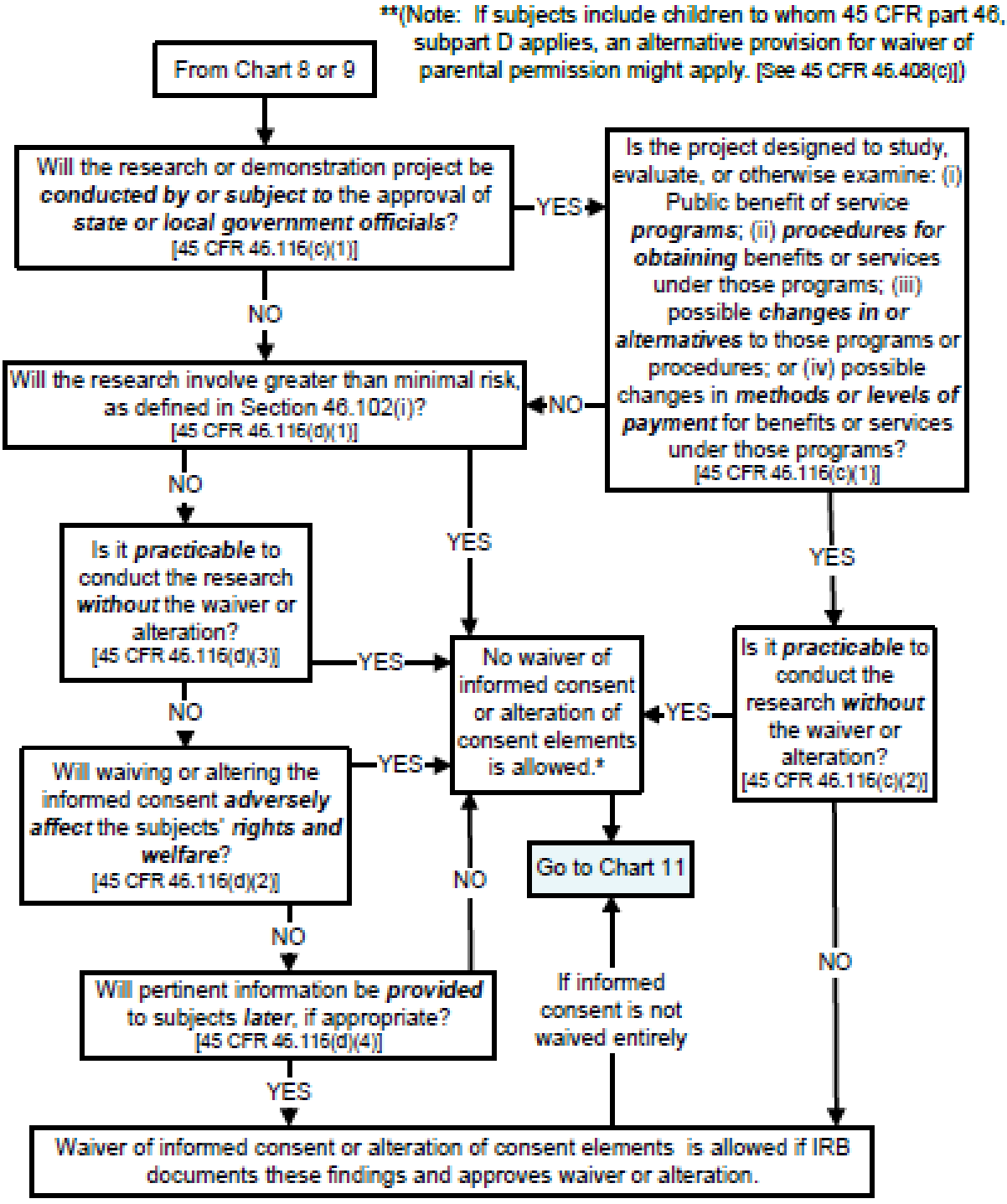


Chart 10: Can Informed Consent Be Waived or Consent Elements Be Altered Under 45 CFR 46.116(c) or (d)?**



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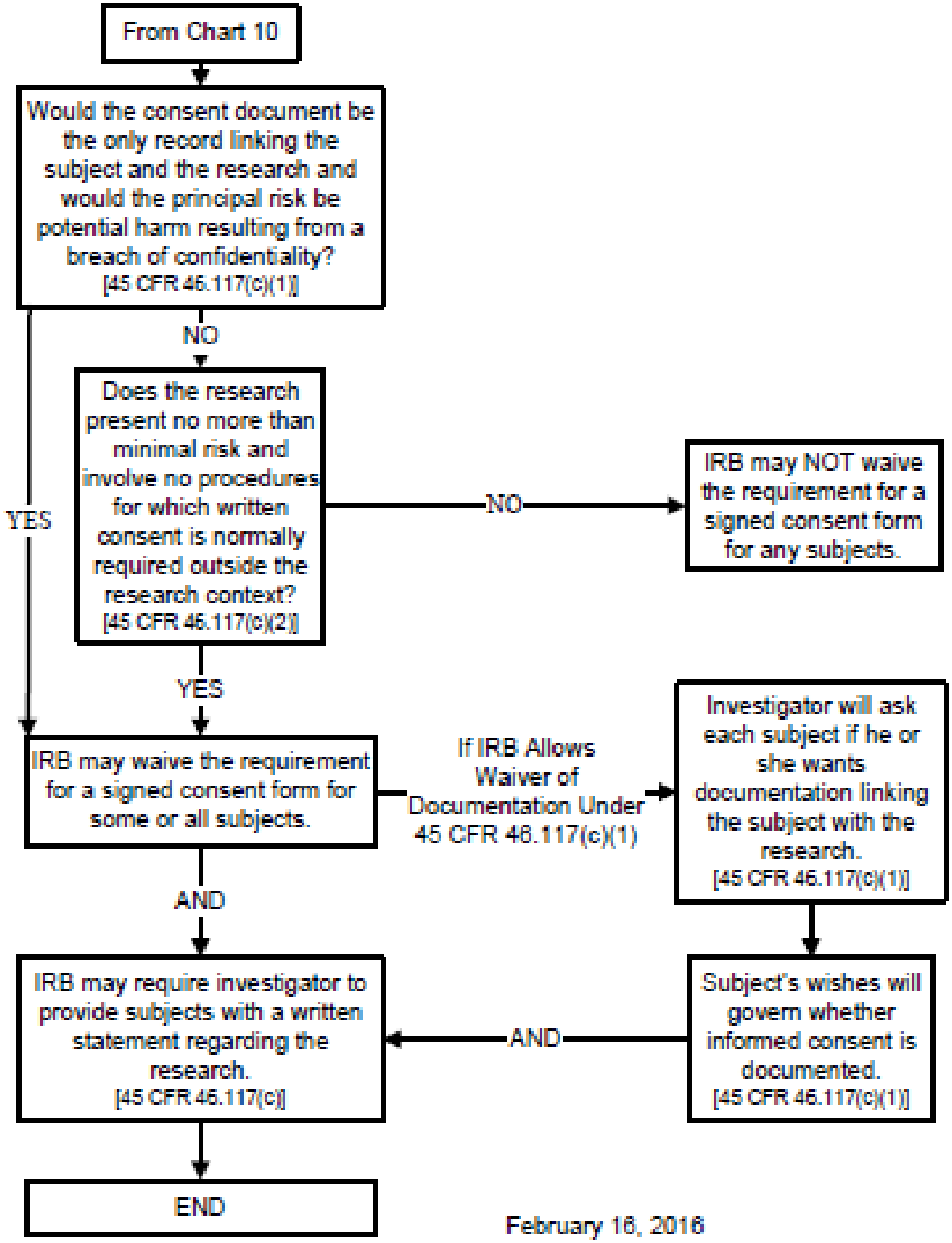
Chart 11: May Documentation of Informed Consent Be Waived Under 45 CFR 46.117(c)?



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