

Antioch College
Institutional Review Board for Human Participants (IRB)
Policy Regarding the Protection of Human Participants¹

Authorization/Charge

In accordance with its Federalwide Assurance on file with Department of Health and Human Services, Antioch College has an Institutional Review Board for Human Participants (IRB). The IRB is charged with ensuring that those individuals participating in research are not subject to undue or inappropriate risks, that participation remains voluntary, and that the conduct of research is upheld to standards outlined in the Common Rule, state regulations, the Federalwide Assurance, and institutional policies. The primary mission of the IRB is to ensure the protection of rights, privacy and welfare of all human participants in research conducted by Antioch College faculty, professional staff, and students. Concurrent with Antioch's commitment to the highest regard for the welfare of human participants is the goal of providing quality service to enhance the conduct of research. To achieve this goal, the IRB has the authority to review, approve, modify or disapprove research protocols submitted by faculty, staff and student investigators. The IRB is a standing committee of College faculty and staff. All IRB members receive training regarding ethical treatment of human participants evidenced by certification from the National Institute of Health (NIH).

Purpose of the IRB

The role of the IRB is to ensure that the welfare, rights and privacy of all human participants in research at Antioch College are consistently maintained. Moreover, the IRB aims to foster a research culture of respect, beneficence, and justice, and to respect the dignity and autonomy of individuals as defined in The Belmont Report issued in 1979 by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. These principles have been set forth in the Department of Health and Human Services, Code of Federal Regulations (Title 45, part 46 of the Code of Federal Regulations, or the "Common Rule").

Purpose of the Policy Regarding the Protection of Human Participants

The purpose of this policy is to clearly detail the definitions, procedures, and regulations governing any research done at Antioch College which involves human participants. These procedures and regulations are intended to function both as a systematic means to protect the welfare, rights and privacy of human participants, as well as to assure the federal government that these measures are in place. This policy applies to ALL research involving human participants at Antioch College or under the auspice of Antioch College, regardless of the source of funding. This includes research conducted by individuals outside of

¹ The basic formulation and structure of this policy was derived from several sources, including:

- a) Title 45 Code of Federal Regulations, part 46 ("The Common Rule")
- b) The Belmont Report—The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1979
- c) The Institutional Review Board policies/procedures of:
 - a. Cornell University
 - b. Kenyon College
 - c. Oberlin College
 - d. The College of Wooster

the College either using human participants or pre-existing or unpublished data gathered from Antioch College. The intended audience for this policy includes research administrators, principal investigators (faculty, staff, and students), and IRB members. The policy describes the review process as well as the requirements and processes of submitting protocols.

Human Participant Research Defined

Human Participant Research is most broadly defined as a process of inquiry, observation or systematic investigation that collects data about individuals who can be individually identified, and that seeks to draw generalizations from the effort. Whether you wish to conduct research resulting in data that individually identifies your participants, or research with confidentiality or anonymity assurances in place, federal law provides participants certain rights and places certain responsibilities on researchers.

The following definitions of human research are derived from the Title 45 Code of Federal Regulations, part 46 (“The Common Rule”):

- **Research** is a systematic investigation designed to contribute to generalizable knowledge.
- **Human participants** are living individuals about whom an investigator obtains data, either through an intervention, interaction or identifiable private information.
- **Intervention** includes both physical procedures by which data are gathered and manipulation of the participant or the participant’s environment that are performed for research purposes.
- **Interaction** includes communication or interpersonal contact between the investigator and the participant (e.g., use of interviews or collection of survey data).
- **Identifiable private information** includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, as well as information provided by an individual which they can reasonably expect will not be made public (e.g., a medical record). Private information must be individually identifiable (i.e., the identity of the participant is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human participants.
- **Minimal risk** means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or test).
- **Informed Consent** is a process facilitated by researchers that ensures participation in a research study is voluntary and based on (1) a disclosure of the information needed to make an informed decision; (2) an understanding of what has been disclosed (accounting for age and language barriers or ensuring the rights of vulnerable populations; and (3) promoting the voluntariness of the decision about whether or not to participate in the research (or to continue participating).

Who Must Submit Protocols to the IRB

At Antioch College, all **faculty, staff, and student research** that conforms to the definitions in the Common Rule must submit protocols for review by the IRB regardless of funding source (federal, state, local, private, or unsponsored) or curricular integration. The Antioch College IRB reviews protocol applications from all disciplines. In accordance with the Federal-Wide Assurance (FWA Number 00021224) issued to Antioch College by the Office for Human Research Protections (OHRP), DHHS, all human participants research funded by the federal government must be performed in accordance with Title 45 Code of Federal Regulations, part 46 (the “Common Rule”). In addition, the actions of Antioch

College officials, researchers, staff, and students must conform to all applicable federal, state, and local laws and regulations.

Independent Faculty research involving human participants conducted at research sites must have approval before research begins. Human participant research includes any research that involves identifiable human participants intended to result in generalizable knowledge, including interview-based research. IRB approval from a previous institution does not constitute IRB approval at Antioch College.

Faculty-Student Collaborative Research, whether on or off-campus, requires IRB approval. When involving rotating student participants or assistants the Principal Investigator need not reapply every quarter, assuming the research topic, methods, and protocols remain the same as in the approved project. However, Principal Investigators must train incoming student researchers on project protocol and submit the final signed page of the IRB application to the IRB Chair before new participants begin research.

Student research involving identifiable human participants intended to result in generalizable knowledge OR any research gleaned information from identifiable human participants that may be shared outside the classroom learning environment **must** be submitted for review at Antioch College. For example, a student oral history project featuring excerpts on a web page, or a student project on diversity presenting aggregate survey data at a research conference or public symposium **must** submit protocols and gain approval prior to engaging in research activities.

Students conducting research while in an **approved Co-op experience** under the auspices of an employer/supervisor's research project are not required to submit an IRB proposal. (Co-op may require a copy of the supervising researcher's IRB approval for the student's co-op file.) Students conducting research during a **self-designed Co-op experience** are required to have IRB approval before the self-design application is approved.

Please note that class assignments and senior project research involving information gleaned from human participants are typically subject to IRB approval as laid out in the Common Rule. A thesis paper, a documentary media project with an intended public audience, or a new media project using interviews to explore a theme would all result from projects with IRB approval. Note that journalism—defined as a narrative exploring and documenting a particular current event and its context— is not considered research and is not subject to IRB review. Participant observation in a public place with no personally identifiable participants would not require IRB approval. Most research involving minors (including participant observation) will require IRB approval including the consent of their legal guardians, though certain educational research activities in educational settings can be exempt. Research involving incarcerated participants can never be exempt from IRB review.

Please consult the Office of Human Participant Protection charts at the end of this document to assess the likely status of your research project.

Expedited Review and Exemptions

The Antioch IRB committee strives to make the full review process as efficient as possible. Expedited Review at Antioch College is available when a project presumes minimal risk to participants. Expedited reviews use the standard IRB application but are reviewed only by the IRB Chair. If the IRB Chair finds the project protocol satisfy the Common Rule, the project will be approved. If the Chair has concerns

that any aspect of the Common Rule is not met, the application will be reviewed by the committee of the whole in a standard review process. Please allow time for feedback and revisions.

Members of the Antioch community who feel no aspect of the Common Rule applies to their research project are invited to apply for Exemption using the **Request for Exempt Status form**.

Resubmissions to the IRB

IRB approval is valid for one year. For multi-year studies, the researcher must resubmit an IRB proposal annually. If significant changes are made to the study anytime during the research process, the research proposal must be resubmitted to the IRB for a new review.

Required Training

Before commencing research, all College researchers must complete the training in human participant research module provided by the National Institute of Health (NIH). To complete this training, researchers must register with the NIH and proceed through the online tutorial available at <https://phrp.nihtraining.com/users/login.php>.

Duties of the IRB

The FWA with OHRP/DHHS details the relationship of Antioch College and the Office for Human Research Protections within the DHHS. This agreement and other DHHS policies empower the IRB with the authority to review, approve, require modification in, or disapprove all research activities conducted by Antioch College investigators. Specifically, the IRB will:

- a) Determine what activities constitute research that involves the use of human participants
- b) Review, approve, require modifications in (to secure approval), or disapprove all research activities covered by the policy prior to the commencement of such research.
- c) Require that voluntary informed consent is obtained from all human participants, and that the information provided to participants as part of informed consent is in accordance with all appropriate regulations and standards.
- d) Notify investigators and the College in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity. IRB approval means that the research has been reviewed and may be conducted within the constraints set forth by the IRB and other appropriate requirements. If research is disapproved, the IRB will include a statement of reasons for its decisions and give the investigator an opportunity to respond in writing or in person.
- e) Conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, but not less than once per year, and have authority to observe or have a third party observe the consent process and the research.
- f) Suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unanticipated harm to participants. Any suspension or termination of approval shall include a statement of reasons for its decisions and shall be reported promptly to the investigator and appropriate institutional officials.

The IRB meets twice monthly to review research submissions, and submissions are due 2 weeks prior to IRB meeting dates.

IRB Membership and Infrastructure

The Antioch College Institutional Review Board for Human Participants consists of 5 members. As required by Title 45 Code of Federal Regulations, part 46 (“The Common Rule”), these members consist of:

- a) Both men and women
- b) One faculty member with a decidedly scientific interest
- c) One faculty member with a decidedly non-scientific interest
- d) One member who is not affiliated with Antioch College nor is a family member of anyone affiliated with Antioch College

By discretion, the IRB may invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. However, these individuals may not vote with the IRB.

Members will be appointed by the President upon recommendation of the Associate Dean of Faculty in consultation with the Vice-President of Academic Affairs. Members will serve terms of one to three-years and should provide representations primarily from social, behavioral, and biological sciences.

Human Subject Regulations Decision Charts

The Office of Human Research Participant Decision Charts are incorporated in the following section as a reference and resource for research project planners. Further resources, including info on Informed Consent, can be accessed from the Office for Human Research Protections of the Department of Health and Human Services (<http://www.hhs.gov/ohrp/policy/consent/index.html>).

Human Subject Regulations Decision Charts

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Available at: <http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html>

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?

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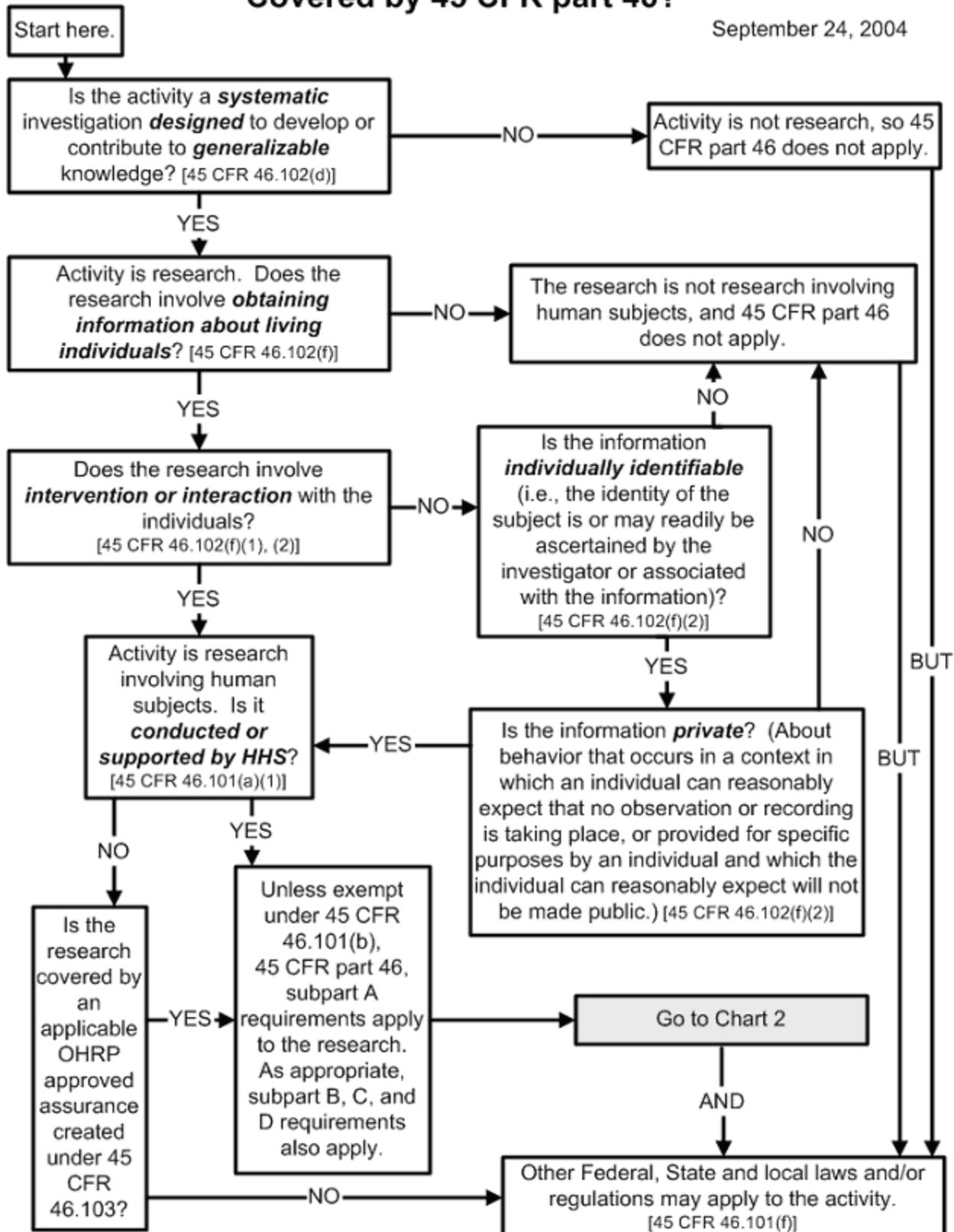


Chart 2: Is the Research Involving Human Subjects Eligible for Exemption Under 45 CFR 46.101(b)?

From Chart 1

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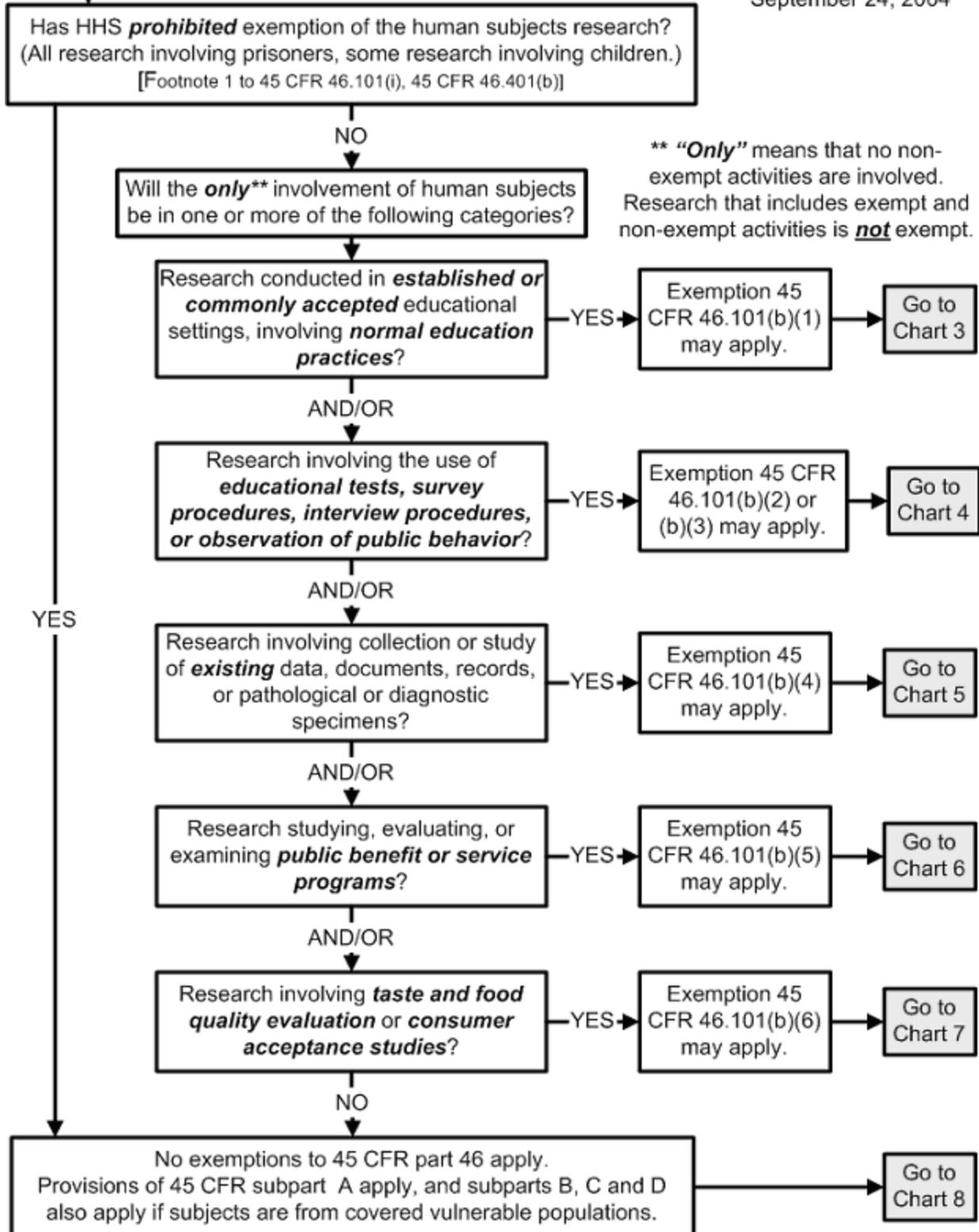


Chart 3: Does Exemption 45 CFR 46.101(b)(1) (for Educational Settings) Apply?

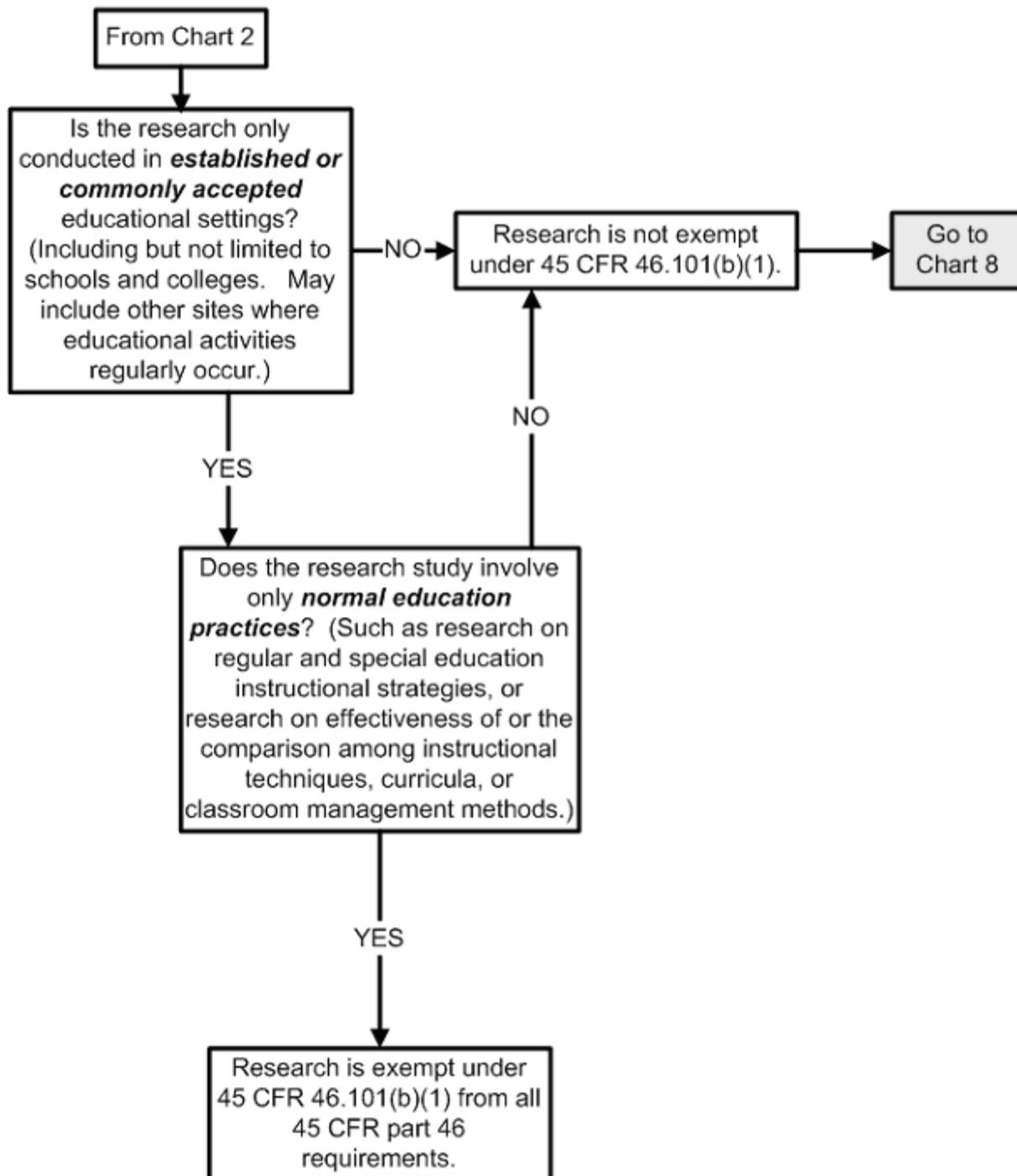
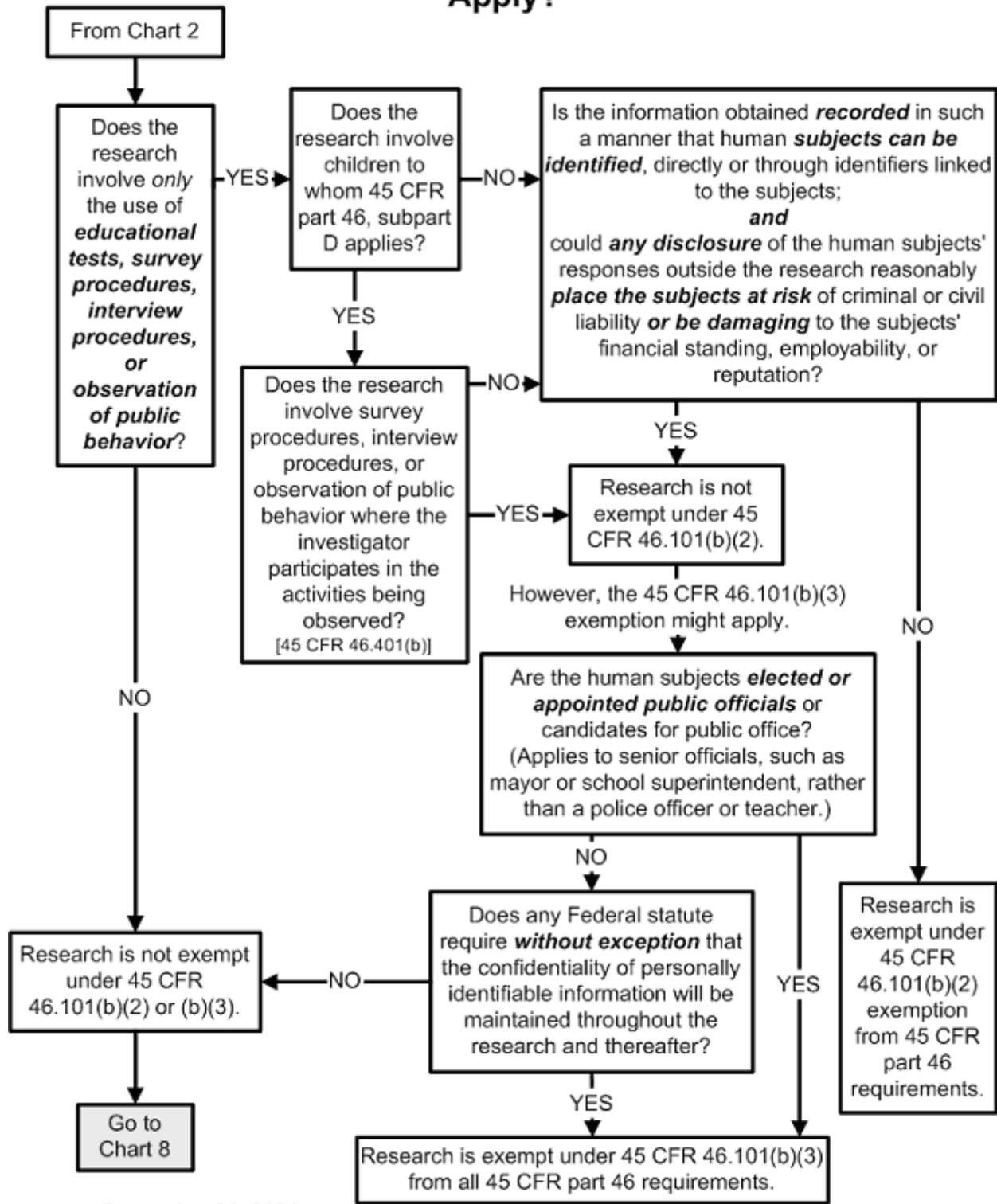
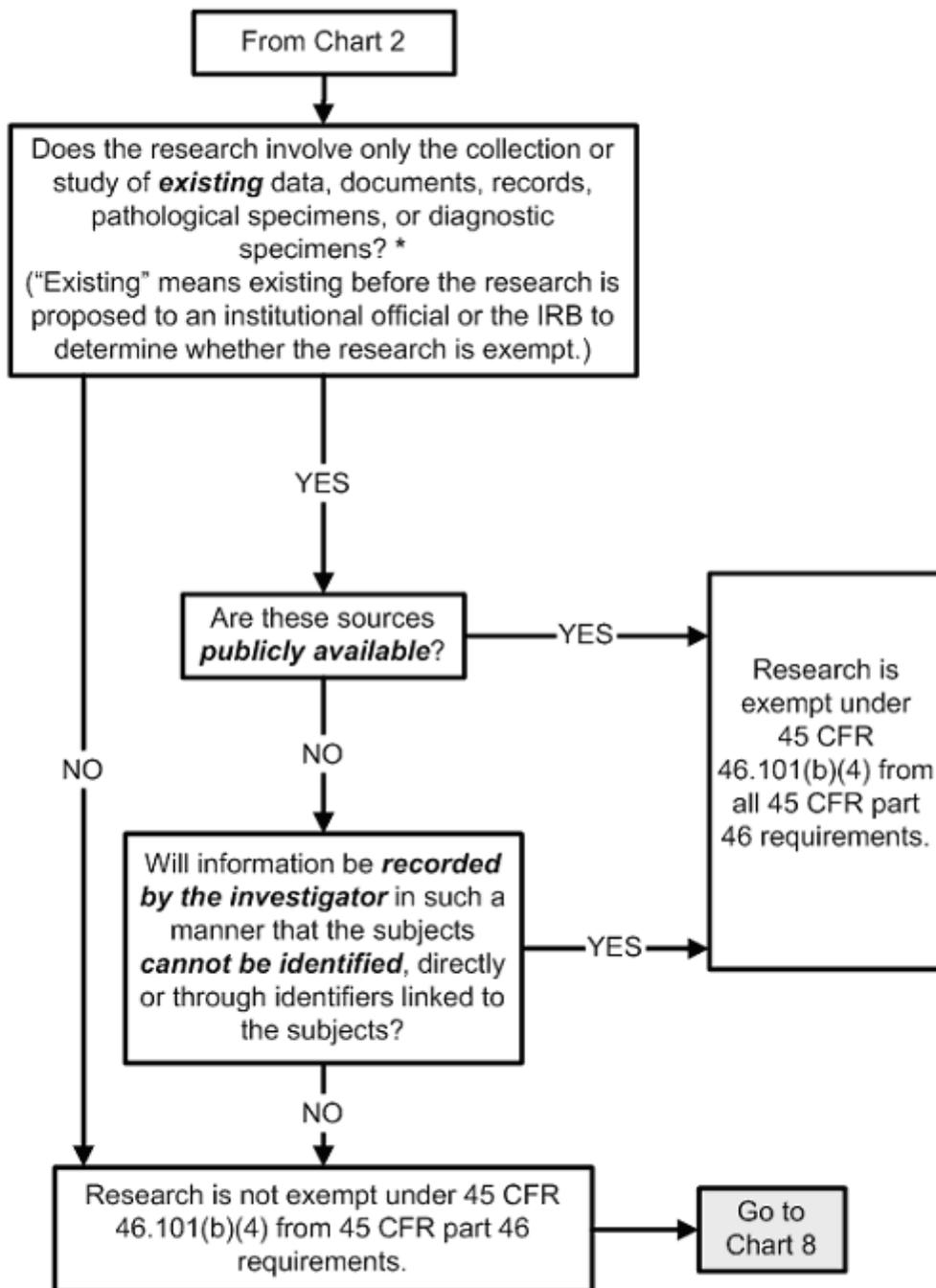


Chart 4: Does Exemption 45 CFR 46.101(b)(2) or (b)(3) (for Tests, Surveys, Interviews, Public Behavior Observation) Apply?



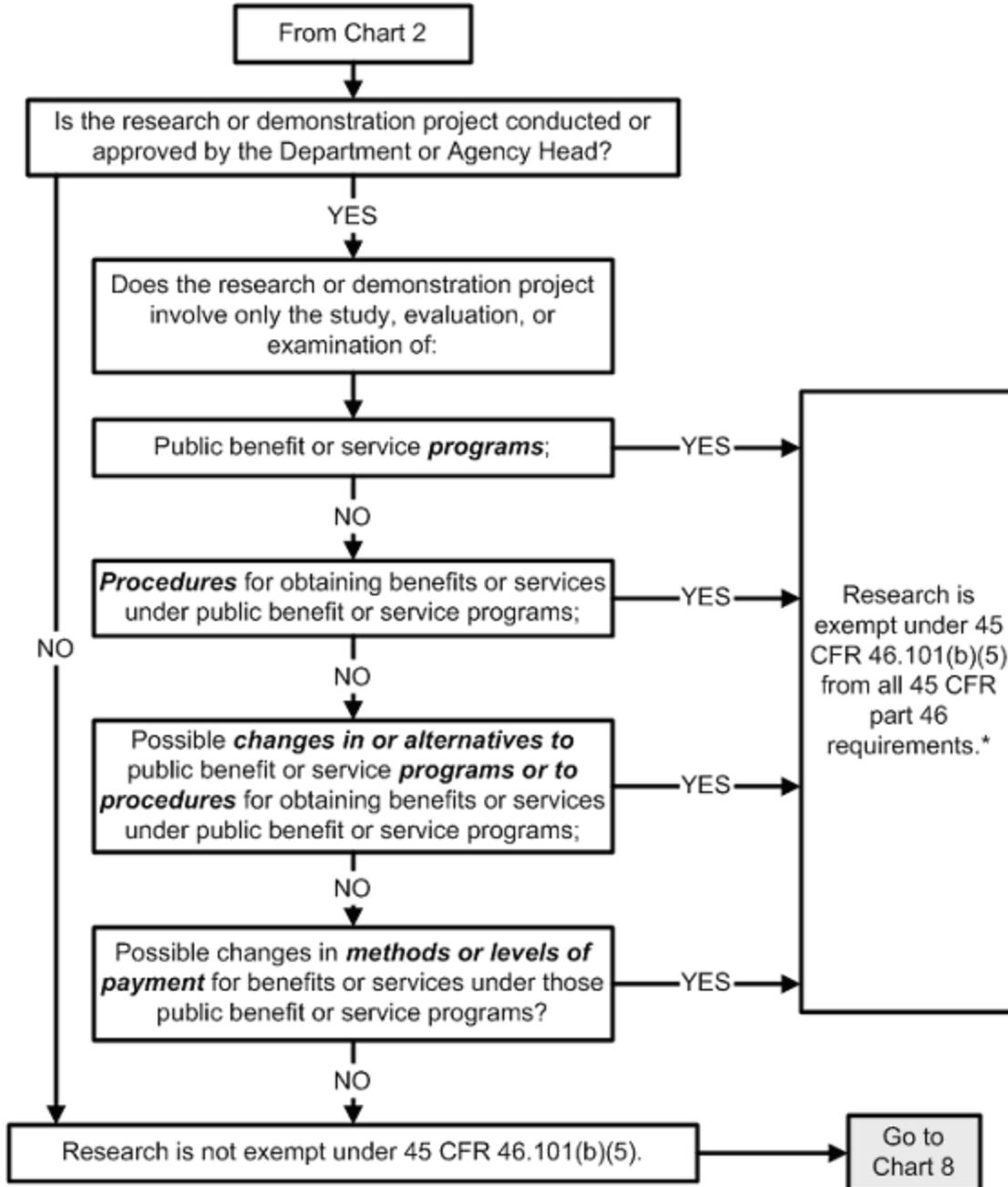
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Chart 5: Does Exemption 45 CFR 46.101(b)(4) (for Existing Data Documents and Specimens) Apply?



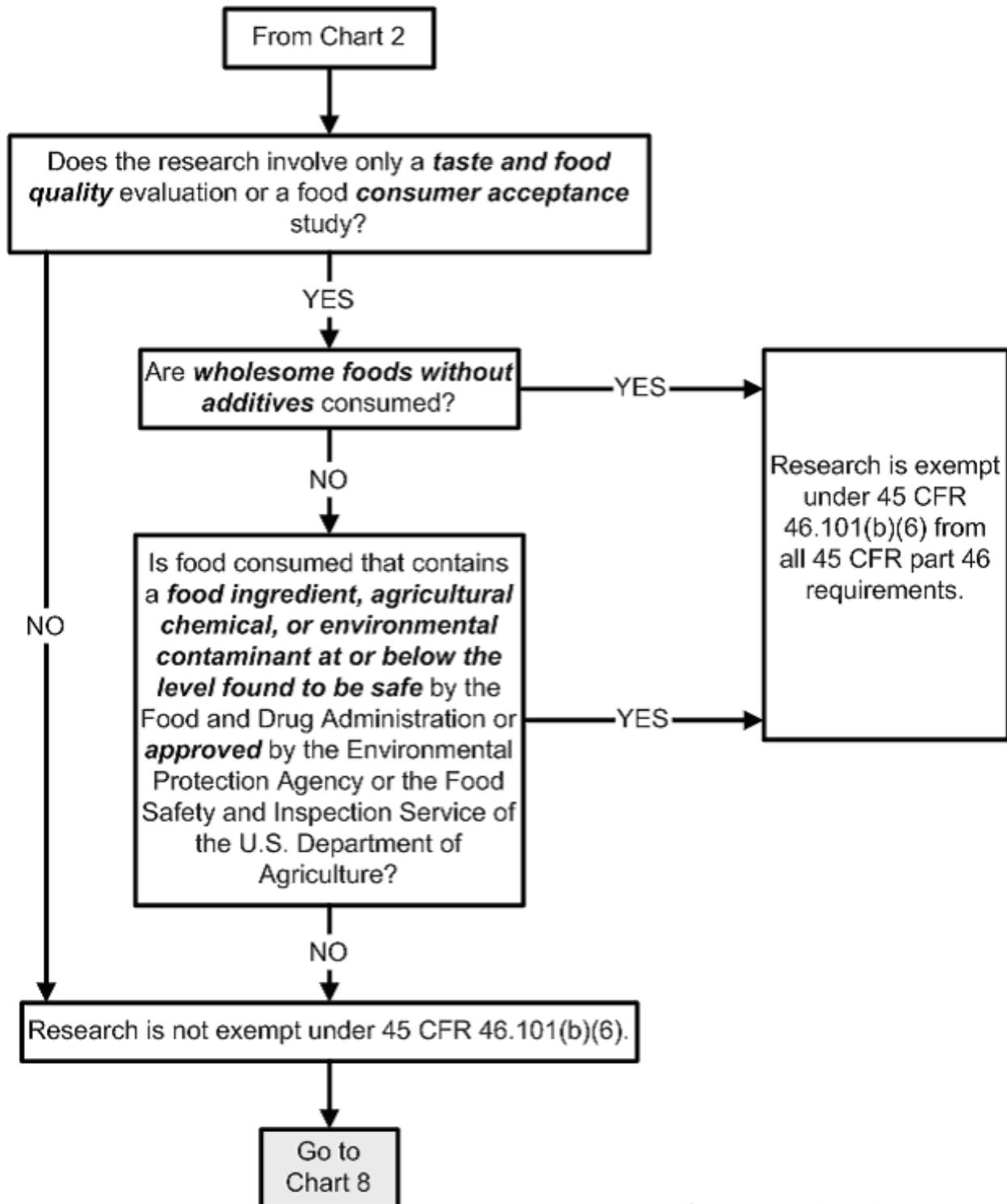
* Note: See OHRP guidance on research use of stored data or tissues and on stem cells at <http://www.hhs.gov/ohrp/policy/index.html#tissues> and #stem, and on coded data or specimens at #coded for further information on those topics.

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/policy/index.html#exempt> for further description of requirements for this exemption.

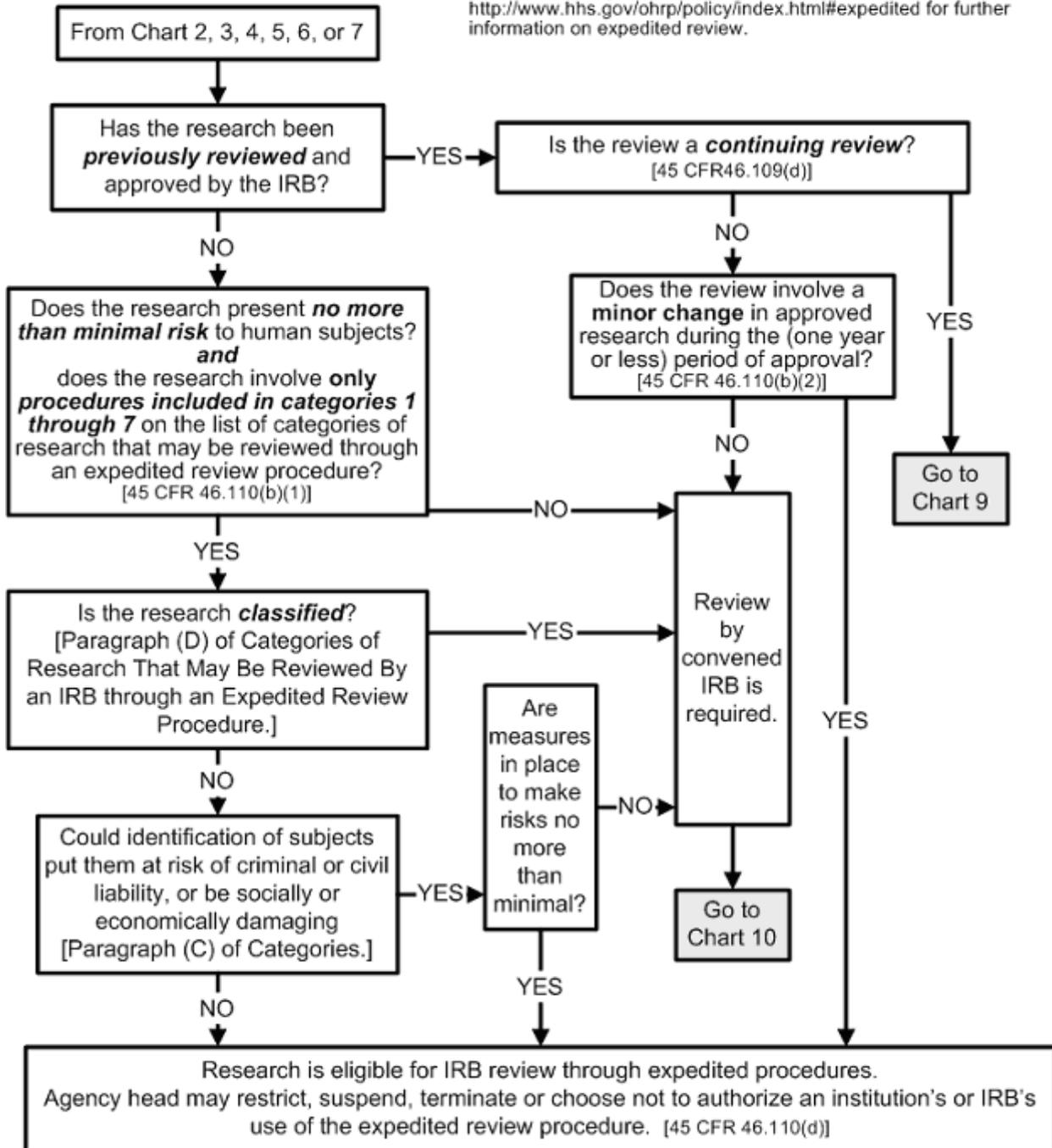
Chart 7: Does Exemption 45 CFR 46.101(b)(6) (for Food Taste and Acceptance Studies) Apply?



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

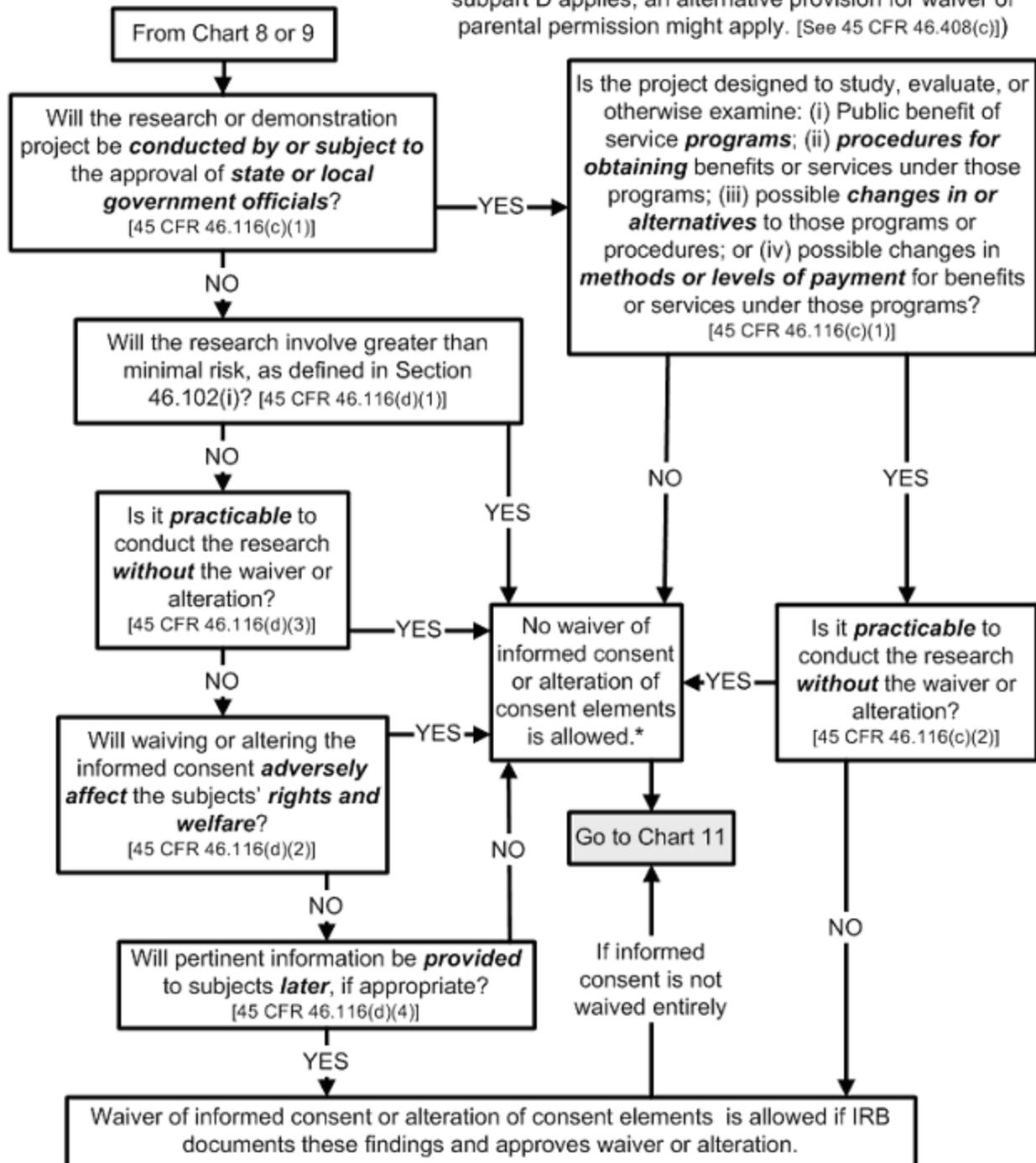
* Note: See expedited review categories and OHRP guidance on the use of expedited review procedures at <http://www.hhs.gov/ohrp/policy/index.html#expedited> for further information on expedited review.



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

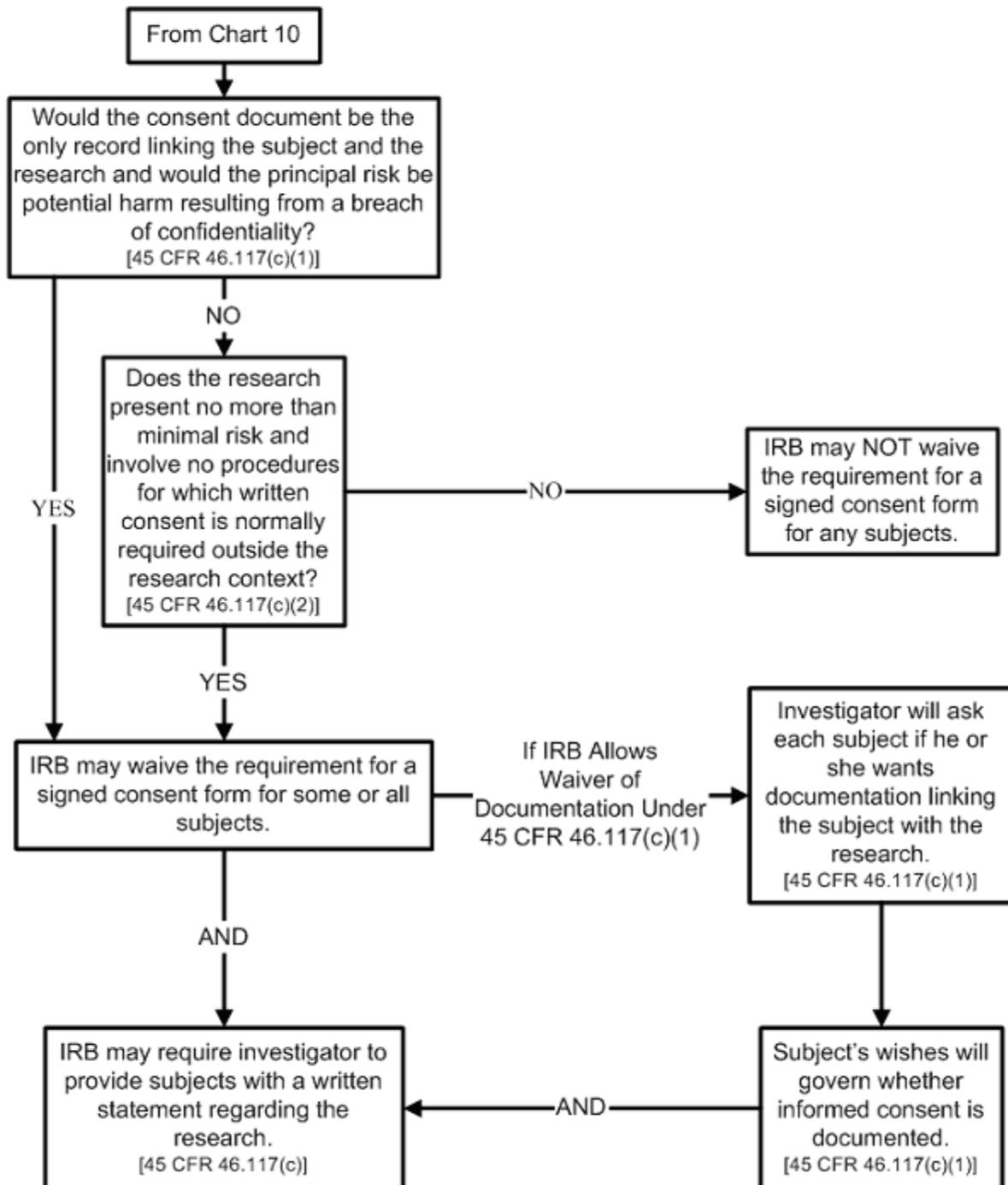
** (Note: If subjects include children to whom 45 CFR part 46, subpart D applies, an alternative provision for waiver of parental permission might apply. [See 45 CFR 46.408(c)])



* Note: See OHRP guidance on informed consent requirements in emergency research at <http://www.hhs.gov/ohrp/policy/index.html#emergency> for further information on emergency research informed consent waiver.

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



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