

# TECHNICAL ASSISTANCE BRIEF

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## When is an IRB Required for Evaluation Activities?

This brief is designed to help First 5 Children and Families Commissions and grantees to determine if and when an Institutional Review Board (IRB) is needed for evaluation activities.



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# Technical Assistance Brief

## WHEN AN IRB IS NEEDED

The purpose of this brief is to assist First 5 Commissions with determining when Institutional Review Board (IRB) approval must be obtained before initiating research and/or evaluation projects and activities.

### OVERVIEW

The Code of Federal Regulations (CFR) Title 45 - Public Welfare, Department of Health and Human Services, Part 46 - Protection of Human Subjects, provides the U.S. policy regarding protection of human subjects in research activities and is generally known as the Common Rule for protection of human subjects. 45 CFR 46 Subpart A states that this policy applies to all research involving human subjects conducted, supported or otherwise subject to regulation by any federal department or agency. In California, the Committee for the Protection of Human Subjects operates in compliance with the federal Common Rule (45 CFR Part 46) and specifies that the Common Rule requirements must be met by all publicly-funded research activities.

Institutional Review Board (IRB) reviews were established to ensure, when research involving human subjects is being conducted, that:

1. Risks to human subjects are minimized
2. Risks are reasonable in relation to the benefits of the research
3. Selection of human subjects is equitable
4. Human subjects give informed consent to participate
5. Informed consent is properly documented
6. Adequate provisions have been made to monitor data collection to protect the human subjects
7. Adequate provisions exist to protect the privacy and confidentiality of human subjects

In the simplest terms, IRB review of research protocols is required when the following conditions exist:

1. The activity meets the Common Rule definition of **research**, which is defined as “a *systematic* investigation, including research development, testing and evaluation, designed to develop or contribute to *generalizable* knowledge.”
2. The research involves **intervention or interaction** with living individuals **or** gathering data in such a manner that human subjects can be **individually identified** (either directly or through identifiers linked to the subjects) and the data being gathered is **private** (provided for specific purposes by the individual where the person can reasonably expect the information will not be made public).
3. None of the specific exemptions in the CFR apply to the research. The most frequently used exemptions for social sciences research are:
  - a. The research is only conducted in established or commonly accepted educational settings (e.g. schools) and involves only normal education practices such as research on the effectiveness of instructional techniques, curricula or classroom management methods.

- b. The research involves only the use of educational tests, surveys, interviews or observation of public behavior and the information is recorded in such a way that individuals cannot be identified (either directly or indirectly through identifiers linked to the subjects) or any disclosure of the individuals' responses could not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation. For research involving children, according to the current policies of the UCLA Office for Protection of Research Subjects:
  - i. Research involving the use of educational tests is exempt;
  - ii. Research involving survey or interview procedures is not exempt; and
  - iii. Research involving observations of public behavior is exempt only when the investigator does not participate in the observed activities.
- c. The research involves only the collection of data that existed prior to the research activities were defined and the data is either already publicly available or the information is recorded in such a way that individuals cannot be identified.
- d. The research is conducted or approved by a federal Department or Agency Head and involves only (1) the study, evaluation or examination of a public benefit or service program, (2) procedures for obtaining benefits or services, (3) possible changes in or alternatives to public benefit or service programs or (4) possible changes in methods or levels of payment for benefits or services. The federal Office for Protection from Research Risks has determined that in order for this exemption to apply, the research must be conducted pursuant to specific statutory authority and the project must not involve significant physical invasions or intrusions upon the privacy of participants.

Research that does not fit any of the exemptions may still be eligible for expedited IRB review, which is a less intensive process, provided it can be shown that the research presents no more than minimal risk to the human subjects and identification of the subjects would not put them at risk of criminal or civil liability or be socially or economically damaging.

Regardless of whether research or evaluation activities require IRB approval, protections should be implemented in all cases where data are captured about individual people where those individuals can be identified either directly or indirectly. These protections include obtaining informed consent from the individuals and ensuring the security of data so that only authorized people can access it for authorized uses. The TA brief and sample policies, procedures, forms and other tools on Client Confidentiality covers these protections.

## APPLICATION TO FIRST 5 COMMISSIONS

There has been considerable debate and some disagreement between First 5 Commissions about when IRB review is required for evaluation activities. The First 5 Commissions in Sacramento and Orange County, among others, have routinely sought IRB review for evaluation-related projects. Conversely, First 5 Alameda County has adopted the position that all of its normal program evaluation activities are exempt from IRB review because they believe that the exemption for the study, evaluation or examination of public benefit or service programs applies to all of their programs. Other counties have disagreed with this position, noting that the language in the CFR states that the exemption for research of public benefit or service programs only applies to federally funded projects with research approved by a federal agency or department head. First 5 Alameda County does obtain IRB approval for formal/special research projects.

The bottom line is that each individual Commission is responsible for making its own determinations about protections for human subjects, including when to seek IRB review. Each evaluation project or activity must be assessed separately. The first question to ask is, is the activity “research” as defined by CFR 46? The following general guidelines have been used by other First 5 Commissions to answer this question:

- Activities to evaluate direct service procedures or accumulate statistical data for performance assessment purposes are considered to be quality assurance activities and not research, as long as
  - ✓ The activities are applied within the normal course of work in a program or agency so that participants (clients) are not subjected to additional burdens beyond what would routinely occur to provide services to those individuals; and
  - ✓ The information gained is used within that program, location or agency to improve services and is not shared outside of the program/agency except on a limited basis, such as aggregated statistics reported to funders for contract compliance purposes where there is no possibility of identifying individual participants.
- Conversely, if there is an intent to accumulate and analyze data in a systematic manner and share the results with other organizations in order to draw conclusions that may affect practices outside of the program/agency that gathered the data, the activity should be considered to be “research.” In general, activities that contribute to generalizable knowledge and thus are considered research are those that attempt to make comparisons or draw conclusions from the gathered data, attempt to reach for generalizable principles of historical or social development, seek underlying principles or laws of nature that have predictive value and can be applied to other circumstances for the purpose of controlling outcomes, create general explanations about all that has happened in the past, or predict the future (*Research Requiring IRB Review*, March 2008, Office of Research Assurances).

Based on these guidelines, First 5 evaluation activities that are strictly for program improvement and contract compliance purposes would generally not be considered to be research and would not require IRB review, although informed consent and client confidentiality protections must still exist. However, evaluation activities that are standardized across several similar programs (for example, several Family Resource Centers) so that results can be compared and shared across programs in order to determine program design changes that can be implemented at a systems level across those programs would be research because there is an intent to produce generalizable knowledge.

Most First 5 evaluation activities that meet the definition of research will also meet the tests of being research involving human subjects because there is some intervention or interaction with individuals by virtue of engaging those individuals in completing surveys, participating in interviews or focus groups, performing assessments of child development or family functioning, and so on. In these situations, one of the specific exemptions in the CFR must be met in order to avoid IRB review. Since most evaluation activities involve “the use of educational tests, surveys, interviews or observation of public behavior” [45 CFR 46.101(b)], arguably the easiest way to ensure that IRB review is not required is to gather such data in a way that ensures that individuals cannot be identified. The key point here is that any activity that qualifies as research involving human subjects will require the First 5 Commission to make an explicit determination as to which exemption in the CFR applies to the activity or else obtain IRB review of the research protocols prior to conducting the research.

To help demonstrate when an IRB is necessary, three scenarios relevant to First 5 Commissions are presented along with a discussion about whether an IRB is necessary.

- **Scenario 1. Evaluation of a School Readiness Project.** Program staff is interested in learning whether a preschool enrichment program has been valuable to children and their families. The investigator plans to issue a survey that can be completed by parents and family members. The aim is to receive responses from at least 75% of parents or caregivers to find out what they liked about the program, and what they felt could be improved. The information will be used to improve next year's service delivery and to communicate with the funder about perceptions of this program, but results are not shared outside of the program other than as highly aggregated data (e.g. in a First 5 annual report) intended only to communicate program status and accomplishments.

**Discussion.** This evaluation does not meet the definition of research. The investigators have designed a systematic investigation, but it is not intended to contribute to generalizable knowledge. The intent of the investigation is to assess the program service delivery for quality improvement and contract compliance purposes.

- **Scenario 2. Evaluation of Home Visiting Outcomes.** A commission is interested in learning from clients about their experiences with a home visiting program, and issues a questionnaire that asks for their name, home address, and detailed information about their experience with the program. Additionally, the investigation involves comparing assessment results of families before and after intervention by the home visiting program using a structured assessment tool called the Life Skills Progression. The results of the investigation will be shared with different agencies in the county, some of which are considering the development of their own home visiting programs.

**Discussion.** The investigation is research involving human subjects, as the intent is to systematically obtain information that could be applied to other home visiting programs (generalizable knowledge). The question about whether the study is exempt from IRB review depends on the evaluation design and must fit under one of the specific exemptions.

- **Scenario 3. Evaluation of a New Program.** A commission is interested in understanding whether a new differential response program results in improved outcomes for children at risk for abuse and neglect. The study includes a control group (children in the current CPS setting) and test group (children and families that will be screened, assessed, and provided a directed intervention). This study will help to determine whether differential response provides better outcomes for children.

**Discussion.** This scenario clearly meets the test for research, as it is systematic investigation that is likely to contribute to generalizable knowledge. Whether or not the investigators plan to present or publish the results, the intent is to test whether a new program improves the outcomes for children and families. Given direct interventions and observations involving children, including possible surveys or interviews with children that do not qualify for exemption, submission to an IRB is recommended.

Regardless of whether evaluation activities are defined as "research," the intent of the regulation, to protect human subjects, should be applied to any situation. Evaluation activities involving human subjects should not cause harm to the participants, and investigators should consider carefully how to minimize harm in any study or evaluation practice. Steps could include aggregating personal data, providing an opportunity for anonymous responses, and requiring informed consent for participation in evaluation activities.

For more information, see the following sources that were used to prepare this brief:

- Code of Federal Regulations, Title 45 Public Welfare Department of Health and Human Services, Part 46 Protection of Human Subjects, online at <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>
- California Committee for the Protection of Human Subjects (CPHS), online at <http://www.oshpd.ca.gov/boards/cphs/>
- The recently updated California Instructions for Researchers, published by the CPHS, are also available online at [http://www.oshpd.ca.gov/Boards/CPHS/InstructionsforResearchers.pdf#Untitled%20\(14\)](http://www.oshpd.ca.gov/Boards/CPHS/InstructionsforResearchers.pdf#Untitled%20(14))
- Additional guidance and vignettes are provided by the National Science Foundation, Interpreting the Common Rule for the Protection of Human Subjects for Behavioral and Social Science Research, online at <http://www.nsf.gov/bfa/dias/policy/hsfaqs.jsp#relation>
- Consent forms and research subject bill of rights can be found on the First 5 website. <http://www.first5eval.com/evaluation/reportingtools.asp>

The remainder of this document includes information published by the Office for Human Research Protections (OHRP) for assistance in determining when an IRB is needed. See Human Subject Regulations Decision Charts, in the following pages. Additionally, the OHRP publishes Quality Improvement Activities Frequently Asked Questions to provide further guidance in determining when an IRB is needed. Included in this document are Frequently Asked Questions for Quality Improvement Projects.

## 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. The charts address decisions on the following:

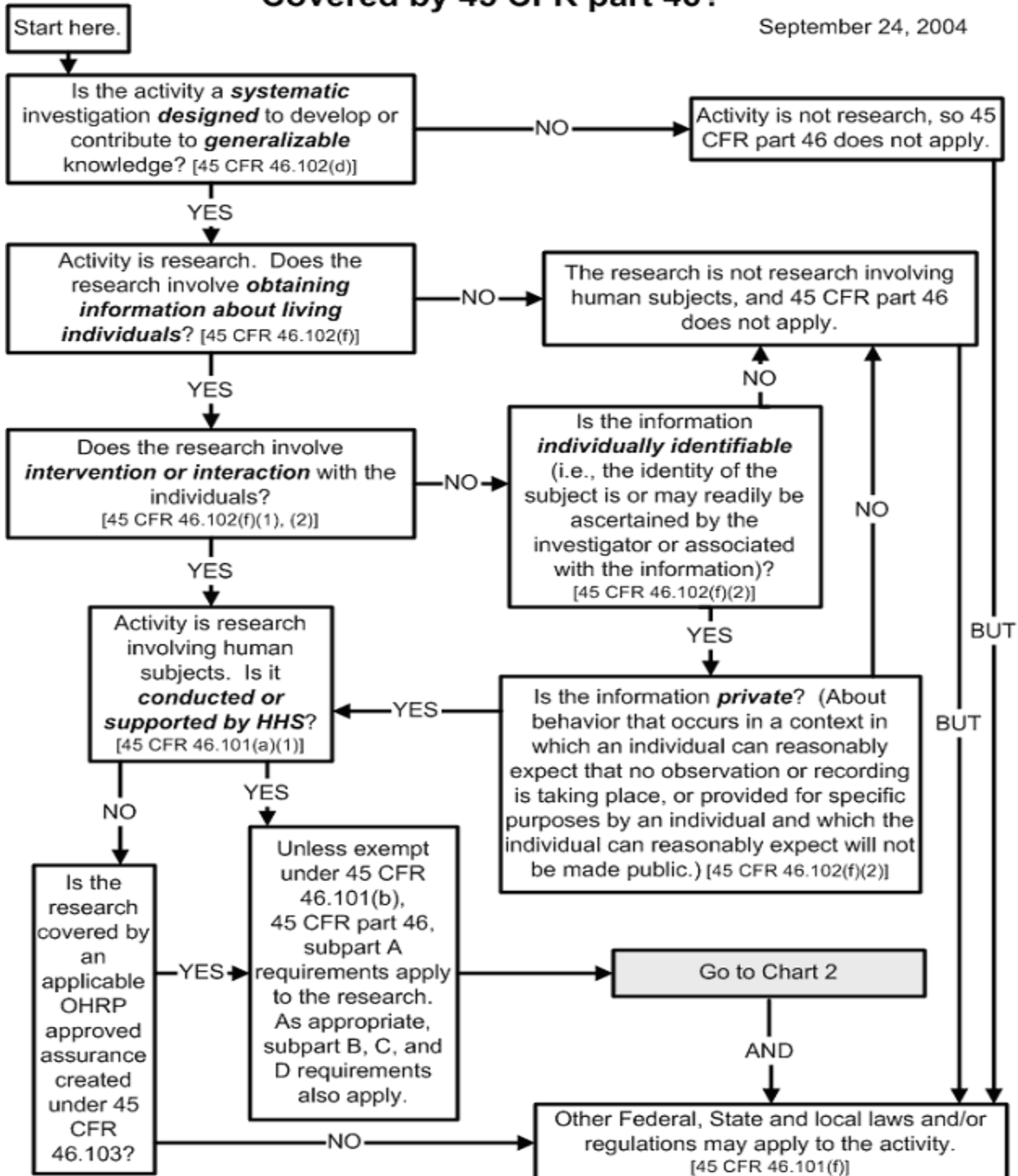
- whether an activity **is research** that must be reviewed by an IRB
- whether the review may be performed by **expedited procedures**, and
- whether **informed consent** or its documentation may be waived.

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.

- 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?

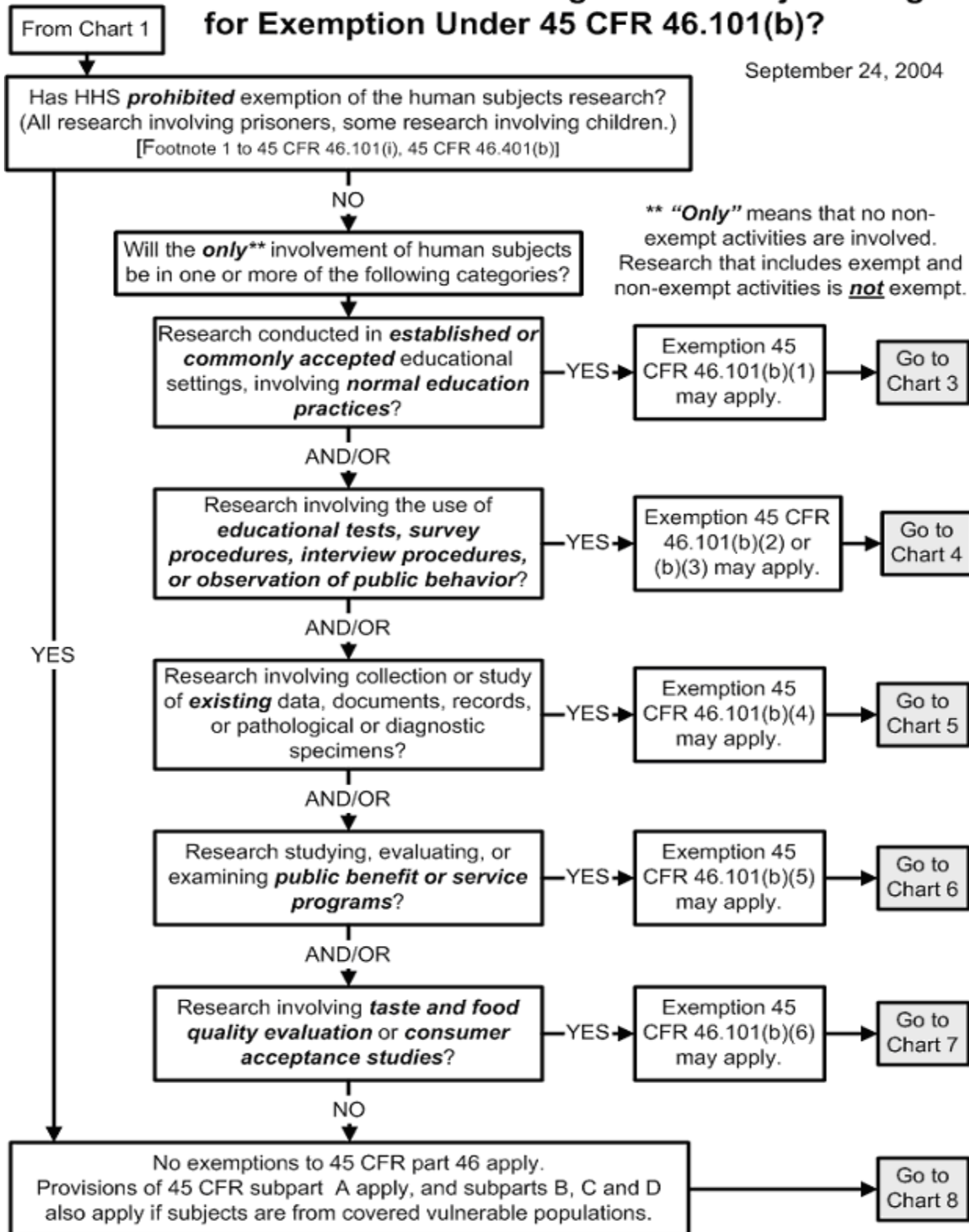
September 24, 2004



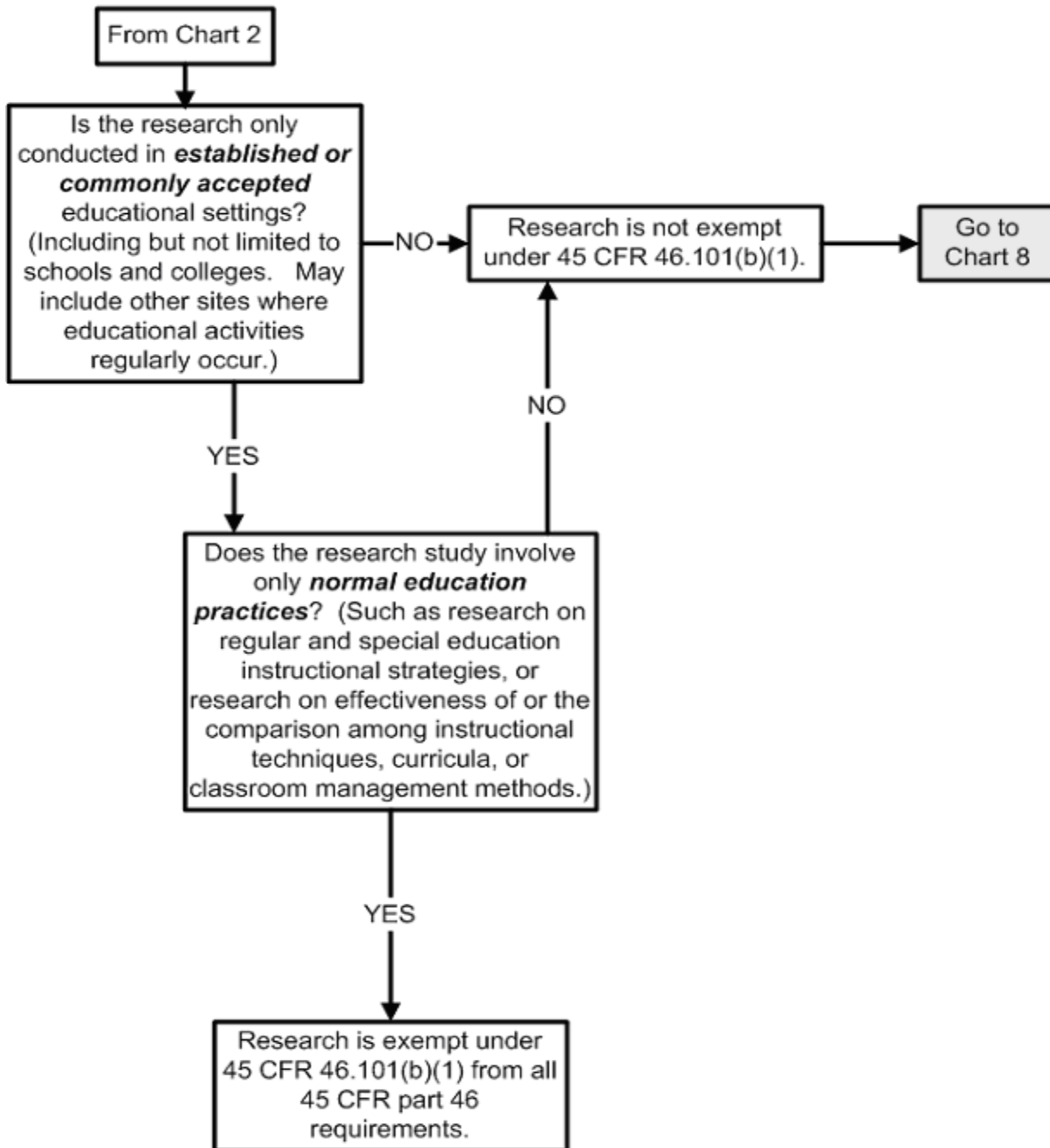


## Chart 2: Is the Research Involving Human Subjects Eligible for Exemption Under 45 CFR 46.101(b)?

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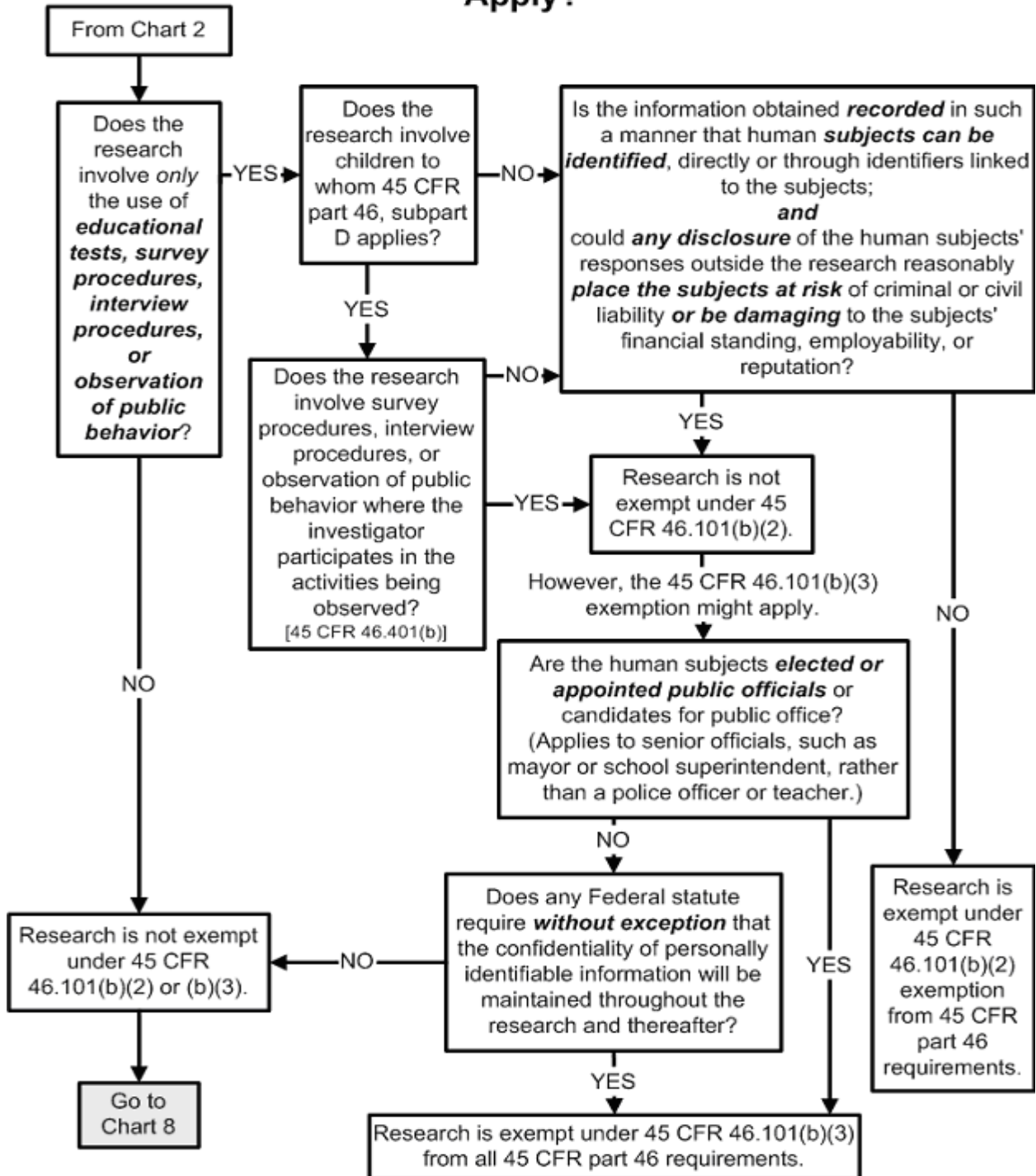


### Chart 3: Does Exemption 45 CFR 46.101(b)(1) (for Educational Settings) Apply?



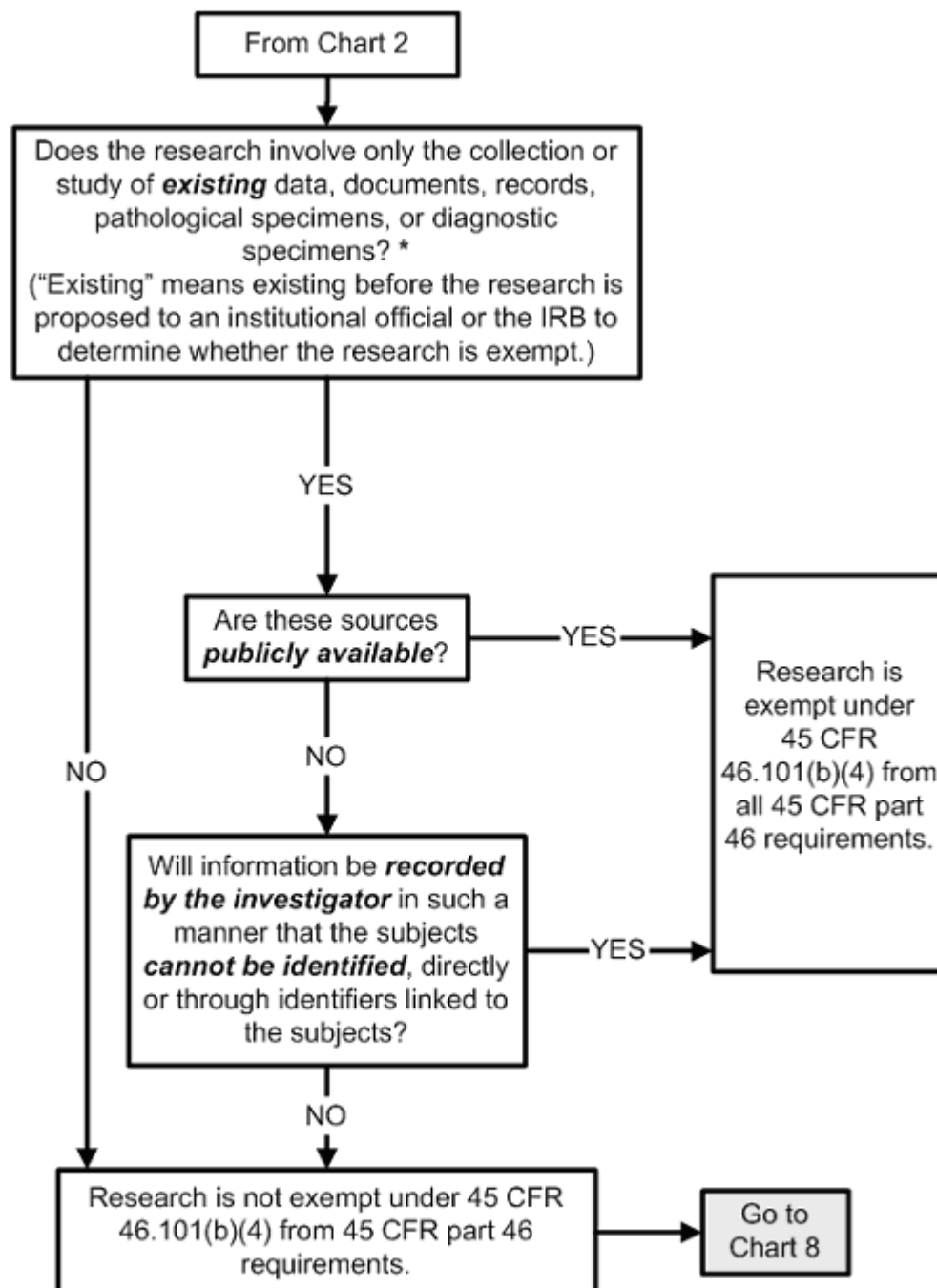
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### Chart 4: Does Exemption 45 CFR 46.101(b)(2) or (b)(3) (for Tests, Surveys, Interviews, Public Behavior Observation) Apply?



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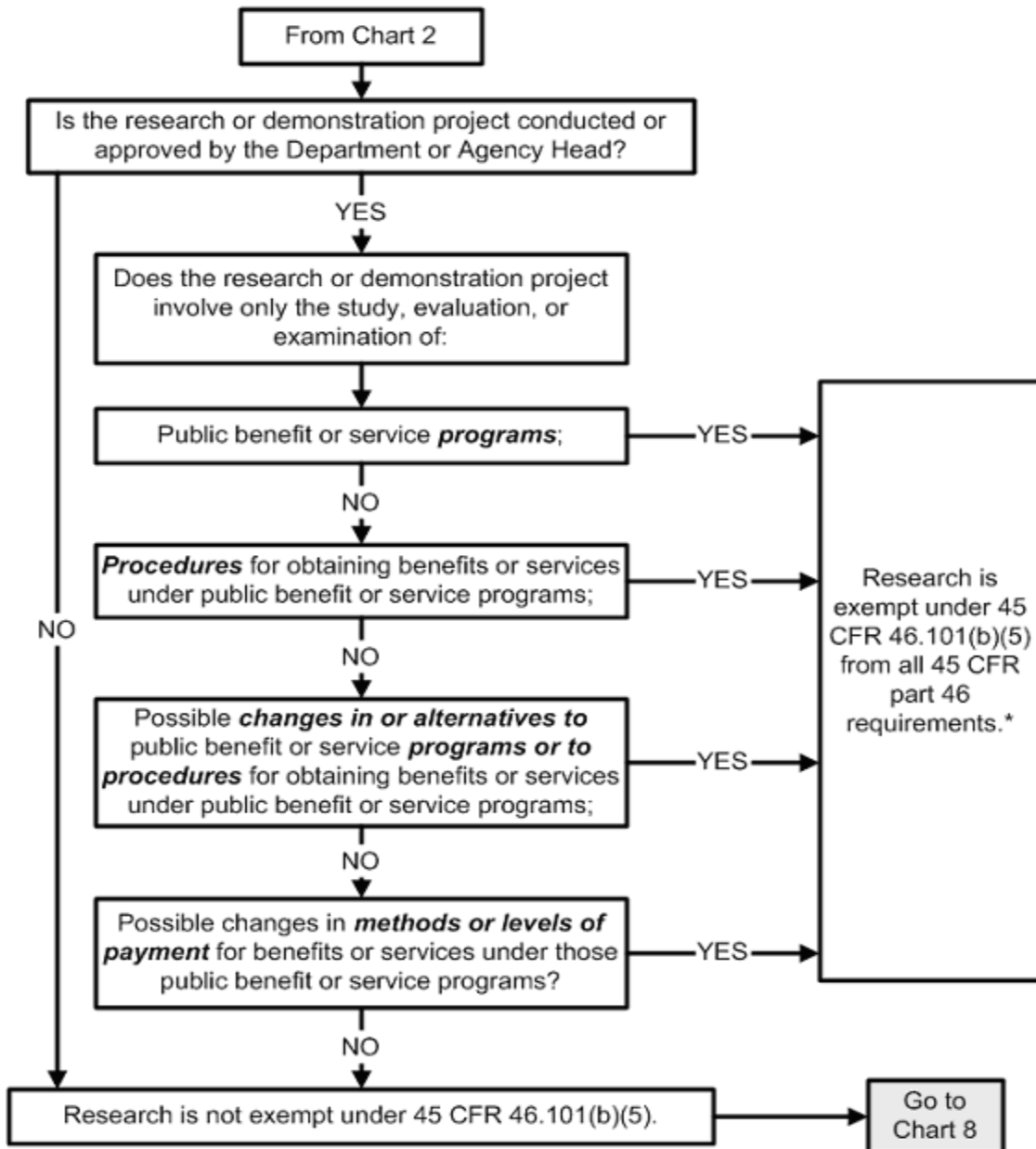
## Chart 5: Does Exemption 45 CFR 46.101(b)(4) (for Existing Data Documents and Specimens) Apply?



\* 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#issues> and #stem, and on coded data or specimens at #coded for further information on those topics.

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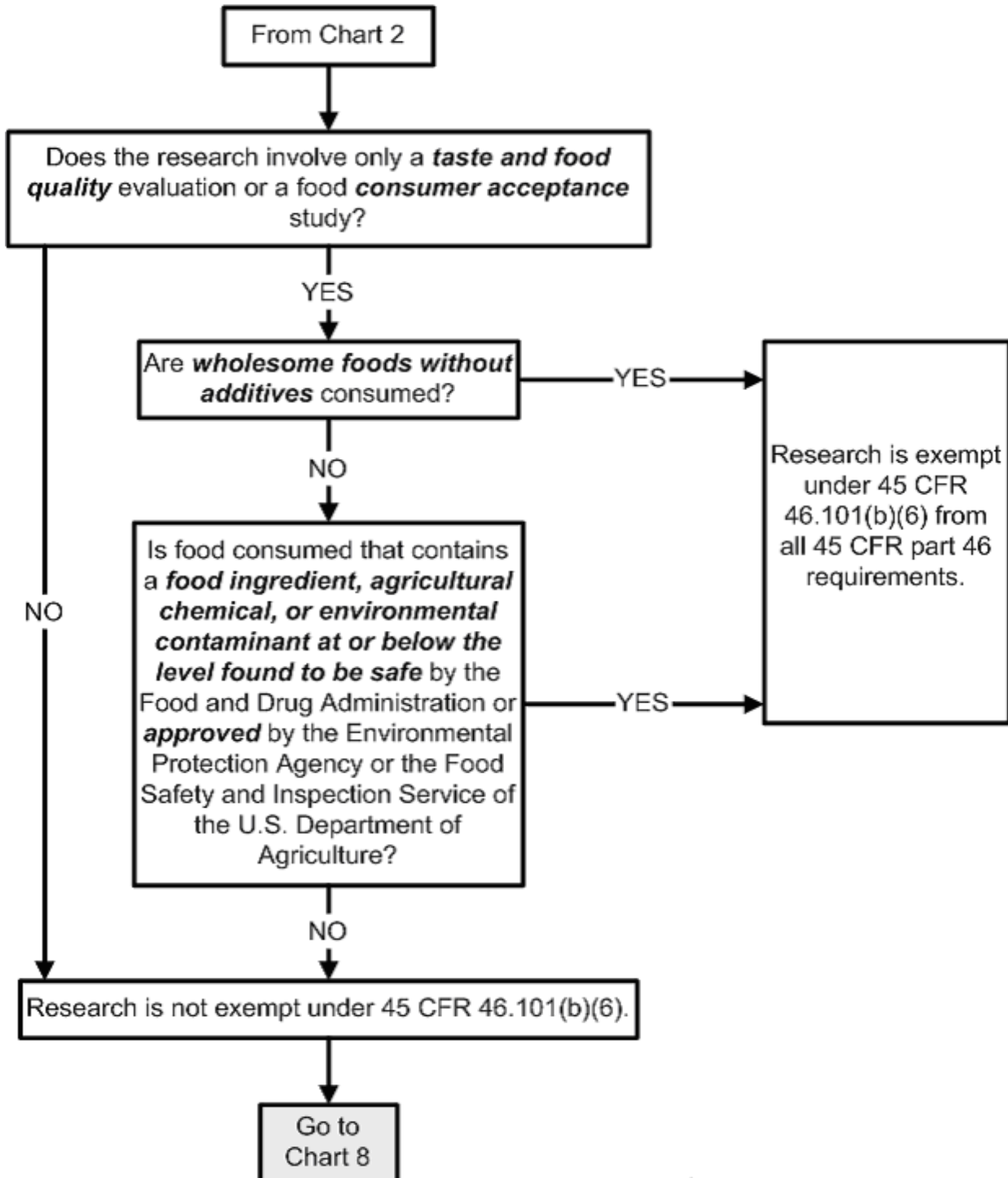
### Chart 6: Does Exemption 45 CFR 46.101(b)(5) (for Public Benefit or Service Programs) Apply?



\* Note: See OHRP guidance on exemptions at <http://www.hhs.gov/ohrp/policy/index.html#exempt> for further description of requirements for this exemption.

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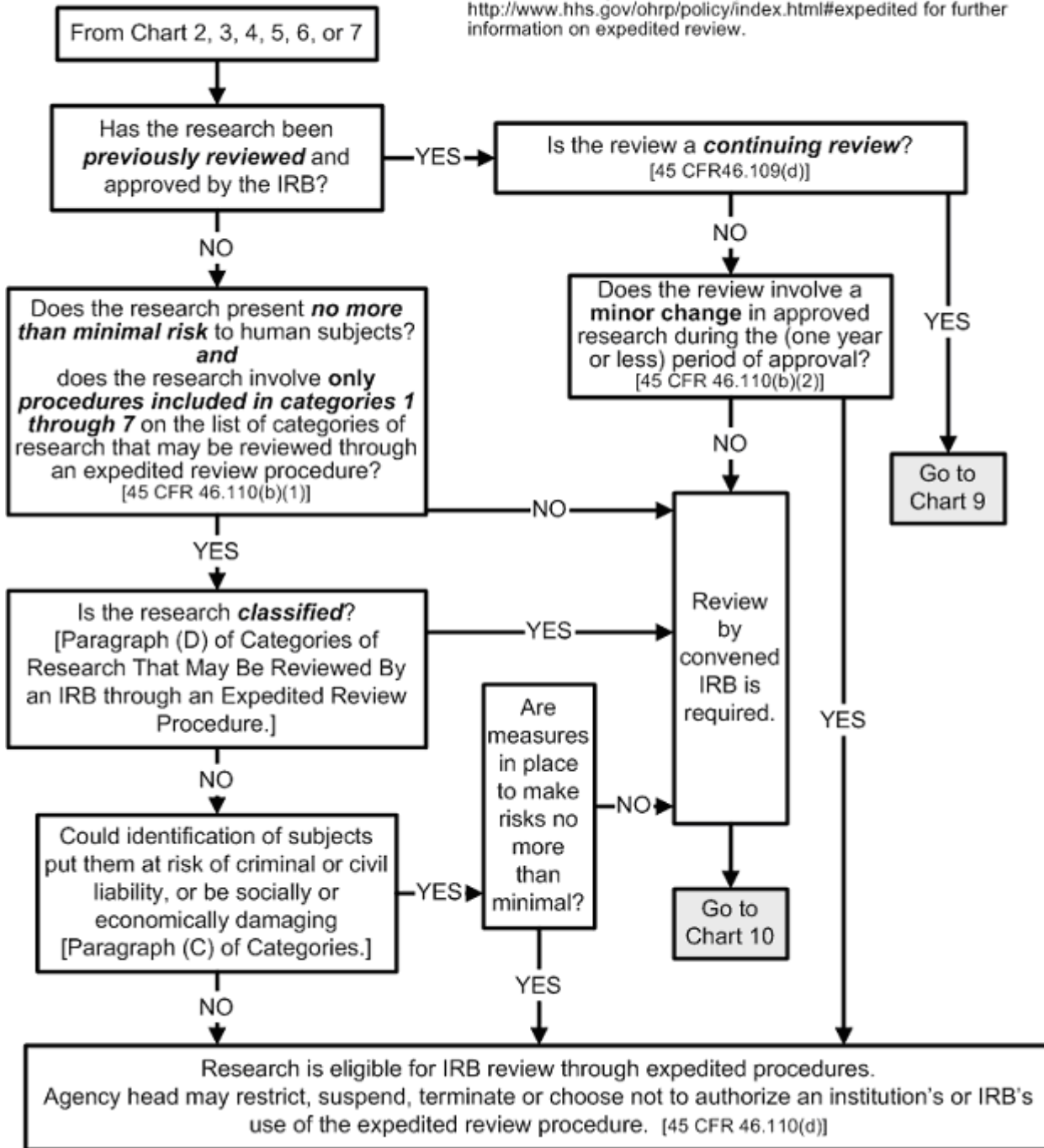
## Chart 7: Does Exemption 45 CFR 46.101(b)(6) (for Food Taste and Acceptance Studies) Apply?



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

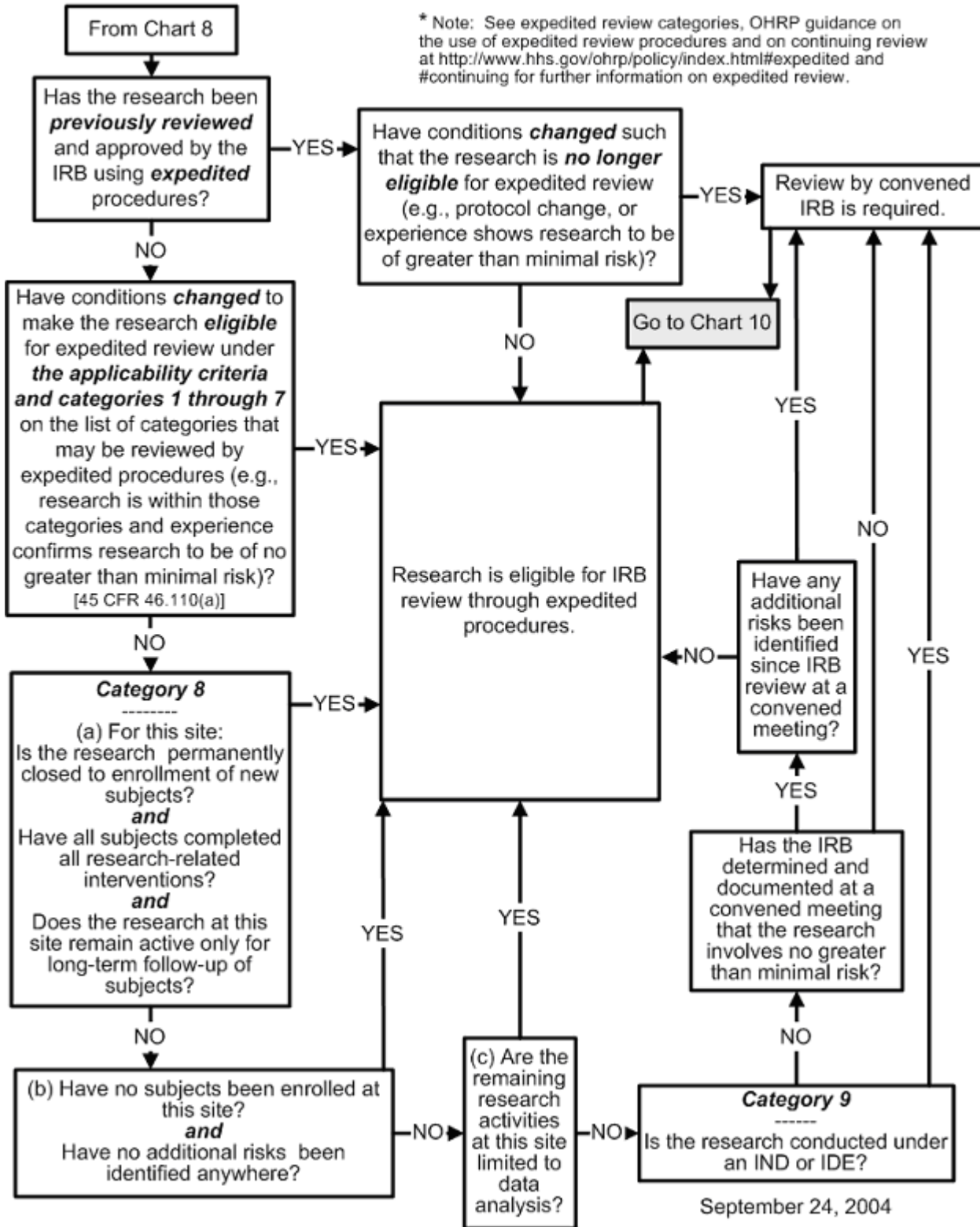
\* Note: See expedited review categories and OHRP guidance on the use of expedited review procedures at <http://www.hhs.gov/ohrp/policy/index.html#expedited> for further information on expedited review.



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

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

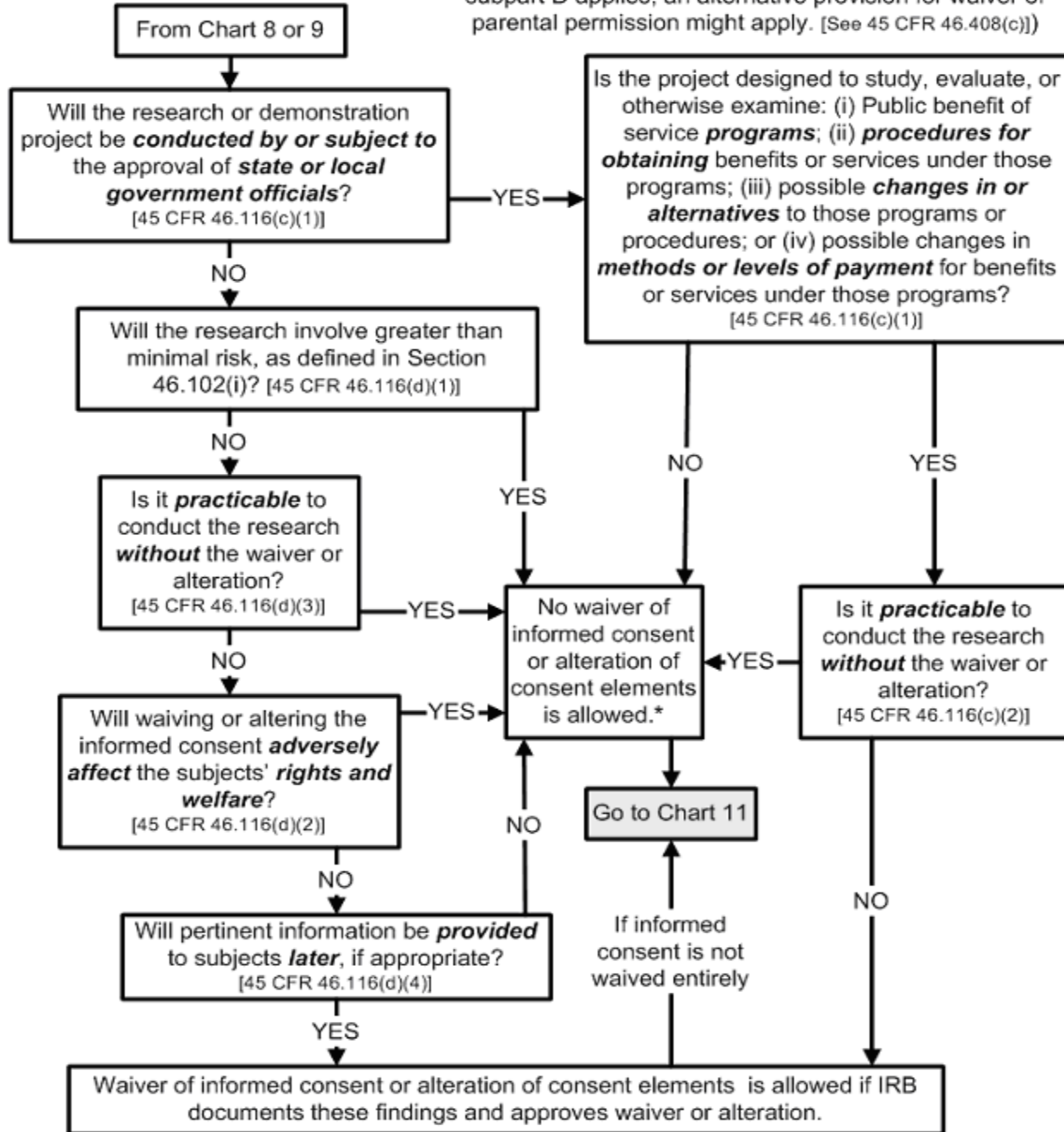


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## Chart 10: Can Informed Consent Be Waived or Consent Elements Be Altered Under 45 CFR 46.116(c) or (d)?\*\*

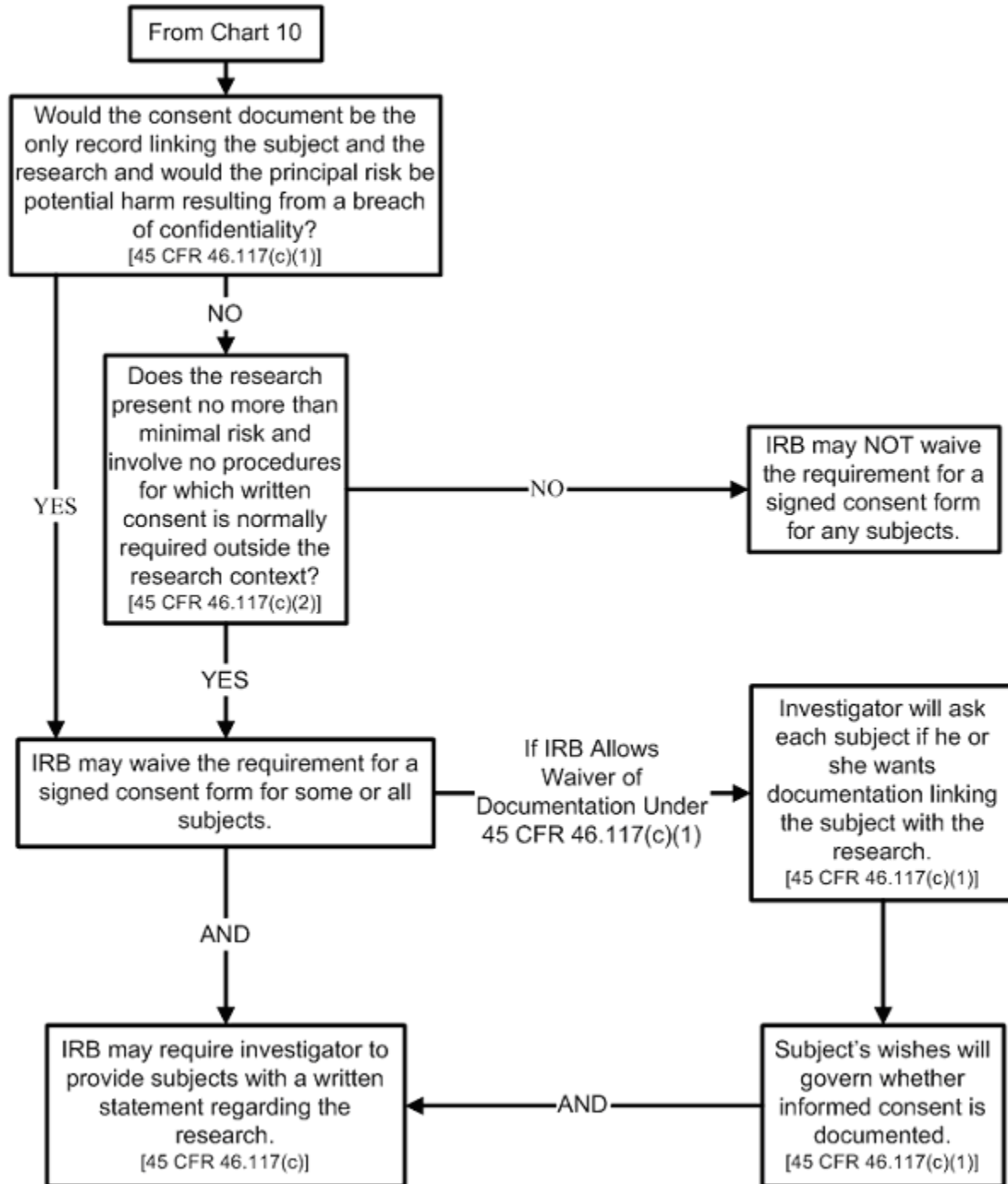
\*\* (Note: If subjects include children to whom 45 CFR part 46, subpart D applies, an alternative provision for waiver of parental permission might apply. [See 45 CFR 46.408(c)])



\* 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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## QUALITY IMPROVEMENT ACTIVITIES FREQUENTLY ASKED QUESTIONS

These FAQs provide guidance that represents OHRP's current thinking on these topics and should be viewed as recommendations, unless specific regulatory requirements are cited. The FAQs may be useful to First 5 Commissions in understanding the intent and application of the laws covered in this brief. The use of the word "must" in OHRP guidance means that something is required under HHS regulations at 45 CFR part 46. The use of the word "should" in OHRP guidance means that something is recommended or suggested, but not required. An institution may use an alternative approach if the approach satisfies the requirements of the HHS regulations at 45 CFR part 46. OHRP is available to discuss alternative approaches at 240-453-6900 or 866-447-4777.

### Commonly Used Abbreviations

CFR — Code of Federal Regulations

FWA — Federalwide Assurance

HHS — Health and Human Services

IEC — Independent Ethics Committee

IRB — Institutional Review Board

OHRP — Office for Human Research Protections

**Question 1:** How does HHS view quality improvement activities in relation to the regulations for human research subject protections?

**Answer:** Protecting human subjects during research activities is critical and has been at the forefront of HHS activities for decades. In addition, HHS is committed to taking every appropriate opportunity to measure and improve the quality of care for patients. These two important goals typically do not intersect, since most quality improvement efforts are not research subject to the HHS protection of human subjects regulations. However, in some cases quality improvement activities are designed to accomplish a research purpose as well as the purpose of improving the quality of care, and in these cases the regulations for the protection of subjects in research (45 CFR part 46) may apply. To determine whether these regulations apply to a particular quality improvement activity, the following questions should be addressed in order: (1) does the activity involve research ([45 CFR 46.102\(d\)](#)); (2) does the research activity involve human subjects ([45 CFR 46.102\(f\)](#)); (3) does the human subjects research qualify for an exemption ([45 CFR 46.101\(b\)](#)); and (4) is the non-exempt human subjects research conducted or supported by HHS or otherwise covered by an applicable FWA approved by OHRP. For those quality improvement activities that are subject to these regulations, the regulations provide great flexibility in how the regulated community can comply. Other laws or regulations may apply to quality improvement activities independent of whether the HHS regulations for the protection of human subjects in research apply.

**Question 2:** Do the HHS regulations for the protection of human subjects in research (45 CFR part 46) apply to quality improvement activities conducted by one or more institutions whose purposes are limited to: (a) implementing a practice to improve the quality of patient care, and (b) collecting patient or provider data regarding the implementation of the practice for clinical, practical, or administrative purposes?

**Answer:** No. Such activities do not satisfy the definition of “research” under [45 CFR 46.102\(d\)](#), which is “...a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge...” Therefore the HHS regulations for the protection of human subjects do not apply to such quality improvement activities, and there is no requirement under these regulations for such activities to undergo review by an IRB, or for these activities to be conducted with provider or patient informed consent.

Examples of implementing a practice and collecting patient or provider data for non-research clinical or administrative purposes include:

- A radiology clinic uses a database to help monitor and forecast radiation dosimetry. This practice has been demonstrated to reduce over-exposure incidents in patients having multiple procedures. Patient data are collected from medical records and entered into the database. The database is later analyzed to determine if over-exposures have decreased as expected.
- A group of affiliated hospitals implements a procedure known to reduce pharmacy prescription error rates, and collects prescription information from medical charts to assess adherence to the procedure and determine whether medication error rates have decreased as expected.
- A clinic increasingly utilized by geriatric patients implements a widely accepted capacity assessment as part of routine standard of care in order to identify patients requiring special services and staff expertise. The clinic expects to audit patient charts in order to see if the assessments are performed with appropriate patients, and will implement additional in-service training of clinic staff regarding the use of the capacity assessment in geriatric patients if it finds that the assessments are not being administered routinely.

**Question 3:** Do quality improvement activities fall under the HHS regulations for the protection of human subjects in research (45 CFR part 46) if their purposes are limited to: (a) delivering healthcare, and (b) measuring and reporting provider performance data for clinical, practical, or administrative uses?

**Answer:** No. Such quality improvement activities do not satisfy the definition of “research” under 45 CFR 46.102(d), which is “...a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge...” Therefore the HHS regulations for the protection of human subjects do not apply to such quality improvement activities, and there is no requirement under these regulations for such activities to undergo review by an IRB, or for these activities to be conducted with provider or patient informed consent.

The clinical, practical, or administrative uses for such performance measurements and reporting could include, for example, helping the public make more informed choices regarding health care providers by communicating data regarding physician-specific surgical recovery data or infection rates. Other practical or administrative uses of such data might be to enable insurance companies or health maintenance organizations to make higher performing sites preferred providers, or to allow other third parties to create incentives rewarding better performance.

**Question 4:** Can I analyze data that are not individually identifiable, such as medication databases stripped of individual patient identifiers, for research purposes without having to apply the HHS protection of human subjects regulations?

**Answer:** Yes. Whether or not these activities are research, they do not involve “human subjects.” The regulation defines a “human subject” as “a living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information....Private information must be individually identifiable (i.e., the identity of the subject 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 subjects.” Thus, if the research project includes the analysis of data for which the investigators cannot readily ascertain the identity of the subjects and the investigators did not obtain the data through an interaction or intervention with living individuals for the purposes of the research, the analyses do not involve human subjects and do not have to comply with the HHS protection of human subjects regulations. (See *OHRP Guidance on Research Involving Coded Private Information or Biological Specimens*, October 2008; available at <http://www.hhs.gov/ohrp/humansubjects/guidance/cdebiol.pdf>.)

**Question 5:** Are there types of quality improvement efforts that are considered to be research that are subject to HHS human subjects regulations?

**Answer:** Yes. In certain cases, a quality improvement project may constitute non-exempt human subjects research conducted or supported by HHS or otherwise covered by an applicable FWA. For example, if a project involves introducing an untested clinical intervention for purposes which include not only improving the quality of care but also collecting information about patient outcomes for the purpose of establishing scientific evidence to determine how well the intervention achieves its intended results, that quality improvement project may also constitute nonexempt human subjects research under the HHS regulations.

**Question 6:** If I plan to carry out a quality improvement project and publish the results, does the intent to publish make my quality improvement project fit the regulatory definition of *research*?

**Answer:** No. The intent to publish is an insufficient criterion for determining whether a quality improvement activity involves research. The regulatory definition under 45 CFR 46.102(d) is “*Research* means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.” Planning to publish an account of a quality improvement project does not necessarily mean that the project fits the definition of research; people seek to publish descriptions of nonresearch activities for a variety of reasons, if they believe others may be interested in learning about those activities. Conversely, a quality improvement project may involve research even if there is no intent to publish the results.

**Question 7:** Does a quality improvement project that involves research need to be reviewed by an IRB?

**Answer:** Yes, in some cases. IRB review is needed if the research involves human subjects, is not exempt, and is conducted or supported by HHS or otherwise covered by an applicable FWA.

**Question 8:** Does IRB review of a quality improvement project that is also non-exempt human subjects research always need to be carried out at a convened IRB meeting?

**Answer:** No. If the human subjects research activity involves no more than minimal risk and fits one or more of the categories of research eligible for expedited review, the IRB chair or another member designated by the IRB chair may conduct the review. The categories of research eligible for expedited review are available at <http://www.hhs.gov/ohrp/humansubjects/guidance/expedited98.htm>.

**Question 9:** If a quality improvement project involves non-exempt research with human subjects, do I always need to obtain informed consent from all subjects (patients and/or providers) involved in the research?

**Answer:** No. The HHS regulations protecting human subjects allow an IRB to waive the requirements for obtaining informed consent of the subjects of the research when (a) the risk to the subjects is minimal, (b) subjects' rights and welfare will not be adversely affected by the waiver, (c) conducting the research without the waiver is not practicable, and (d) if appropriate, subjects are provided with additional pertinent information after their participation ([45 CFR 46.116\(d\)](#)). Other applicable regulations or laws may require the informed consent of individuals in such projects independent of the HHS regulations for the protection of human subjects in research.

**Question 10:** If a quality improvement project is human subjects research requiring IRB review, do I need to obtain separate IRB approval from every institution engaged in the project?

**Answer:** No, not if certain conditions are met. The HHS protection of human subjects regulations allow one IRB to review and approve research that will be conducted at multiple institutions. An institution has the option of relying upon IRB review from another institution by designating that IRB on its FWA and submitting the revised FWA to OHRP, and having an IRB Authorization Agreement with the other institution (see [http://www.hhs.gov/ohrp/assurances/assurances\\_index.html](http://www.hhs.gov/ohrp/assurances/assurances_index.html) for information on FWAs and IRB Authorization Agreements).