Economic Roundtable

POLICY ON PROTECTION OF HUMAN SUBJECTS

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I. PURPOSE OF THE POLICY

The purpose of this policy is to protect human subjects of original research conducted by the Economic Roundtable by ensuring that they are aware of their rights and protections, that the risk of harm to them is minimized, and that benefits from research are maximized. The Belmont Report provides the framework for protecting human subjects. The three central principles it sets forth of respect for persons, beneficence, and justice are the governing values for this policy on protection of human subjects adopted by the Economic Roundtable board of directors. All Economic Roundtable research projects will be held to the standards set by the *Belmont Report* and Title 45, Part 46 of the Code of Federal Regulations.

II. WHO MUST REQUEST APPROVAL FOR HUMAN SUBJECTS RESEARCH?

Anyone who engages in research involving human subjects must complete a request for approval. This includes:

- Economic Roundtable staff and volunteers
- Researchers funded by the Economic Roundtable
- Researchers working with confidential data held by the Economic Roundtable about human subjects

Human subject research is research that involves obtaining data from or about living human beings.

III. DEFINITIONS

anonymous data: data that can never be connected with the person providing them. This can be accomplished by questionnaires that are returned by mail, or questionnaires that are collected by one of a group of subjects, and returned to the researcher. Only questionnaires that fall within the totally anonymous category are eligible for the implied consent.

confidential data: data that can be connected at some point, no matter how brief, to the person providing them. This includes questionnaires that the researcher collects personally from a group of subjects (unless a ballot box or envelopes are used). In this case it is possible to put a specific questionnaire at some point in the pile that would allow the researcher to match the data with a specific respondent if he or she so desired. It also may apply in cases where the researcher is familiar with the handwriting of one or more of his or her subjects.

data: facts, figures, and information. For the purpose of this policy, the term "data" is considered to be material from primary sources analyzed as part of research efforts.

deception: intentionally misleading or providing untruthful information, any concealment, withholding information from participant, trickery, or deceit.

emergency use: use of a test article on a human subject in a life-threatening situation in which no standard acceptable treatment is available, and in which there is not sufficient time to obtain IRB approval.

human subject: any specific living person, or information about a living person, who is the subject (participant) or object of study for the purpose of expanding our knowledge or understanding.

individually identifiable: the identity of the subject is or may readily be ascertained by the investigator

intervention: both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

interaction: communication or interpersonal contact between investigator and subject.

IRB: Institutional Review Board (see section VIII for composition). This body oversees the protection of human subjects.

IRB approval: determination by the IRB that the reviewed has been reviewed and may be conducted within the constraints set forth by the IRB and by other institutional and government requirements.

minimal risk: Federal guidelines state, "*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 tests."

naturalistic studies: observations performed without any intervention except the observations themselves.

original research: any activity conducted for the purpose of expanding knowledge or understanding, including the collection and analysis of data from questionnaires, observation, manipulation, sampling, experimentation, *etc*. Research using human subjects, even if it is simply verifying existing hypotheses, theses, theories, or ideas, is considered original research. Works dealing entirely with properly attributed secondary sources are not considered original research for the purposes of this policy.

Data gathering for fundraising, recruiting staff, or management of Economic Roundtable affairs are excluded from the category of original research under the IRB's purview.

principal investigator: the primary person conducting the research.

private information: information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (for example, a medical record). 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.

review: a process of oversight resulting in an acknowledgment of the status ("approved," "pending required amendments," or "not approved") of a project under the guidelines of this policy.

risk: potential for physical, psychological, social, or financial harm.

unreasonable harm: any physical, psychological, social, or financial damage or injury, which might have been avoided without sacrificing the goals of the activity, as well as any damage or injury whatsoever whose extent can not be justified by the contribution of the research to the expansion of human understanding.

IV. GENERAL PRINCIPLES

All researchers conducting original research are responsible for protecting their subjects from the risk of unreasonable harm. The principal investigator has initial responsibility for determining whether such a risk exists. If there is any doubt about risks, or if the research involves any of the circumstances outlined in VII-B or VII-C below, the principal investigator should contact the IRB chair or a member of the IRB.

The principal investigator should refer to and follow this policy, guidelines of relevant professional organizations and, where appropriate, those of governmental funding and regulatory agencies.

At the minimum, research activities should conform to the following.

1. The principal investigator and all co-investigators with access to human subjects or confidential data have certificates on file with the Institutional Review Board showing that they have completed the National Institutes of Health Human Participant Protections Education for Research Teams. (http://cme.nci.nih.gov)
2. The principal investigator is responsible for ensuring that research staff members are qualified to safeguard adequately the well being of the subjects.
3. Subjects should be made fully aware of any risks.
4. The principal investigator shall explain to subjects, prior to their participation, the objectives of the research, the procedures to be followed, and the risks and potential benefits. In general this explanation should also be offered in writing. Investigators shall not use individuals as subjects unless satisfied that the subjects, or others legally responsible for the subject's well being, freely consent to participation with a full understanding of the consequences. Unless this requirement is waived, subject consent is indicated in writing on an "informed consent" form.
5. If the data gathered is not anonymous, the principal investigator should ensure that the data are properly archived or destroyed.
6. Investigators shall respect the privacy of their subjects. Investigators shall protect confidential information given them, advising subjects in advance of any limits upon their ability to ensure that the information will remain confidential.
7. Subjects shall not be induced to participate by means or in circumstances that might affect their ability to decide freely. Rewards for participation should be in line with the burden imposed by participation.
8. It shall be made clear to subjects that they are free to withdraw from active participation in the research at any time. Subjects who indicate a desire to withdraw shall be allowed to do so promptly and **without** penalty or loss of benefits to which any subject is otherwise entitled. At the minimum, this shall be clearly stated as part of the informed consent statement.
9. Subjects of human research are generally provided the opportunity of access to the benefits of that research at its conclusion.
10. An investigator shall disclose to a subject, upon request, the source of support for the research.

V. INFORMED CONSENT

Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

In seeking informed consent the following information shall be provided to each subject:

1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
2. A description of any reasonably foreseeable risks or discomforts to the subject;
3. A description of any benefits to the subject or to others that may reasonably be expected from the research;
4. A disclosure of appropriate alternative procedures or courses of treatment, if any, which might be advantageous to the subject;
5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
6. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
7. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and
8. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

When appropriate, one or more of the following additional elements of information shall also be provided to each subject:

1. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) that are currently unforeseeable;
2. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

3. Any additional costs to the subject that may result from participation in the research;
4. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
5. A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and
6. The approximate number of subjects involved in the study.

The IRB may approve a consent procedure that does not include, or that alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided that:

1. Both of the following conditions are met:
    a. The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and
    b. The research could not practicably be carried out without the waiver or alteration;

    or
2. All four of the following conditions are met:
    a. The research involves no more than minimal risk to the subjects;
    b. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
    c. The research could not practicably be carried out without the waiver or alteration; and
    d. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

VI. PROCEDURES

Level of review: Research using human subjects falls into one of three categories: Level I: Exempt (no foreseeable risk), Level II: Expedited (minimal risk), and Level III: Full Board (more than minimal risk and protected subjects). The Human Subjects Review Committee Chair will determine which level of review is necessary for a given project. All original research with human subjects must be submitted for IRB review and approval. The eleven charts attached to this policy, provided by the federal Office for Human Research Protections, will be used to assist in determining whether:

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

The Institutional Review Board will review a list of all projects initiated or completed at or by Economic Roundtable staff, contractors and volunteers at least once a year.

Application documents: Submit two copies of the following to the IRB Coordinator:

- The Request for Approval form (copy attached)
- The full protocol for the research and/or any relevant grant application(s)
- Copies of any source instruments (e.g., questionnaires, interview scripts, manipulation protocols, debriefing forms, *etc*.). Provide translations if these are not in English.
- A proposed informed consent document or narrative.
- The NIH certificate of completion (http://cme.nci.nih.gov) for the principal investigator and all co-investigators for the project.

Approval of a human subject research proposal is good for one year, unless the project has acceptable but potential risk, in which case approval is given for a six-month period. If the project will continue beyond the approval period, Principal Investigators are required to resubmit documents for review prior to the expiration date of the initial approval. These documents should include a status report of the project to date including:

- The number of subjects accrued;
- A summary of adverse events and any unanticipated problems involving risks to subjects or others and withdrawal of subjects from the research or complaints about the research since the last review;
- A summary of any relevant amendments or modifications to the research since the last review;
- Any other relevant information, especially information about risks associated with the research; and
- A copy of the current informed consent document and any newly proposed consent document.

In the initial approval letter, principal investigators are asked to promptly report any unanticipated problems or adverse effects of the research to the Institutional Review Board.

Cooperative research: In cooperative research projects that involve more than one institution, each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with the standards set by the Code of Federal Regulations Title 45, Part 46. An institution participating in a cooperative project may enter into a joint review arrangement whereby another qualified IRB reviews the project in order to avoid duplication of effort.

Appeals: In the event that an application is denied because the Institutional Review Board feels the risks outweigh the benefits of the research, and the investigator disagrees with the IRB's disapproval decision, the researcher may appeal the decision by resubmitting the *same* application form and: 1) a letter of appeal presenting the researcher's arguments for approval; and 2) any other pertinent information in support of the appeal. The letter should be directed to the Chair of the IRB. Applications submitted for appeal will be considered by the full IRB at the next scheduled meeting date. The final decision of the IRB will be stated in writing to the investigator. If the proposal is not approved, the research cannot be conducted. The researcher may at any point submit a revised proposal, which will be reviewed as a new application.

Adverse event reporting: Investigators must report adverse events that occur during the course of their research with human subjects to the IRB in a timely fashion. An adverse event, as defined by the Department of Health and Human Services, is "an undesirable and unintended, although not necessarily unexpected, result of therapy or other intervention (e.g., headache following spinal tap or intestinal bleeding associated with aspirin therapy)." An adverse event in non-medical research can include an undesirable and unintended consequence of, or reaction to, procedures. An unanticipated adverse event can also be defined as any adverse experience whose nature, severity, and frequency of risk were not described in the information provided for IRB review or in the consent form.

VII. TYPE OF IRB REVIEW

The type of review conducted by the IRB will be determined based on which on the three following levels of risk is presented by a project.

A) Level I: Exempt Research and Review (no foreseeable risk)

Nature of the Study: Research activities involving "no foreseeable risk" and in which the only involvement of human subjects will be in one or more of the following categories:

1. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), surveys, interviews, or observation of public behavior, **unless**:
    a. information is recorded in such a manner that subjects can be identified, directly or through identifiers linked to the subjects; **and**
    b. any disclosure of the human subjects' responses outside the research could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing, employability or reputation.
2. Research involving the use of tests, surveys, interviews, or observation of public behavior that is not exempt under the preceding paragraph, if
    a. the human subjects are elected or appointed public officials or candidates for public office; **or**
    b. Federal statute(s) require(s) without exception that the confidentiality of personally identifiable information will be maintained throughout the research and thereafter.
3. Research involving the collection or study of existing data, documents, records, or specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified directly or through identifiers linked to the subjects unless the subject studied is a public figure.
4. Research and demonstration projects which are conducted by or subject to the approval of the head of the Department or Agency to be studied and that are designed to study, evaluate, or otherwise examine;
    a. public benefit or service programs;
    b. procedures for obtaining benefits or services under those programs;
    c. possible changes in or alternatives to those programs or procedures; **or**
    d. possible changes in methods or levels of payment for benefits or services under those programs.

5. Taste and food quality evaluation and consumer acceptance studies,
    a. if wholesome foods without additives are consumed **or**
    b. 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 Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.
6. A preliminary investigation of the feasibility of a study, usually done on a small scale (usually fewer than 10 subjects/participants) and exploratory in nature. Or a focus group of a small, targeted group of subjects, led by a moderator, whose opinions and perceptions on a certain topic are elicited. Both procedures are typically designed to help the investigator refine data collection procedures and instruments or prepare a better, more precise research design. Such studies do not contribute to generalizable knowledge and therefore are not considered research and do not require IRB review. However, if the pilot data will be used for actual research purposes, IRB review and approval is required before pilot study data collection commences.

Nature of the Review: Review is conducted by the IRB chair.

EXCEPTIONS TO LEVEL I: EXEMPT RESEARCH—PROJECT AUTOMATICALLY MOVES TO A LEVEL II: EXPEDITED OR III: FULL BOARD REVIEW
1. Research involving subjects under 18 years of age when survey, interview, or participant observation methods are used (participant observation is any observation that entails interaction between an investigator and a subject);
2. Prisoners, pregnant women, people not competent to provide informed consent, or fetuses;
3. Use of tissue from autopsy;
4. Use of personal records such as health care information, drug and alcohol treatment records, psychiatric treatment records, educational records, and other records protected by the Federal Privacy Act and other federal and state laws.

B) Level II: Expedited Research and Review (minimal risk)

Nature of the Study: Research activities involving "no more than minimal risk" and in which the only involvement of human subjects will be in one or more of the following categories:

1. Recording of data from subjects 18 years of age or older using non-invasive procedures routinely employed in clinical practice.
2. Voice recordings made for research purposes such as investigations of speech.
3. Moderate exercise by healthy volunteers.
4. The study of existing data, documents, records, pathological specimens, or diagnostic specimens.
5. Research on individual or group behavior or characteristics of individuals such as perception, cognition, game theory, or test development, where the investigator does not manipulate subjects' behavior and the research will not involve stress to subjects.

6. Collection of hair and nail clippings, in a non-disfiguring manner.

Nature of the Review: Two members of the IRB (usually including the chair) review the documentation presented with the proposal. Recommendations for improvements are sent in writing (electronic text is acceptable as long as a paper copy is kept for the records of the institution). Questions of clarity require a written response from the researcher (electronic text is acceptable as long as a paper copy is kept for the records of the institution).

C) Level III: Full Board Review (more than minimal risk or protected subjects)

Nature of the Study: Research that is potentially harmful to the subject.

1. Research published with the identity of the subject, including photographs, video or audio recordings.
2. Invasive collection of body fluid (lymph and blood - except blood from healthy adults) or tissue samples.
3. Manipulative observations including deception, or stressful physiological recordings.
4. Research involving subjects under the age of 18.
5. Subjects unable to provide informed consent due to cognitive impairment.
6. Subjects who are under the professional care of the researcher.
7. Procedures that are potentially harmful to the subjects (even if the researcher views the harm as not unreasonable) are also subject to Level III: Full Board review.

Nature of the Review: At least three members of the IRB (including the chair and the representative from the public), review the documentation presented with the proposal at a scheduled meeting of the committee to which all members have been invited. Recommendations for improvements may be sent in writing (electronic text is acceptable as long as a paper copy is kept for the records of the institution) or the IRB may choose to meet with the researcher as appropriate. Questions of clarity require a written response from the researcher (electronic text is acceptable as long as a paper copy is kept for the records of the institution). Minutes from any face-to-face meeting become part of the permanent record of the IRB.

VIII. INSTITUTIONAL REVIEW BOARD

Composition: the Institutional Review Board will have a minimum of five regular members:

1. A community member who has no institutional or family connection with the research
2. A non-scientist
3. One or more members qualified to discuss the research under consideration

The IRB will include both women and men, and will include individuals from multiple professions. Alternate members with similar qualifications and diversity may be appointed to serve on the IRB when regular members are unavailable

The chair of the Economic Roundtable board of directors shall serve ex officio as a non-voting member of the IRB.

Appointment: The chair of the Economic Roundtable board of directors appoints the IRB chair and other members. Members of the IRB will serve annual terms and may serve as many consecutive terms as he or she is invited and willing.

Training: All members of the committee must complete the National Institutes of Health Human Participant Protections Education for Research Teams. (http://cme.nci.nih.gov). The chair of the IRB may specify additional training for members.

Compensation: the Economic Roundtable will not compensate service on the IRB.

Conflict of Interest: Individuals with a conflict of interest, for example the investigators carrying out the research, will not be members of the IRB or participate in IRB deliberations.

Authority: The Economic Roundtable IRB has the authority to:

1. Disapprove, modify or approve studies in order to protect human subjects.
2. Require progress reports from the investigators and oversee the conduct of the study.
3. Suspend or terminate approval of a study.
4. Place restrictions on a study.

Procedures: The Institutional Review Board exists as a standing committee. The IRB reviews proposals and research activities when convened by the IRB chair. A majority of the IRB members must be present to constitute a quorum. The quorum is the count of the number of members present. If the number present falls below a majority, the quorum fails. A quorum is required for Level III reviews. Materials must be distributed to all IRB members at least one week before the scheduled meeting date unless the IRB members unanimously approve later distribution. The action of the IRB is generally by consensus; if there is no consensus, the IRB will make its decision based on the vote of a majority of members in attendance at the meeting.

Applicants should submit in advance of the IRB meetings appropriate materials documenting original human subjects research (see Section VI above) to the IRB Coordinator.

Types of IRB Action: Based on its review the IRB will determine which of the following three actions to take on research protocols. In each case, the IRB shall notify the principal investigator of its action in writing.

Approve: The protocol is approved as submitted.

Pending: Problems identified in the protocol are not serious and generally fall into two categories: 1) the investigator needs to clarify an aspect of the study or provide additional information, or 2) minor changes need to be made in the informed consent document. In these cases, approval can be given after the investigator rewrites the informed consent and/or submits to the Chair a written response to the IRB's questions and concerns. The Chair will then poll IRB members to receive final approval.

Disapprove: The IRB will disapprove the proposed research if it places the subjects at risks that far outweigh the benefit or value of the knowledge to be gained, or it raises such serious ethical questions as to be unacceptable. In the event a disapproval is foreseen, the investigator will be invited to attend the meeting of the IRB to discuss the protocol. A research activity may be disapproved only after a full IRB review has been conducted.

Staffing: The IRB Coordinator will be a member of the Economic Roundtable staff designated by the chair of the Economic Roundtable board of directors to carry out this responsibility. If potential conflicts of interest, available time, or other constraints prevent the IRB Coordinator from providing adequate staff support to the IRB, the IRB may encumber up to $1,000 in Economic Roundtable funds annually to obtain independent staff support. The chair of the Economic Roundtable board of directors must approve encumbrance of additional funds.

Liability Coverage: Liability coverage for IRB members is provided by Economic Roundtable insurance policies.

Removal: The chair of the Economic Roundtable board of directors may remove members from the IRB if she or he determines such action is required to protect human subjects of the Economic Roundtable's research or to fulfill the public benefit objectives of the Economic Roundtable. Members of the IRB may appeal their removal to the full board of directors of the Economic Roundtable, which shall have final authority to determine the composition of the IRB.

IRB Records: Documentation of IRB activities will be maintained at the Economic Roundtable office for at least three years following the completion of research and will include the following:

1. Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects;
2. Documentation of actions taken through procedures of exempt and expedited review in the IRB minutes and in other appropriate files;
3. Minutes of IRB meetings in sufficient detail to show attendance; actions taken; vote on these actions including the number of members voting for, against, and abstaining; basis for requiring changes in or disapproving research; length of approval granted for projects; and a written summary of the discussion of contested issues and their resolution;
4. Records of continuing review activities;
5. Copies of all correspondence between the IRB and the investigators.
6. Budget and accounting records.
7. Emergency use reports.
8. Statements of significant new findings provided to subjects.
9. A roster of IRB members.

IX. ADOPTION OF POLICY ON PROTECTION OF HUMAN SUBJECTS

This Policy was reviewed and approved by the Economic Roundtable board of directors on October 20, 2006 and governs all subsequent research undertaken by the Economic Roundtable. The Economic Roundtable board of directors must approve changes to this policy.

Economic Roundtable Institutional Review Board (IRB)

Application Form for IRB Approval

Must be completed for all projects involving human subjects

315 W. 9th St. Suite 1209
Los Angeles, CA 90015
Phone: 213-892-8104
Fax: 213-892-8105

Use separate sheets of paper and follow the format below to provide requested information

TITLE	Use a fully descriptive project title that identifies the human subjects to be studied.
PRINCIPAL INVESTIGATOR	The Principal Investigator at the Economic Roundtable.
FUNDING	Indicate the funding source and include a budget if it is not part of the proposal.
RISK LEVEL	Identify the level of risk that this project will create for human subjects as defined in Section VII of the Economic Roundtable policy on protection of human subjects: __ Less than minimal risk __ Minimal Risk __ Greater than minimal risk but with direct benefit to subjects __ Greater than minimal risk but no direct benefit to subjects Briefly summarize the facts that support the risk level you have identified. If the study involves greater than minimal risk, identify all direct benefits to the human subjects as well as any additional safeguards.
LEVEL OF REVIEW	Indicate the level of IRB review you are requesting for this project: __ Level I: Exempt Research and Review (no foreseeable risk) __ Level II: Expedited Research and Review (minimal risk) __ Level III: Research and Full Board Review (more than minimal risk or protected subjects) The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.
HEALTH INFORMATION	Identifiable Health Information: (1) Do you need to access or use patient/subject identifiable health information (e.g. medical records, mental health information, lab reports, x-rays, tissue samples) for this research study? **If yes**, go to question (2). **If no**, you do not need to satisfy HIPAA education requirement. (2) Have all investigators and individuals authorized to obtain identifiable health information in this study completed an education program regarding federal (HIPAA) and state privacy requirements? **If yes**, Please provide certificates of completion and go to question (3). **If no**, Your study will not be reviewed until all of the requested information is provided. Your application may be returned to you for completion.

	(3) Describe the specific procedures and safeguards that will be used to de-identify health information of human subjects in this project
INFORMED CONSENT	If not fully explained in the attached proposal or research protocol, indicate the type of informed consent that will be utilized in the study. If a waiver of written informed consent is requested a script of the proposed verbal informed consent should be provided. Generally the IRB will require a copy of this script to be given to the study subject. If a waiver of informed consent is requested please make certain the protocol justifies this request.
LOCATION	Indicate the location where the human subjects involvement will occur.
TIME PERIOD	Beginning and ending dates of project
SUBJECTS	If not fully explained in the attached proposal or research protocol, describe the characteristics of the human subjects that will be involved in the project including their gender and age distribution. When special populations are included or when some or all of the subjects are likely to be vulnerable to coercion or undue influence, indicated what additional safeguards will be taken to protect the rights and welfare of these subjects.
CONTACT	If not fully described in the attached proposal or research protocol, explain who will make the initial contact with the subjects and how contact will be made.
INDUCEMENTS	If not fully described in the attached proposal or research protocol, state whether subjects will receive inducements before or rewards after the study, and if so, what the inducements or rewards will be.
CONFIDENTIAL-ITY	If not fully described in the attached proposal or research protocol, explain the provisions made to maintain confidentiality of data and who will have access to the data.
ATTACHMENTS	Attach the following additional documentation to this request for IRB approval: 1) A transmittal letter stating that no funds will be disbursed to individuals to do research involving human subjects until the proposed project has been reviewed and approved by the IRB. 2) A copy of the grant application or research protocol. 3) Copies of any source instruments (e.g., questionnaires, interview scripts, manipulation protocols, debriefing forms, etc.). Provide translations if these are not in English. 4) A proposed informed consent document or narrative. 5) The NIH certificate of completion (http://cme.nci.nih.gov) for the principal investigator and all co-investigators for the project. 6) Any other documents related to ethical treatment of human subjects.

Signature of Principal Investigator

Date of Signature

Print Name of Principal Investigator

Title

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

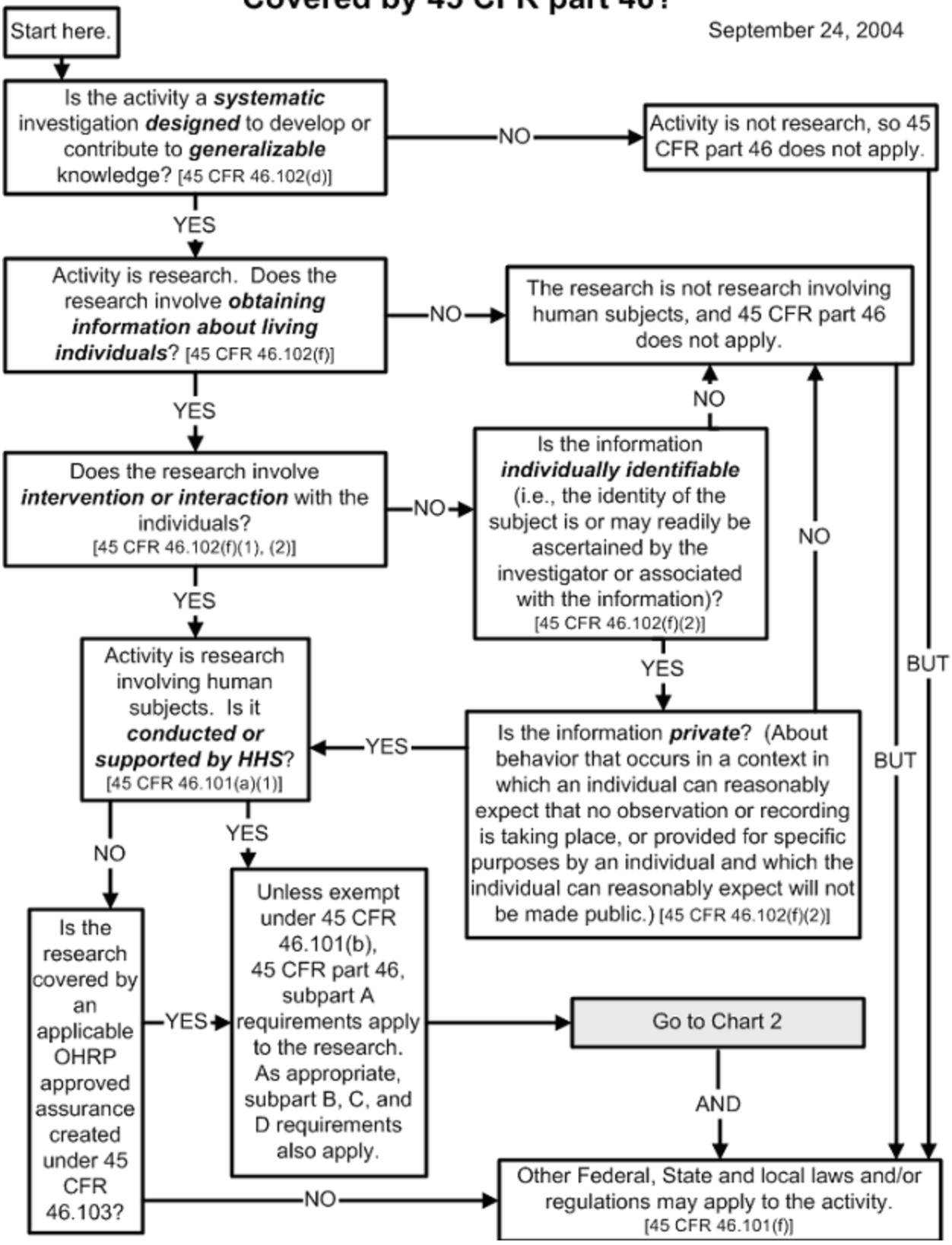

Chart 2: Is the Research Involving Human Subjects Eligible for Exemption Under 45 CFR 46.101(b)?

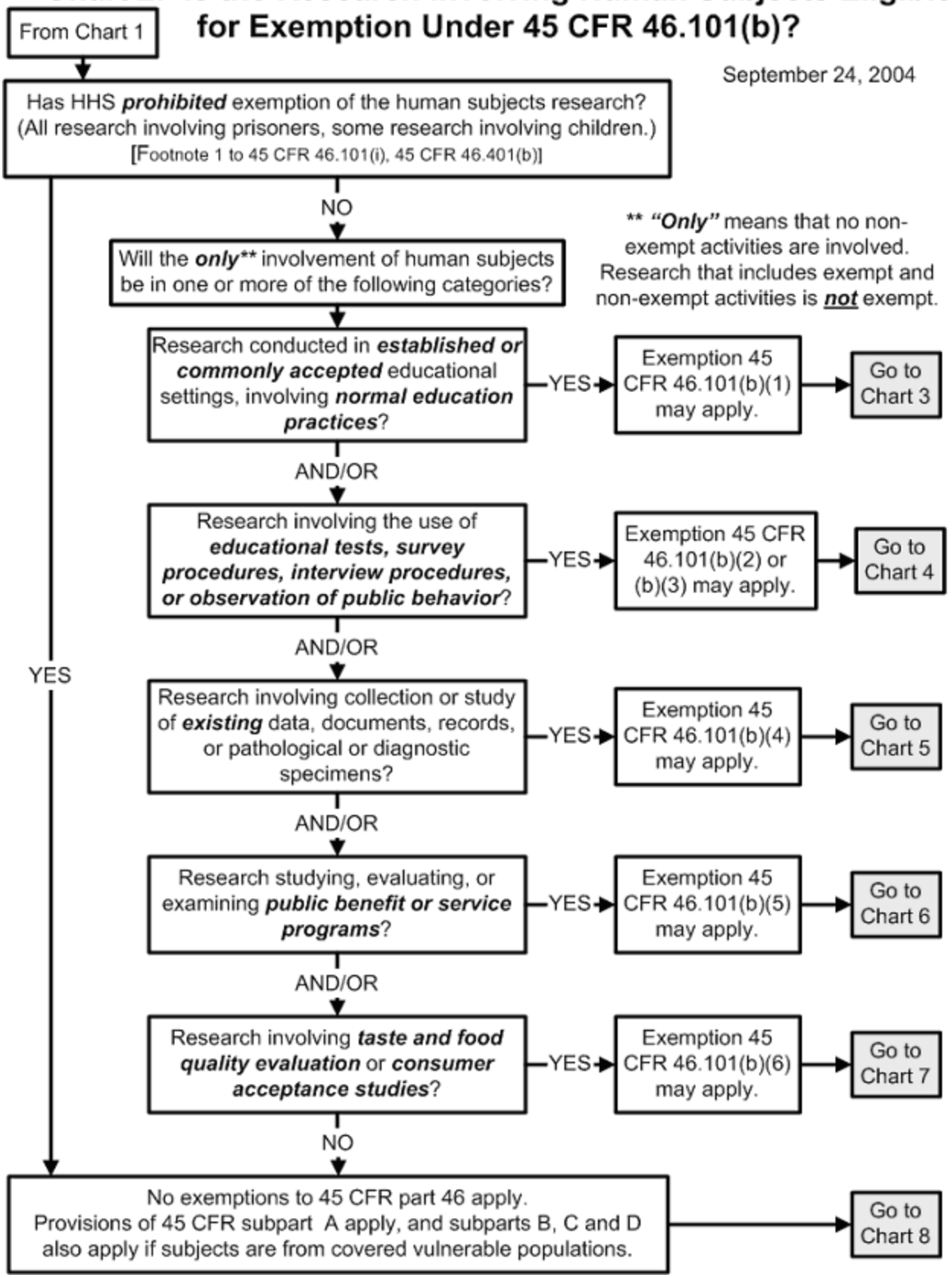

Chart 3: Does Exemption 45 CFR 46.101(b)(1) (for Educational Settings) Apply?

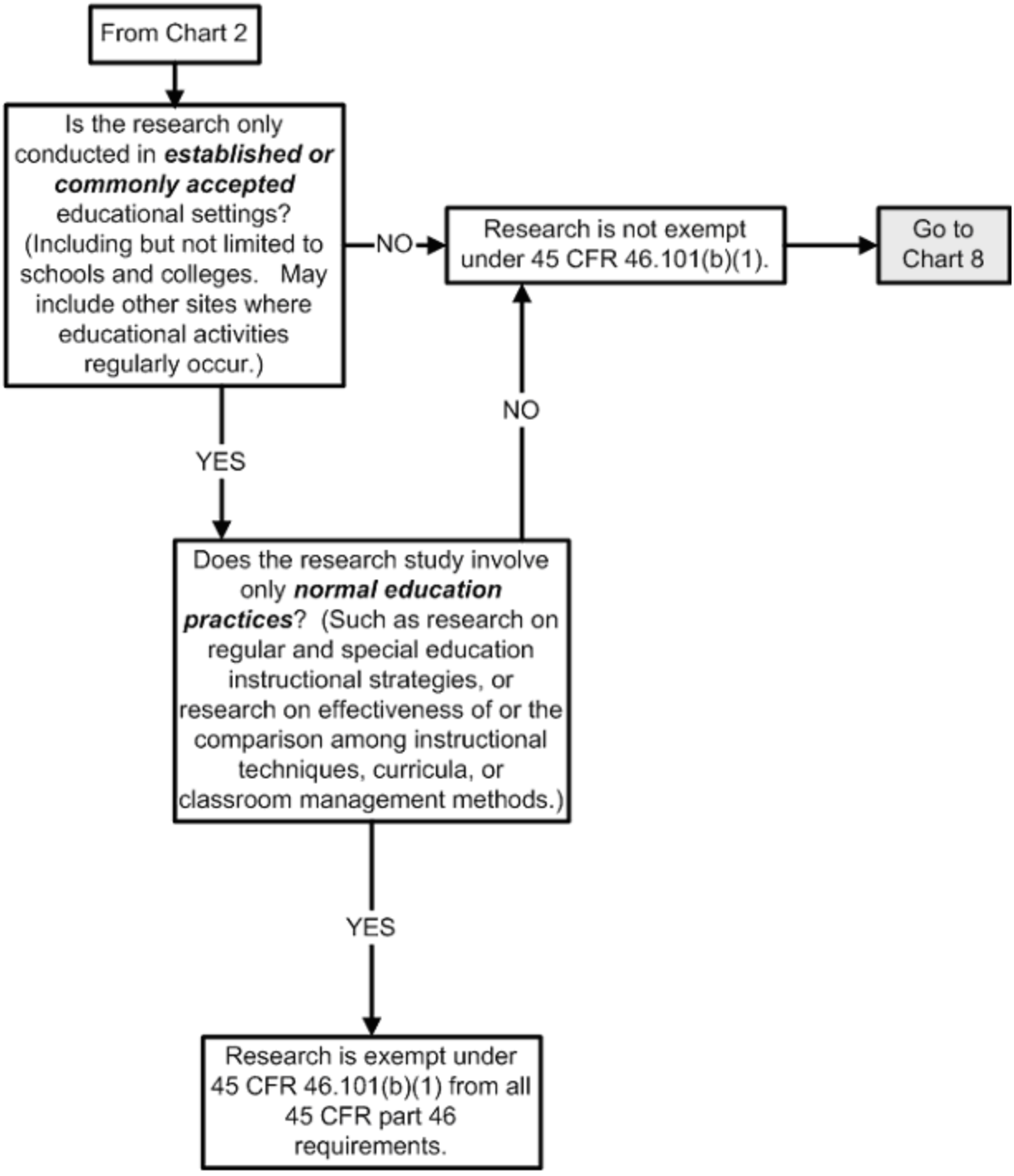

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Chart 4: Does Exemption 45 CFR 46.101(b)(2) or (b)(3) (for Tests, Surveys, Interviews, Public Behavior Observation) Apply?

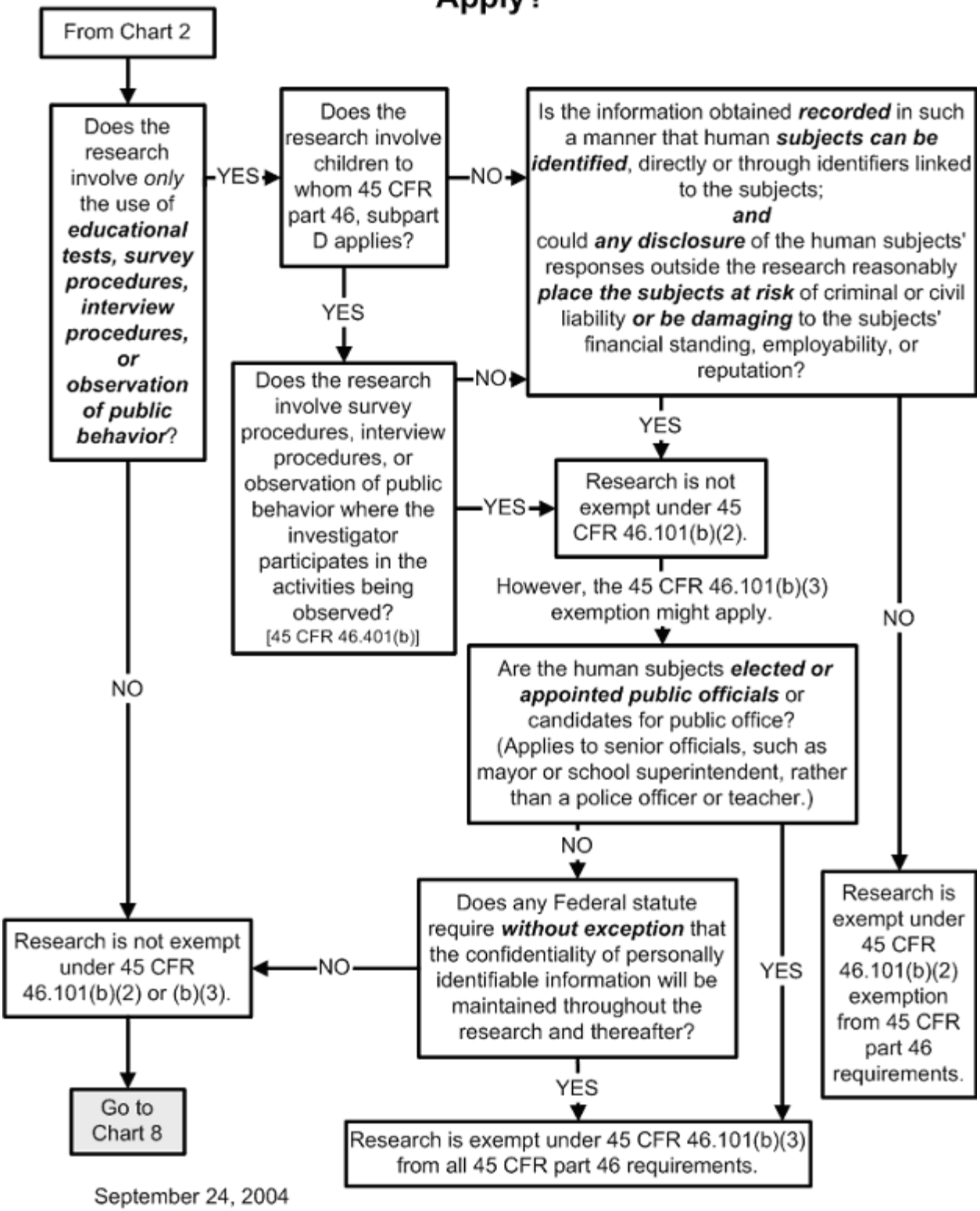

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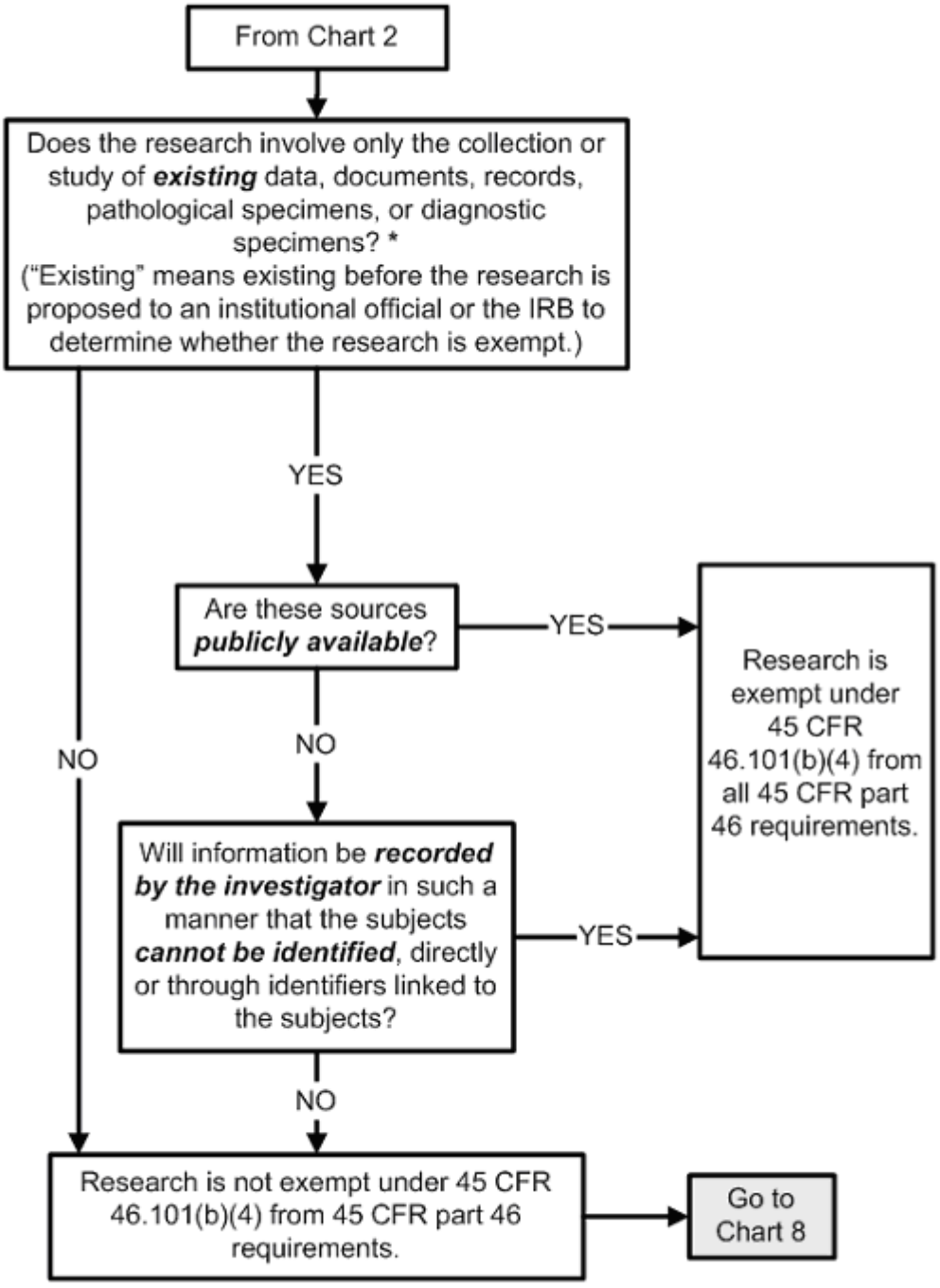
Chart 5: Does Exemption 45 CFR 46.101(b)(4) (for Existing Data Documents and Specimens) Apply?



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

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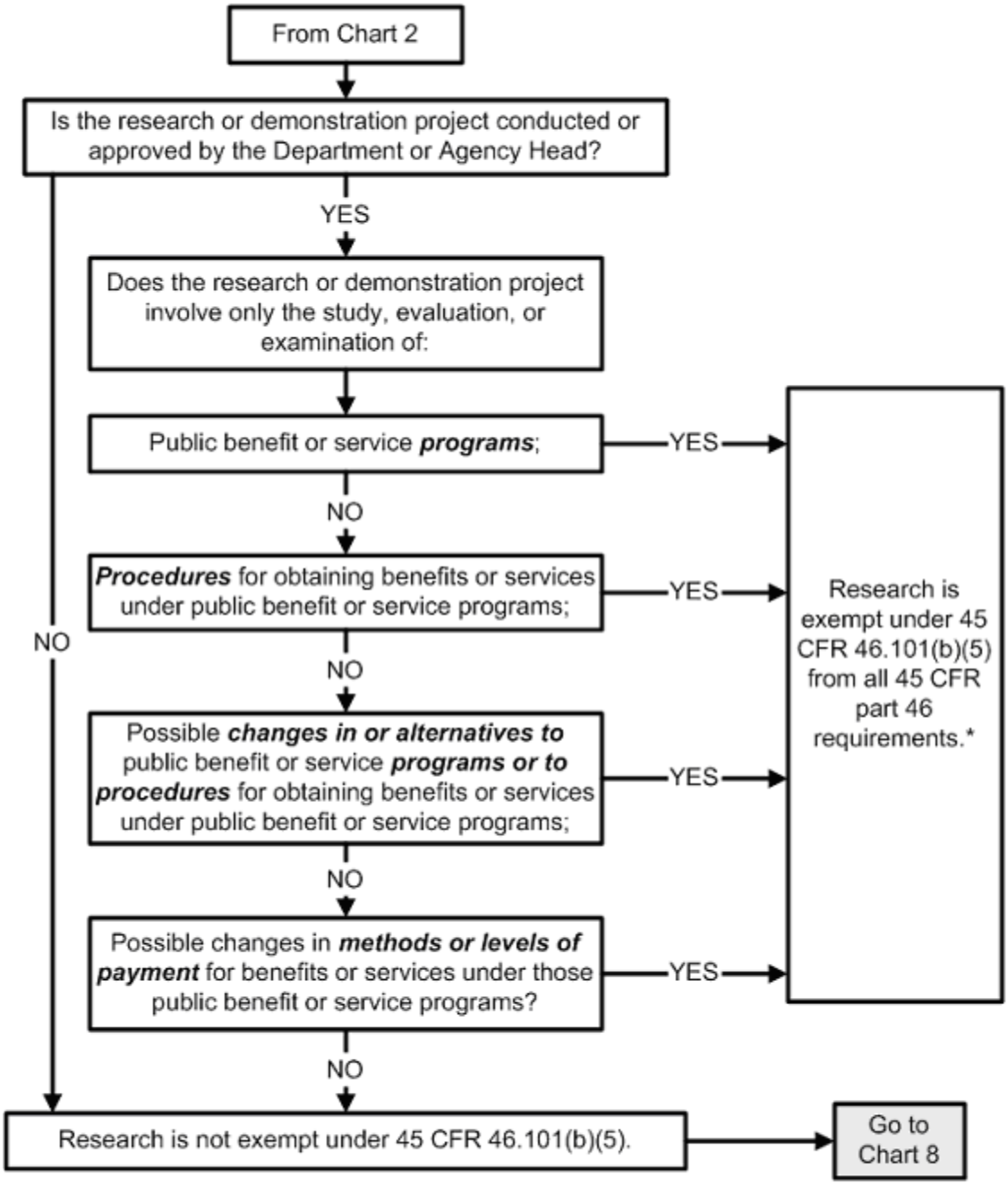
Chart 6: Does Exemption 45 CFR 46.101(b)(5) (for Public Benefit or Service Programs) Apply?



* 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?

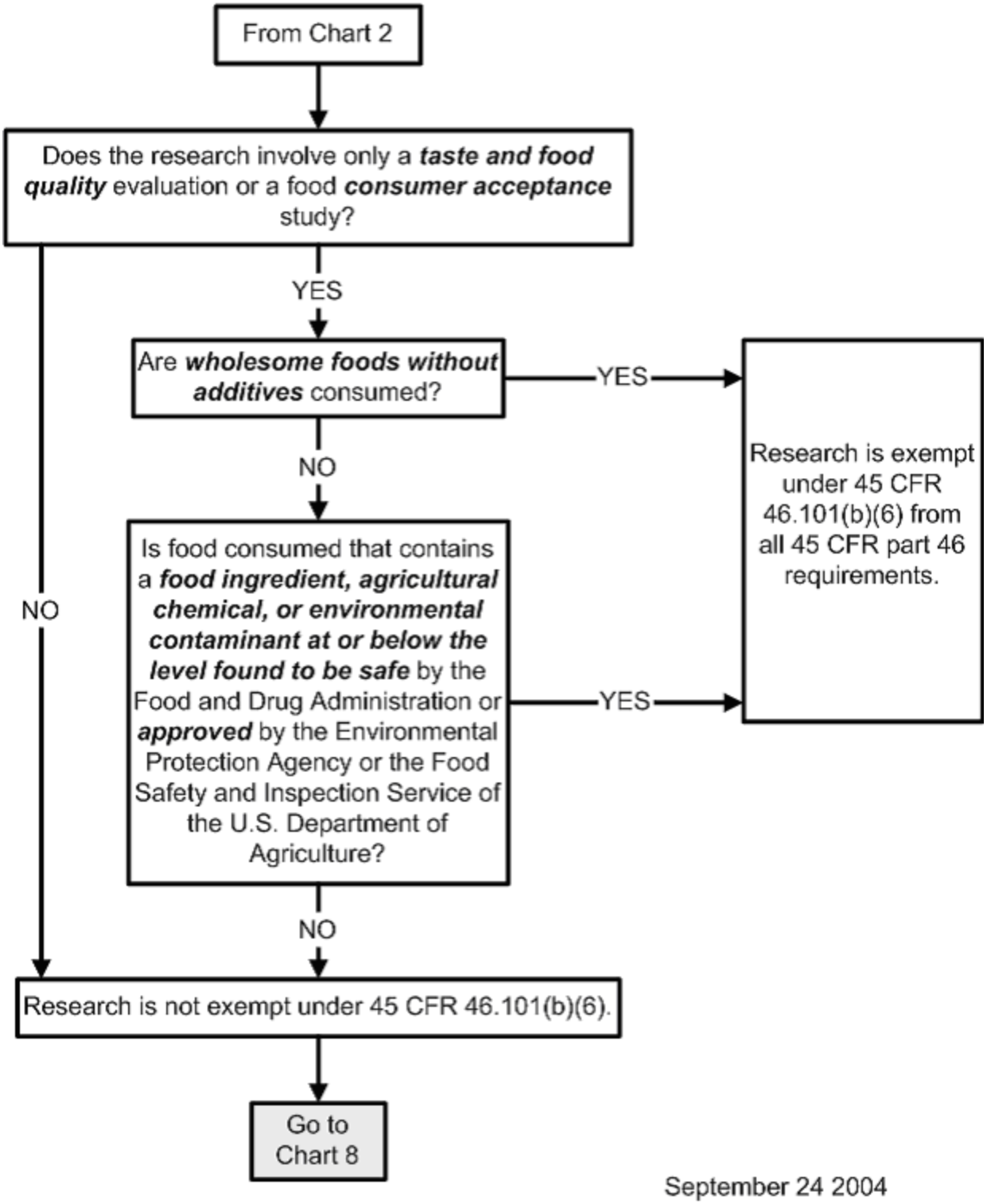

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Chart 8: May the IRB Review Be Done by Expedited Procedures Under 45 CFR 46.110?*

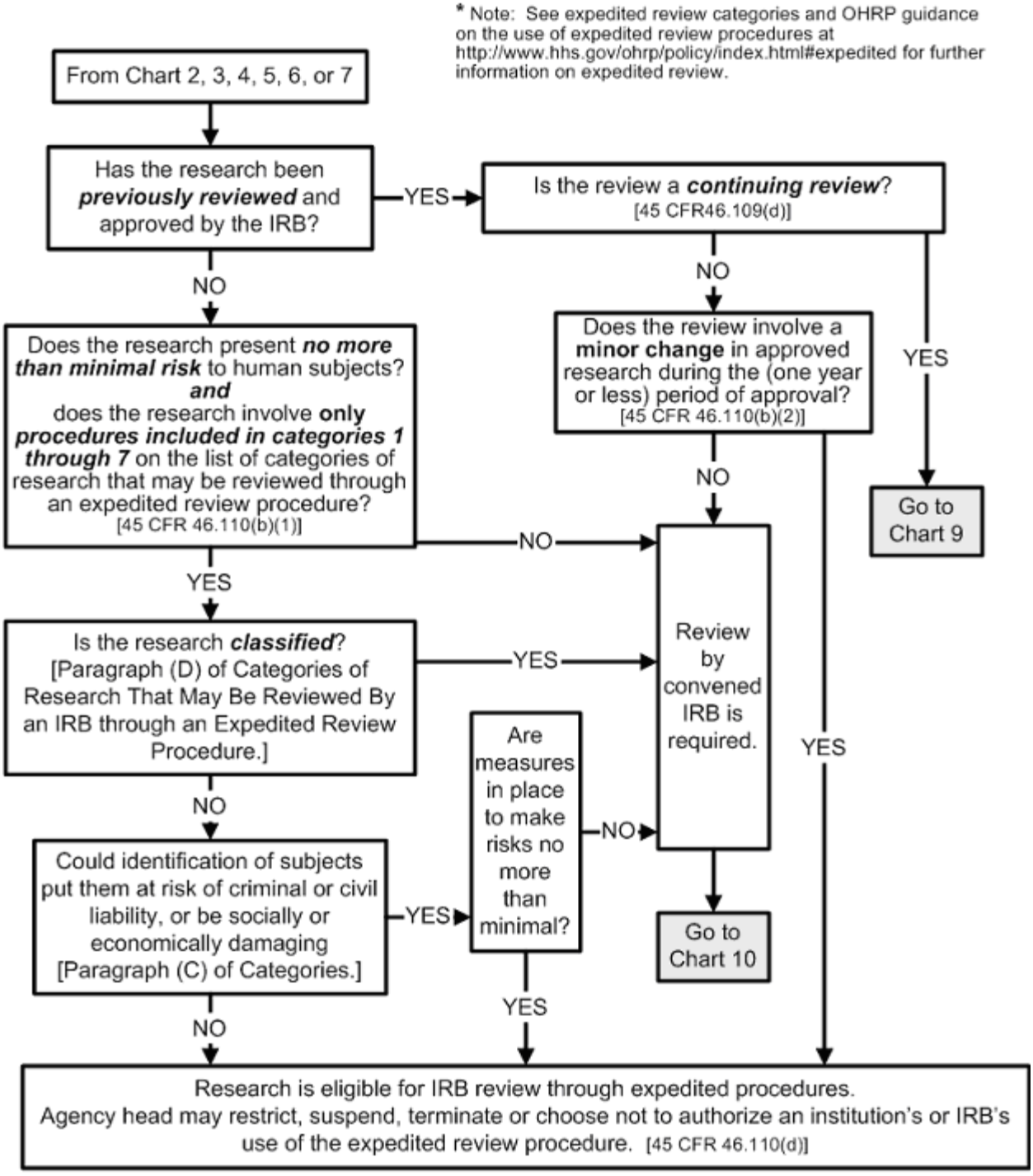

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Chart 9: Can Continuing Review be Done by Expedited Procedures Under 45 CFR 46.110?

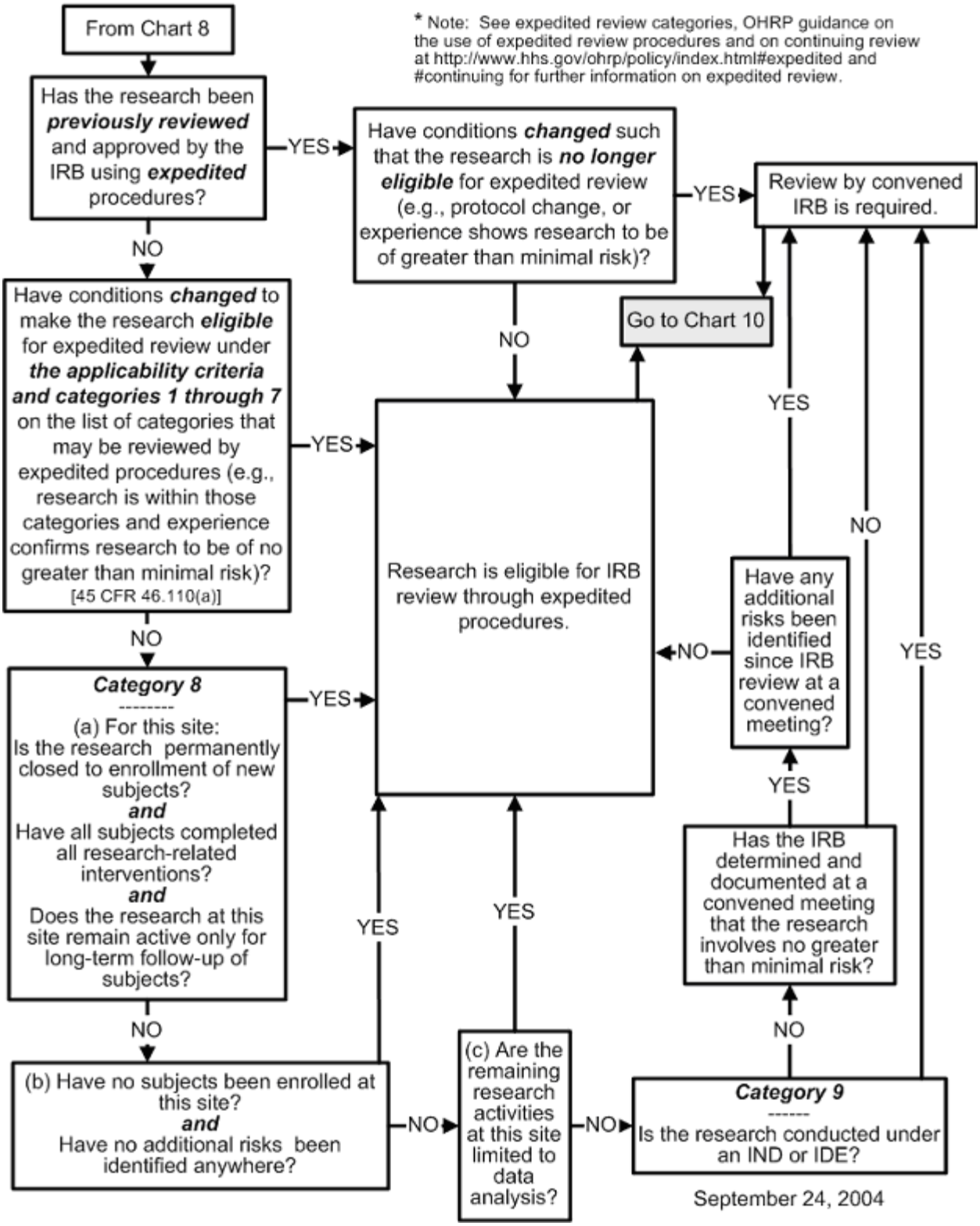
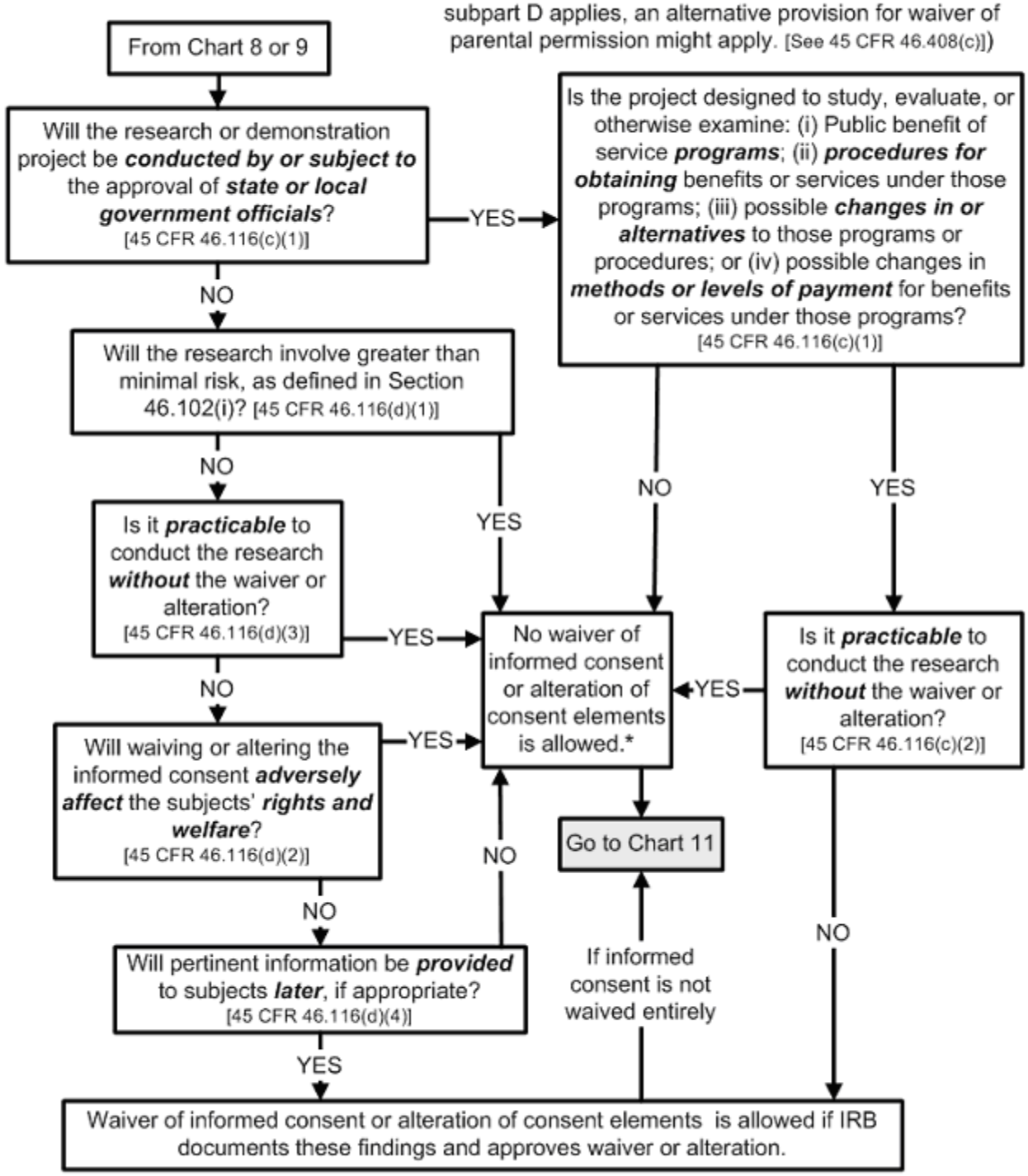


Chart 10: Can Informed Consent Be Waived or Consent Elements Be Altered Under 45 CFR 46.116(c) or (d)?**

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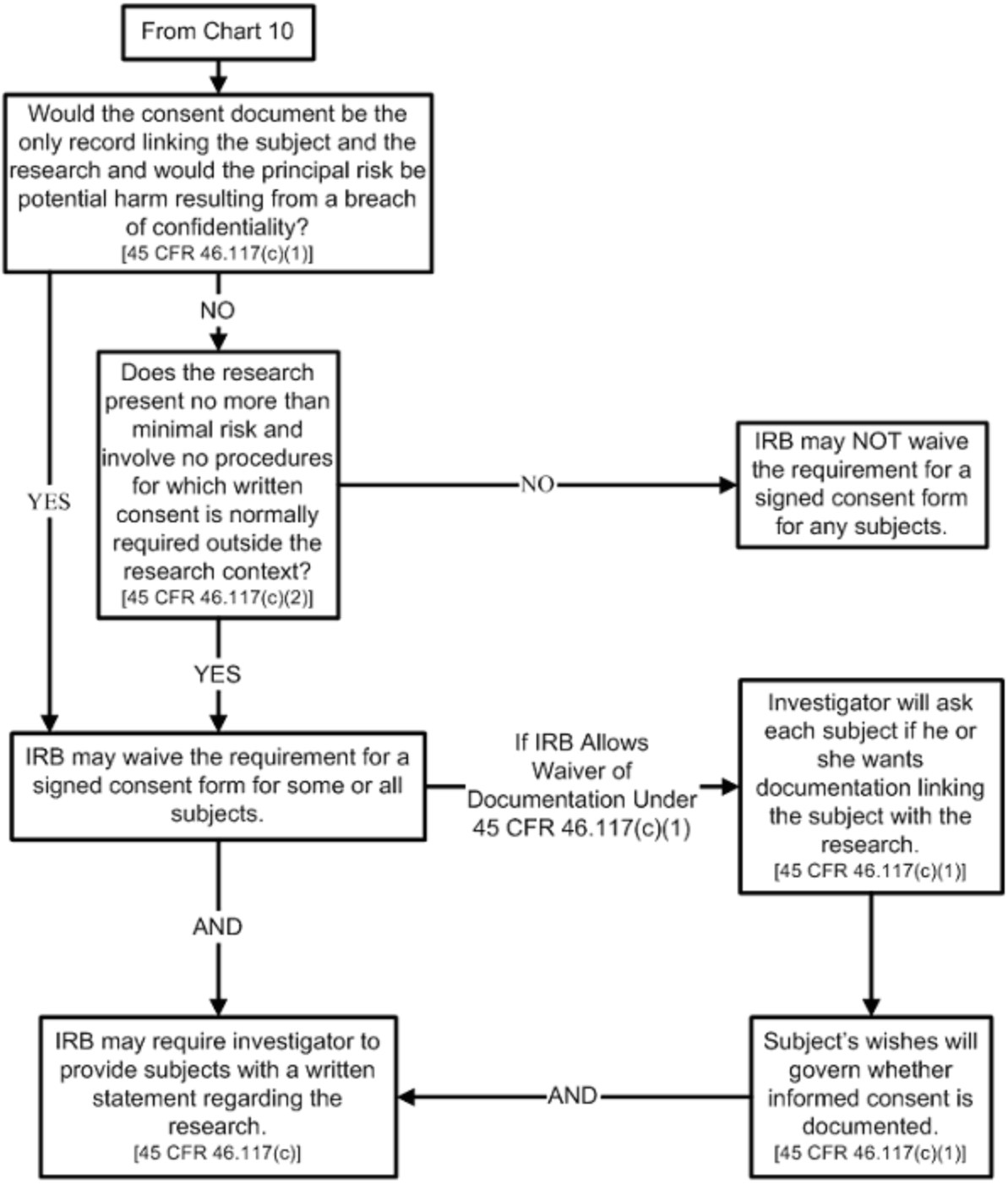
Chart 11: Can Documentation of Informed Consent Be Waived Under 45 CFR 46.117(c)?



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