Institutional Review Board

Policy and Procedures Governing Research with Human Subjects

UA Fort Smith, August 2009

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Policy and Procedures Governing Research with Human Subjects Basis

This policy originates from the United States Code of Federal Regulations (CFR) Title 45 Part 46 Protection of Human Subjects, Subparts A through D, attached in the Appendix, and as amended from time to time.

Applicability

This policy applies to all human subjects research that is conducted by or under the supervision or control of the University of Arkansas – Fort Smith (University) employees or students in connection with their responsibilities, whether on or off campus, and regardless of the source of funding for the research activity. This policy also applies to all human subjects research that is conducted by an external party on University property or using University facilities or resources.

Definitions

The following commonly used terms are defined in accordance with 45 CFR 46.102, as amended from time to time.

Human subject - A living individual about whom an investigator (whether professional or student) conducting research obtains: (1) data through intervention or interaction with the individual or (2) identifiable private information.

Legally authorized representative - An individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.

Minimal risk - 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.

Research - A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities.

Consent - Legally effective and informed consent obtained from each subject or the subject's legally authorized representative. In the case of research involving a minor, consent shall be obtained from the parents or a legal guardian as well.

Human subjects research - Research involving human subjects the purpose of which is to develop or contribute to generalizable knowledge.

Quorum - A quorum is defined as two-thirds of the full committee excluding the non-voting member.

Additional terms commonly used in human subjects research and in this policy shall be defined in accordance with 45 CFR 46.102, .202, 302, and .402.

Principles

The University follows the ethical principles regarding human subject research as set forth in The Nuremberg Code and the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research entitled, "Ethical Principles and Guidelines for the Protection of Human Subjects of Research" (also known as the Belmont Report). The University acknowledges and accepts its responsibilities for protecting the rights and welfare of human subjects of research.

Responsibilities of Researchers

Researchers have the primary responsibility for assuring the day-to-day protection of the rights and welfare of human subjects. Specifically, the researchers are responsible for:

1. Obtaining and demonstrating certification of ethics training.
2. Research design.
3. Adhering to ethical codes; applicable federal, state, and local laws and regulations; and the applicable policies and procedures of the University, the sponsoring agency, and cooperating institutions, if any.
4. Training and supervising staff and students assisting in the research.
5. Obtaining legally effective, informed consent from subjects.
6. Fully disclosing the research protocol and potential risks to human subjects and complying with the requirements of the IRB to minimize risk to the research subjects.
7. Retaining required records.
8. Obtaining the prior approval of the IRB to initiate the research or to change approved research protocols involving human subjects.
9. Reporting promptly to the IRB any adverse events involving research subjects that are, or reasonably may be thought to be, related to the research activity.

IRB Responsibilities

The IRB is responsible for:

1. Reviewing all human subjects research to ensure compliance with 45 CFR 46.109 and, for sponsored research projects, any additional sponsor requirements.
2. Documenting IRB activities as required by applicable regulations (in accordance with the requirements at 46 CFR 45.115, and policies; and providing advice and counsel to investigators engaged in research involving human subjects.
3. Developing policy, procedures, information, and instructions for researchers who wish to engage in human subjects research.
4. Reporting to the appropriate funding agency unanticipated problems involving risks to human subjects and others.
5. Reporting to the appropriate University officers and to appropriate funding agency any serious or continuing failure of investigators to comply with the requirements and determination of the IRB.

Dean of the College that Supports the Research

The Dean is responsible for:

- Assuring that faculty, staff, and students in the supporting college are kept informed of the University policy and procedures and of their responsibilities for protecting the rights and welfare of human subjects involved in research.
- Promptly reporting to the IRB any unanticipated problems involving risks to human subjects.

IRB Coordinator

The IRB Coordinator is responsible for:

1. Assisting investigators with the preparation and submission of protocols.
2. Receiving and reviewing all protocols and requests for exemption to ensure that there are no obvious errors or omissions.
3. Reviewing and approving, or distributing for review and approval by an IRB member, all requests for exemption.
4. Distributing protocols for Expedited Review or Full Review, as appropriate, to voting members of the IRB.
5. Obtaining additional information, clarifications, or expert advice as requested by reviewers or the IRB.
6. Scheduling all meetings and ensuring that business is only in presence of a quorum of the voting members in accordance with this Policy and 45 CFR 46.108.
7. Preparing and maintaining adequate documentation of all IRB activities in accordance with 45 CFR 46.115.
8. Informing investigators of the outcome of reviews including requests for additional information/clarification, disapprovals, conditional approvals, and approvals.
9. Documenting that all investigators and research staff have completed the appropriate, mandatory training to engage in human subjects research.
10. Distributing requests for protocol modifications or continuations to the expedited reviewer or full IRB as appropriate.
11. Sending reminders to the principal investigator of a protocol, annually or more often if so stipulated by the IRB, of impending protocol reporting or expiration deadlines.
12. Preparing additional reports or correspondence as directed by the IRB Coordinator or Provost and Senior Vice-Chancellor for Academic Affairs.

Exemptions

Research activities in which the only involvement of human subjects will be in one or more of the categories described in 45 CFR 46.101(b) are exempt from this policy. Researchers must notify the IRB of plans to engage in such research and request an exemption using the approved IRB form, Request for Exemption.

The IRB Coordinator or a member of the IRB will review the Request for Exemption and notify the researcher of the determination. The researcher may begin the research immediately upon receipt of confirmation from the IRB Coordinator that the research is exempt. The reviewer will use the Human Subject Decision Charts (see the Appendix) as amended from time to time) located on the IRB Web site in determining the status of the research. If the research does not qualify for exemption, the IRB Coordinator will request that the researcher submit a Request for Review of Human Subjects Research protocol form for review by the appropriate review method. The researcher must then wait for approval by the IRB.

Documented (i.e., written or witnessed) informed consent (see Informed Consent) of the participants is not required for research activities that qualify for exemption. However, the IRB requires that at a minimum all participants be informed of the following:

1. Name(s) and contact information of the principal researcher(s).
2. Purpose of the research activity.
3. That refusing, for any reason, to participate will not adversely affect any other relationship with the University, the researchers, or any third party (such as a sponsor or business entity).
4. Contact information for the IRB Coordinator to allow participants to get additional information about the rights of research subjects.

Special Condition for Exemption of Research Involving Minors

The scope of the exemption at 101 (b)(2) contains a restriction for research involving minors in accordance with the special protections accorded children in Subpart D. The only research activities involving children that qualify for exemption under 101 (b)(2) are those involving educational tests or observation where the investigators do not participate in the activity being observed and either the data are recorded without individual identifiers or disclosure of the recorded responses would not place the subjects at risk of criminal or civil liability or be damaging to their financial standing, employability, or reputation.

Internal Assessment of Programs, Courses, or Services and Research Methods Classes

The following activities are not, by definition, human subjects research and do not require submission of either a Request for Exemption or a Human Subjects Research Protocol Form:

1. Anonymous surveys intended solely for internal assessment to improve services (e.g., Web pages, custodial services, customer/client service, or quality assurance).
2. Anonymous surveys the purpose of which is to provide information/ documentation for accreditation or other, similar academic purposes.
3. A class project where the sole purpose of the research is to teach the students research methods. Participants must not be exposed to more than minimal risk or all data must be collected anonymously. The instructor must destroy data and any class reports or presentations no later than the last day of the semester.

NOTE:

- Data collected for internal assessment, service improvement, accreditation, or similar academic purposes as described in this section cannot be used for generalizable uses (e.g., presentation at professional meetings, professional publications, etc.) until the researcher gains IRB approval prior to data collection or seeks exemption for the use of existing, anonymous data under 45 CFR 46.101 (b)(4) prior to the completion of data collection and analysis. There are no exceptions.
- Data gathered for required reporting to accreditation agencies or other similar academic purposes are not, by definition, human subjects research and do not require submission of either a Request for Exemption or a Human Subjects Research Protocol Form.

Oral History for Historical Texts, Publications, Documentaries, and Journalistic Works

Provided that the research is carried out in accordance with the Oral History Association's Oral History Evaluation Guidelines, Principles and Standards, researchers do not need to seek an exemption or IRB approval.

Institutional Review Board (IRB)

Composition

The Provost and Senior Vice-Chancellor for Academic Affairs shall appoint members to the IRB so that the membership complies with 45 CFR 46.107, as amended from time to time, and so that the full-committee membership includes one community member, one student representative, and faculty representatives as follows: one member from the College of Health Sciences; College of Science, Technology, Engineering, and Mathematics; College of Business; College of Education; College of Humanities and Social Sciences; College of Languages and Communication; and a dean appointed by the Provost will be an ex officio, non-voting member. The Director of Assessment and Accountability, or his or her designated representative, will be an ex officio, non-voting member.

Serving on the Institutional Review Board (IRB) is an honor and a privilege. On a yearly rotating basis, student organizations in the College of Health Sciences, the College of Education, the Department of Psychology, or the Department of Criminal Justice will hold elections to select a student representative to the IRB. Initially, a senior and junior student will be elected. The senior student serves as a voting member of the committee, and the junior student serves as member-elect for one year before becoming a voting member during the student's senior year. At that time, the student organizations will elect another junior member-elect.

When reviewing protocols in accordance with the requirements of 45 CFR 46 Subpart C, Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects , the composition of the IRB shall include at least one voting member who is a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity. This voting member may be a regularly appointed member of the IRB or may be appointed as a voting member solely for protecting research subjects who are, or who become in the course of the project, prisoners.

The IRB may, at its discretion, invite individuals with competence in special areas to assist in the review of protocols that require expertise beyond or in addition to that available from the IRB members. These individuals may not vote with the IRB.

Membership Terms

Members of the IRB will serve three-year terms, unless they are selected to fill a vacancy that occurs during the middle of a term. New terms will begin in the fall semester.
Terms shall expire on a staggered basis to ensure that the voting membership always includes experienced members.

IRB Coordinator

The Provost and Senior Vice-Chancellor for Academic Affairs will appoint the IRB Coordinator. The Coordinator will serve as Chair of the IRB Committee. In the event that the Coordinator is unable to continue his or her duties, the Provost and Senior Vice-Chancellor for Academic Affairs will designate a replacement to serve as Coordinator. In the event that the Coordinator is temporarily unable to serve, or is unable to attend one or more meetings of the IRB, the Coordinator shall appoint an Acting Chair from the membership. The Acting Chair must have at least one year of experience as an IRB member.

Meetings

During the academic year, the IRB shall meet, as needed, on a monthly basis to conduct business and review protocols. During the summer term, the IRB will meet as needed provided that a quorum of the voting membership is available to properly conduct business.

It is strongly encouraged that all applications for summer research be submitted by May 1 to ensure timely review.

Types of Review

Expedited Review

Protocols will be evaluated for review by expedited review procedures using the Human Subjects Decision Charts (see the Appendix) and as amended from time to time. Expedited review procedures will be carried out in accordance with 45 CFR 46.110. To qualify for Expedited Review, the research must appear in the list, Categories of Research That May Be Reviewed by the Institutional Review Board (IRB) through an expedited review procedure published by the Secretary of the U.S. Department of Health and Human Services as periodically republished in the Federal Register.

In accordance with 45 CFR 46.110(b) the IRB will use the expedited review procedure to review either or both of the following:

- Some or all of the research appearing on the list and found by the reviewer(s) to involve no more than minimal risk.
- Minor changes in previously approved research during the period (of one year or less) for which approval is authorized.

Full Review

All human subjects research that does not qualify for an exemption or review using Expedited Review procedures shall be reviewed at a duly convened meeting of the IRB in accordance with 45 CFR 46.1 08(b). Projects that require Full Review will be reviewed at a meeting where a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting.

Designation of Reviewers for Expedited and Full IRB Review of Protocols

Exempt or Expedited Review

Protocols that qualify for Exempt or Expedited Review will be assigned in rotation to two voting members of the IRB. Of the two members, at least one will have one or more years of experience on the IRB Committee. No member will be assigned a protocol submitted by a member who has an actual or perceived conflict of interest. In the event that the exempt or expedited reviewers do not feel that the research can be approved as described in the protocol, the reviewers will refer the protocol for Full Review. Exempt or expedited reviewers may not disapprove the research. All members will be notified, in writing, of protocols that have been approved by Exempt or Expedited Review. (45 CFR 46.110). The duties of the exempt or expedited reviewers include:

1. Reviewing all materials, including the grant proposals, if any, related to the assigned protocol. All materials need to be reviewed by IRB before submitting to the granting entity.
2. Informing the IRB Coordinator if, in the reviewer's opinion, additional information, expertise, or consultation is necessary.
3. Conducting informal queries of the Principal Investigator or other experts in order to provide a thorough review or providing the IRB Coordinator with clear instructions regarding recommendations, required modifications, and or the need for further information/clarification.
4. Determining whether the research meets the criteria for IRB approval.
5. Notifying the IRB Coordinator, in writing, of his or her decision either to approve or refer the research to the full IRB for further consideration.

Full Review

Protocols that require Full Review will be scheduled for the next scheduled IRB meeting. Each protocol will be assigned two voting-member reviewers. The responsibilities of the reviewers include:

1. Reviewing all materials, including the grant proposals, if any, related to the assigned protocol.
2. Informing the IRB Coordinator if, in the reviewer's opinion, additional expertise or consultation is necessary.
3. Discussing the protocol informally with the investigator(s), as necessary, to gain additional information or clarification.
4. Leading the discussion of the protocol at the meeting.
5. Coordinating the review, including comments and questions, with the Secondary Reviewer as necessary.
6. Assessing whether the protocol meets the criteria for approval.
7. Providing recommendations for IRB action, including changes or requests for additional information to the IRB Coordinator.

Criteria for IRB Approval

Prior to granting approval of the research, the IRB must determine that the requirements of 45 CFR 46.111 are met. These requirements include:

1. Minimizing risks to the subjects by using procedures that are consistent with sound research design, do not expose subject to unnecessary risk, and where appropriate use procedures already being performed on the subjects.

2. Ensuring that the risks to the subjects are reasonable in relation to the anticipated benefits to the subjects and the importance of the information to be gained.
3. Selecting subjects in an equitable manner.
4. Seeking and appropriately documenting legally effective, informed consent from each subject or from the subject's legally authorized representative.
5. Making adequate provisions, when appropriate, for monitoring the data collected to ensure the safety of the subjects.
6. Providing adequate protection for the privacy of the subjects and maintaining the confidentiality of the data as appropriate.
7. Ensuring that appropriate additional protections are in place when some or all of the subjects are members of vulnerable populations.

Approval Period for Initial Approvals

Approval to engage in human subjects research will not be granted retroactively. Requests for exemption and protocols for research subject to Expedited or Full review must be approved prior to initiating the research. There are no exceptions.

Human subjects research that has been determined to be exempt will be approved for an indefinite period subject to any changes that the researcher(s) wish(es) to initiate. (See Approval for Modifications to Previously Approved Research, below).

In accordance with 45 CFR 46.109, human subjects research that has been approved by Expedited or Full Review will be approved for a maximum of one year from date of review. Shorter approval periods may be approved for projects where the degree of risk warrants additional oversight. In the case of protocols reviewed and conditionally approved by the full IRB, the approved research period will become effective as of the date the conditions are met by the researcher. Regardless of the protocol expiration date, the researcher must get IRB approval prior to initiating changes in the approved research.

Approval of Continued Research

As stated above, research that has been determined to be exempt is approved for an indefinite period. For projects that are approved by Expedited or Full Review, the investigator must submit an Annual Report request permission to continue the research, and receive approval prior to the expiration date of the approved protocol. If continuation of the research is not approved prior to the expiration date, the investigator must halt all research until a full protocol has been submitted for appropriate review and approval. There are *no* exceptions.

Approval of Modifications to Previously Approved Research

For research that has been determined to be exempt, the researcher must resubmit a Request for Exemption prior to initiating any changes, other than in number of subjects, in the research.

For research that has been approved by Expedited or Full Review, the researcher must submit a Request for Protocol Modification and receive approval prior to modifying any aspect of the previously approved protocol.

Informed Consent

In accordance with 45 CFR 46.116, a researcher must obtain the legally effective, informed consent of a subject or a subject's legally authorized representative prior to involving the subject in the research. The researcher must:

1. Provide the elements of informed consent in a language that is readily understandable by the participant or the participant's representative.
2. Gain the consent under circumstances that allow the subject or the subject's representative sufficient opportunity to decide whether or not to participate.
3. Avoid the possibility of coercion or undue influence.
4. Ensure that the consent does not include any language that requires or appears to require the subject or the subject's representative to waive his or her legal rights, or releases or appears to release the researcher or research staff, the University, or the sponsor (if any) from liability for negligence.

Required elements of informed consent shall be determined in accordance with 45 CFR 46.116.
Basic elements include:

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 that 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, that 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.
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.

Additional elements that must be included if applicable are:

1. A statement that the particular treatment or procedure may expose the subject (the embryo or fetus, if the subject is or may become pregnant) to risks 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 and that may relate to the subject's willingness to continue participation will be provided to the subject.

6. The approximate number of subjects involved in the study.

Requesting Waiver or Alteration of Informed Consent

Requests for waiving or altering the elements of informed consent must be justified in writing and meet all of the conditions set forth in 45 CFR 46.116 (c) or (d).

Documentation of Informed Consent

The researcher must document informed consent in accordance with 45 CFR 46.117. Subject to any waiver or alteration as referenced above, the informed consent of the participant must be gained by one of the following methods:

- A written consent document that contains the required elements of informed consent. This form may be read to the subject or the subject's legally authorized representative. The researcher must give either the subject or the representative adequate opportunity to read it before it is signed.

- A short written consent document stating that the required elements of informed consent have been presented orally to the subject or the subject's legally authorized representative. This method requires a witness to the consent process and an IRB approved written summary of what is to be said to the subject or the representative. The short form itself must be signed by the subject or the representative. Identification of the relationship to subject should be documented. The witness must sign both the short form and a copy of the summary, and the person actually obtaining consent must sign a copy of the summary. A copy of the summary must be given to the subject or the representative, in addition to a copy of the short form.

A request to waive the requirement to obtain a signed consent form may be granted only if:

- The only record linking the subject and the research is the consent document and the principal risk is the potential harm resulting from a breach of confidentiality. Each subject must be asked whether she or he wants documentation linking her/him with the research, and the subject's wishes will govern.
- The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

Assent of Minors

The requirement for assent of children is prescribed at 45 CFR 46 Subpart D. Minor children are persons who have not attained the legal age for consent under the applicable law of the jurisdiction in which the research will be conducted. When minor children are the subjects of research, in addition to the consent of the parents or legal guardian(s), the researcher must gain the assent (affirmative agreement) of the children. Failure to object cannot be construed as consent. Prior to engaging in research involving minors, the researcher should see Additional Protections for Children Involved as Subjects in Research (see below).

Additional Protections for Pregnant Women, Human Fetuses, and Neonates Involved in Research

The IRB will review and approve research on subjects in these categories only in accordance with the requirements of 45 CFR 46 Subpart B. Investigators are cautioned to ensure that the submitted protocol complies with any additional requirements of this Subpart or approval will be withheld.

Additional Protections Pertaining to Biomedical

and Behavioral Research Involving Prisoners as Subjects

Research involving prisoners must be initially approved by the Provost and Senior Vice-Chancellor for Academic Affairs.

Additional Protections for Children Involved as Subjects in Research

The IRB will review and approve research on subjects in these categories only in accordance with the requirements of 45 CFR 46 Subpart D. Investigators are cautioned to ensure that the submitted protocol complies with any additional requirements of this Subpart or approval will be withheld.

Appendix
Decision Charts

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

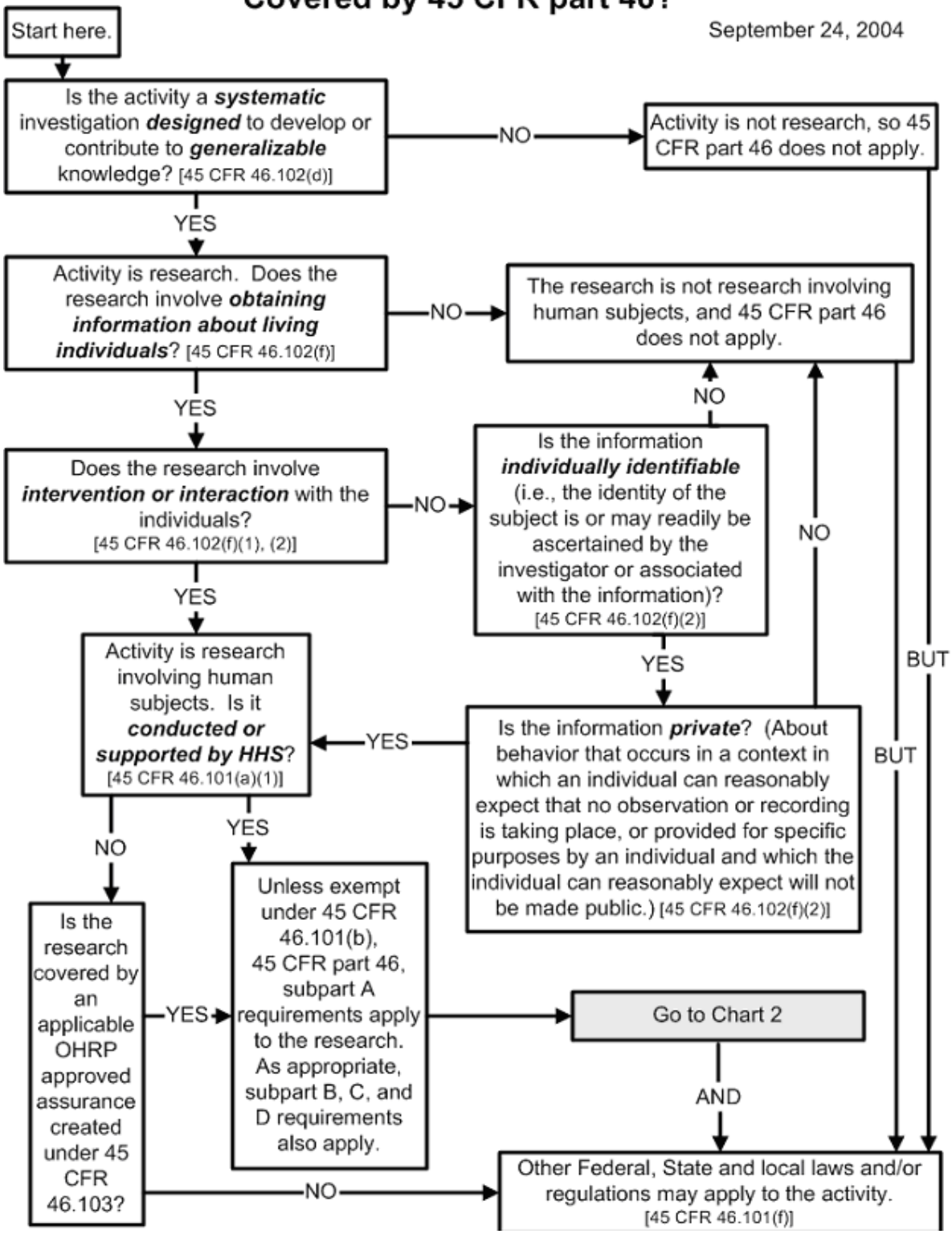


Chart 2: Is the Research Involving Human Subjects Eligible for Exemption Under 45 CFR 46.101(b)?

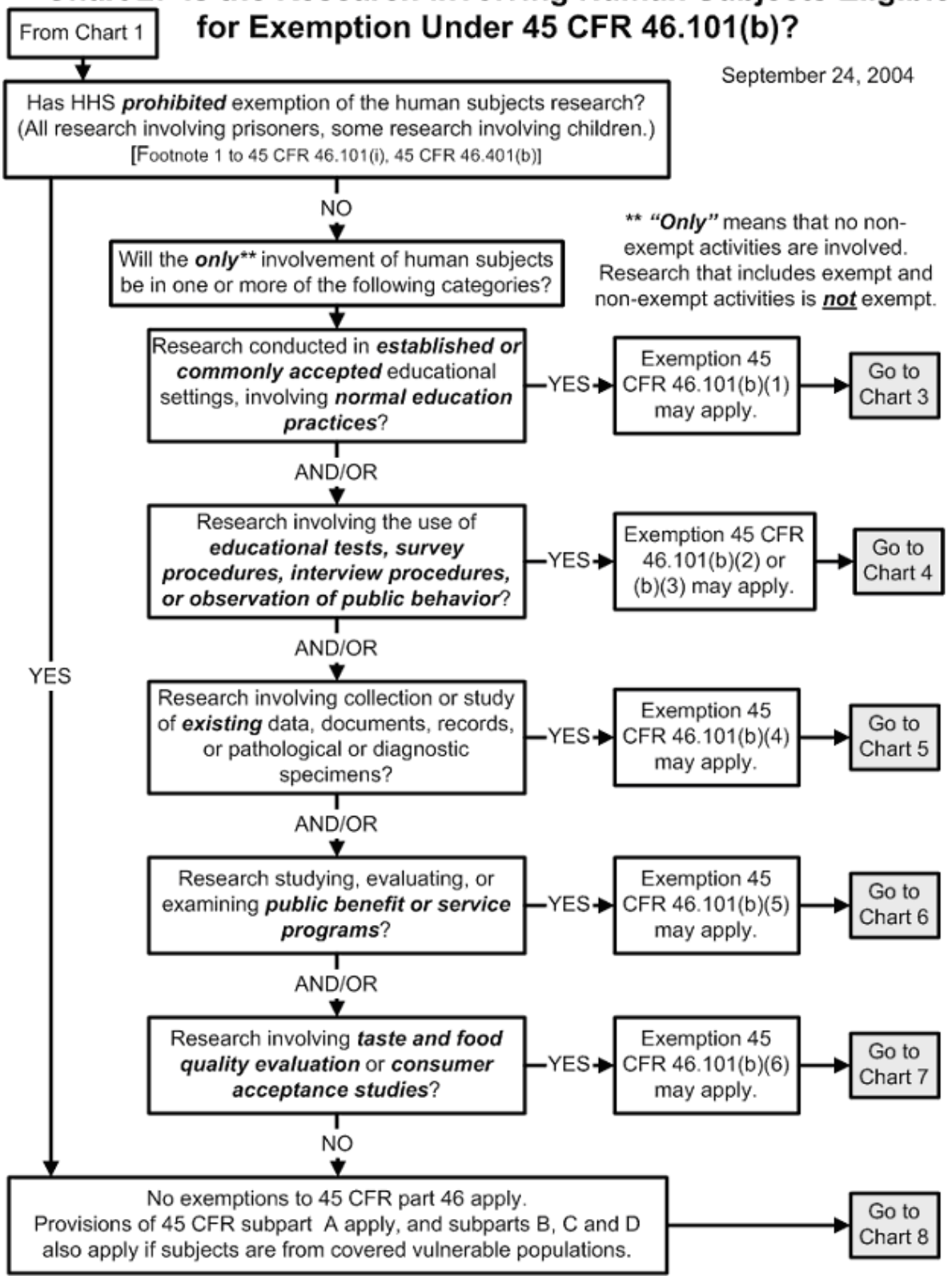
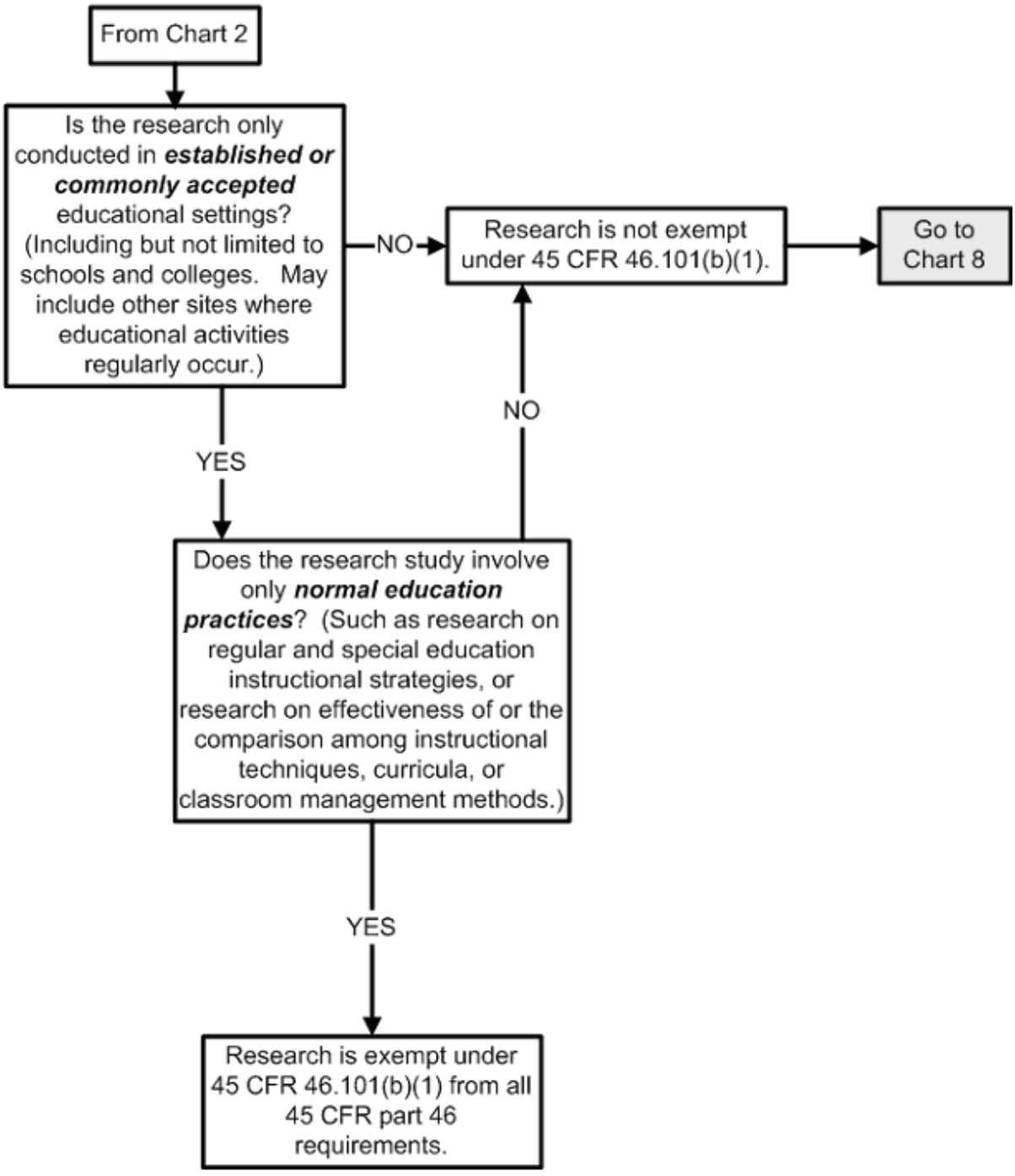
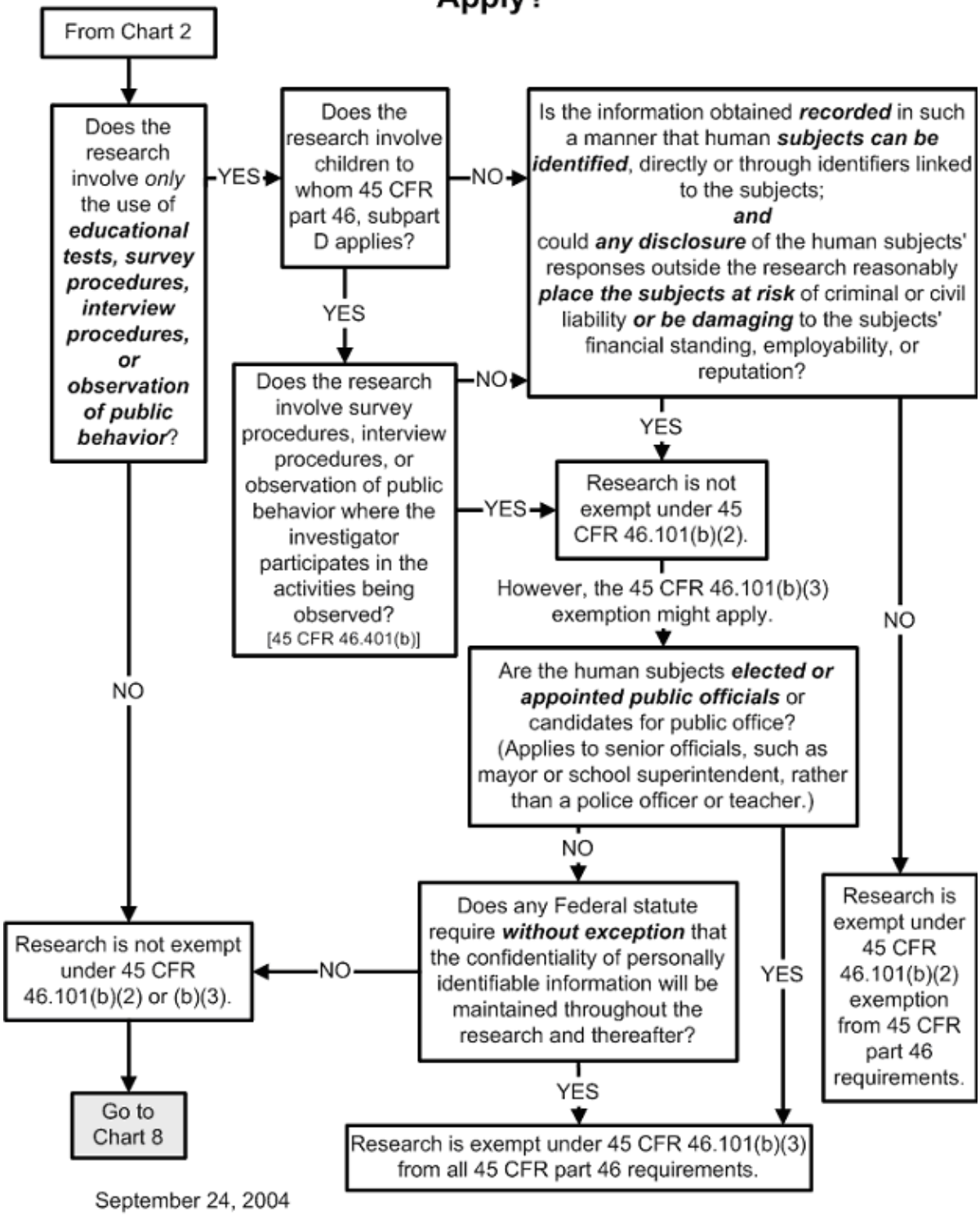


Chart 3: Does Exemption 45 CFR 46.101(b)(1) (for Educational Settings) Apply?



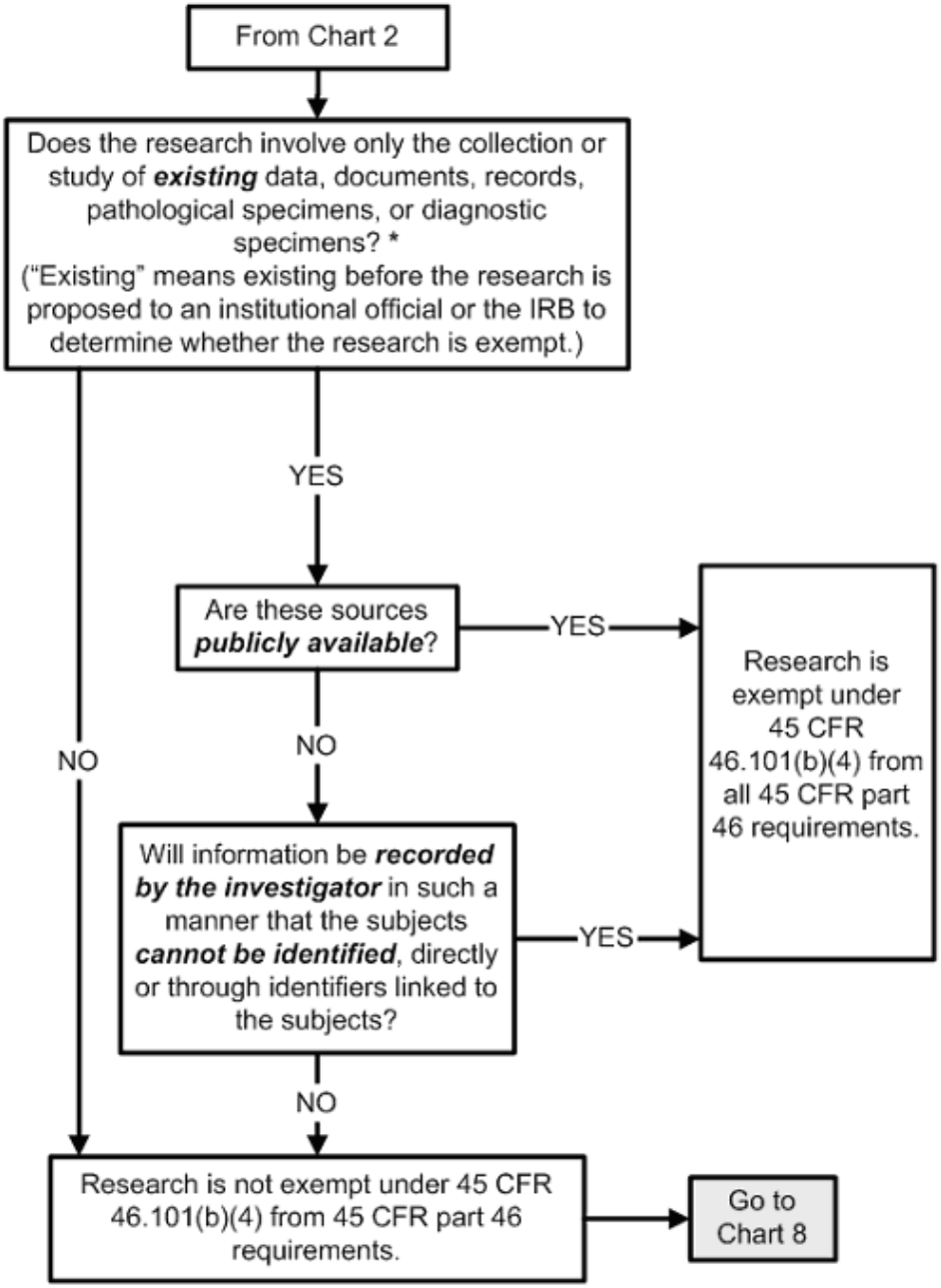
September 24, 2004

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



September 24, 2004

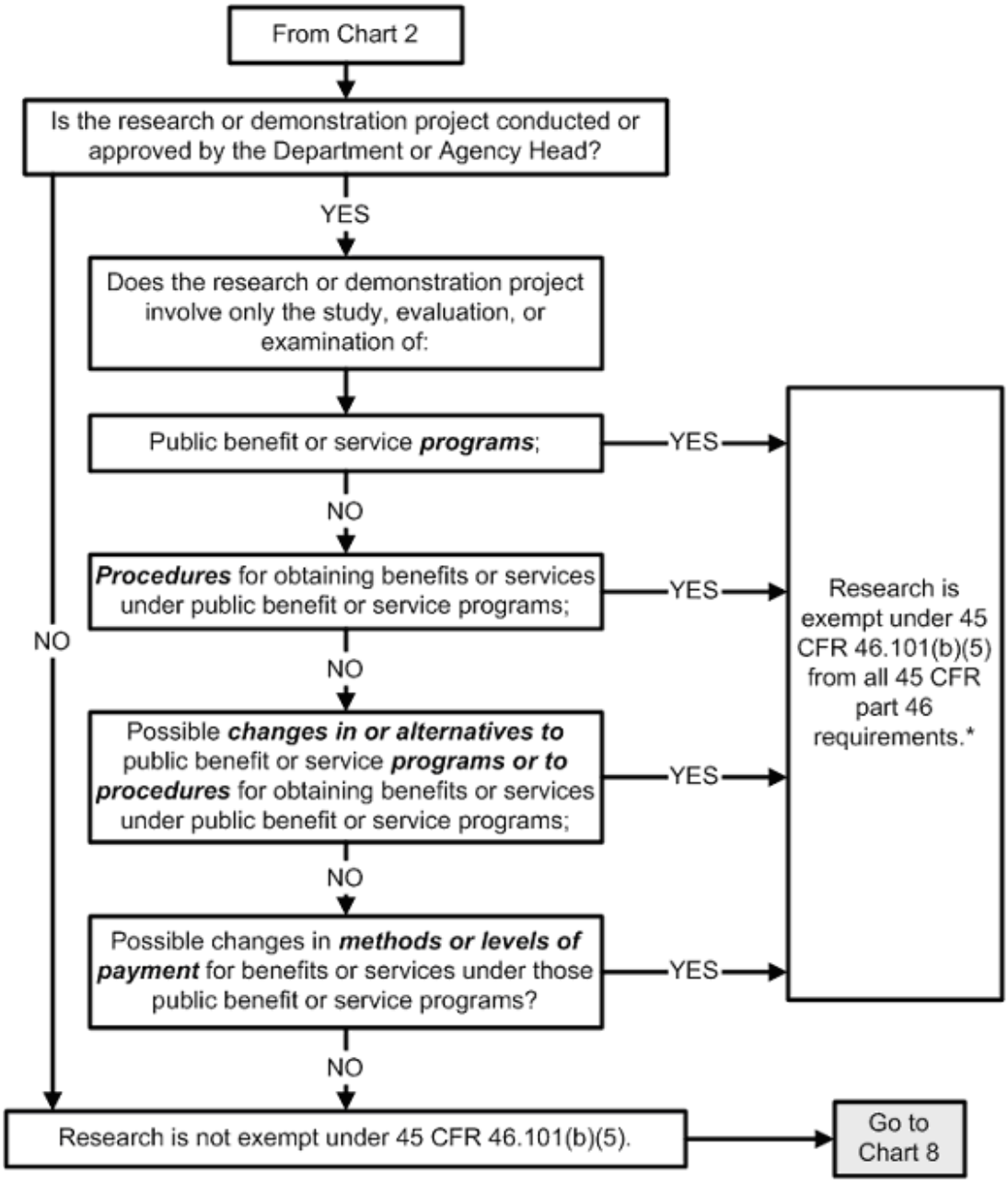
Chart 5: Does Exemption 45 CFR 46.101(b)(4) (for Existing Data Documents and Specimens) Apply?



* 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.

September 24, 2004

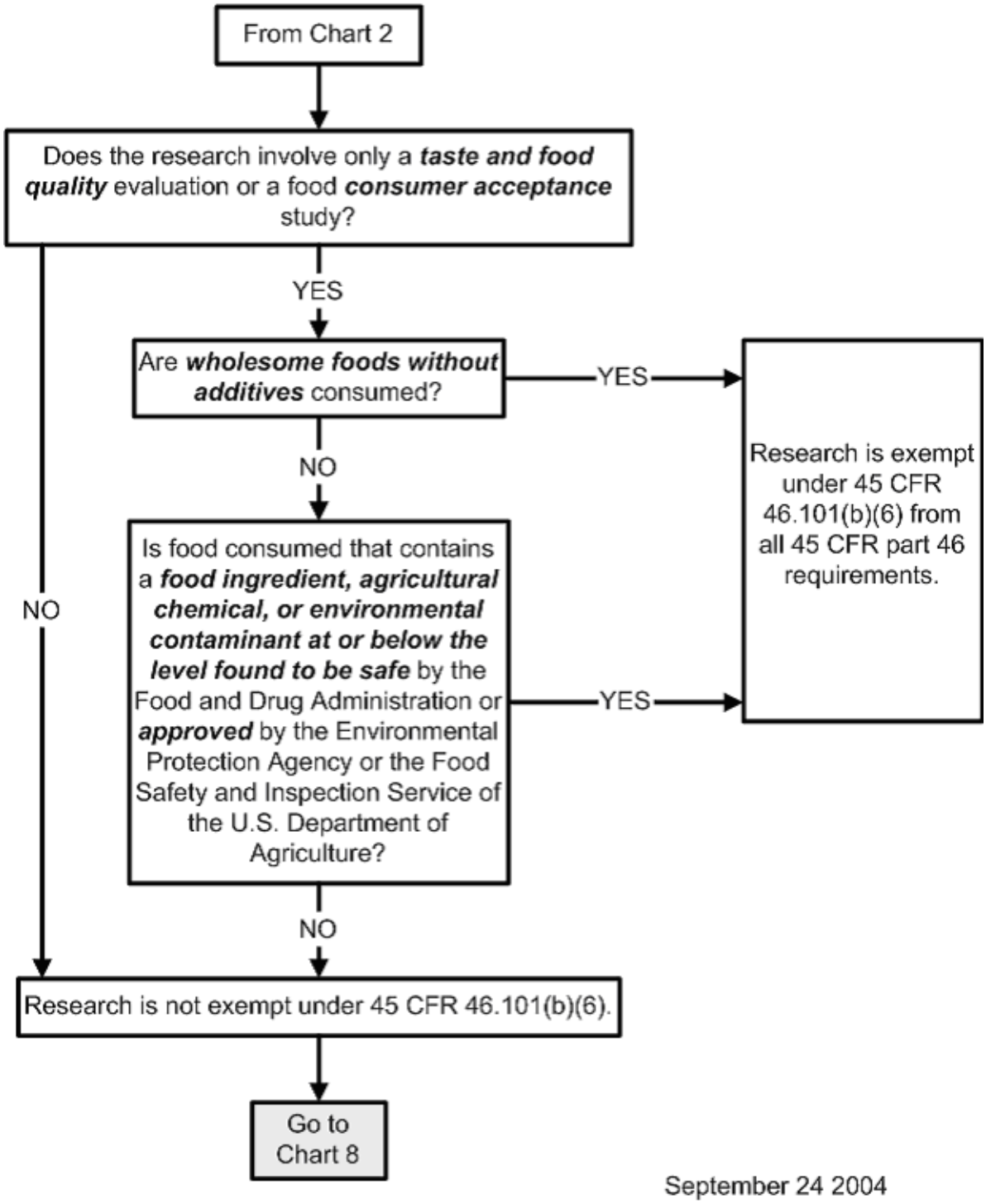
Chart 6: Does Exemption 45 CFR 46.101(b)(5) (for Public Benefit or Service Programs) Apply?



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

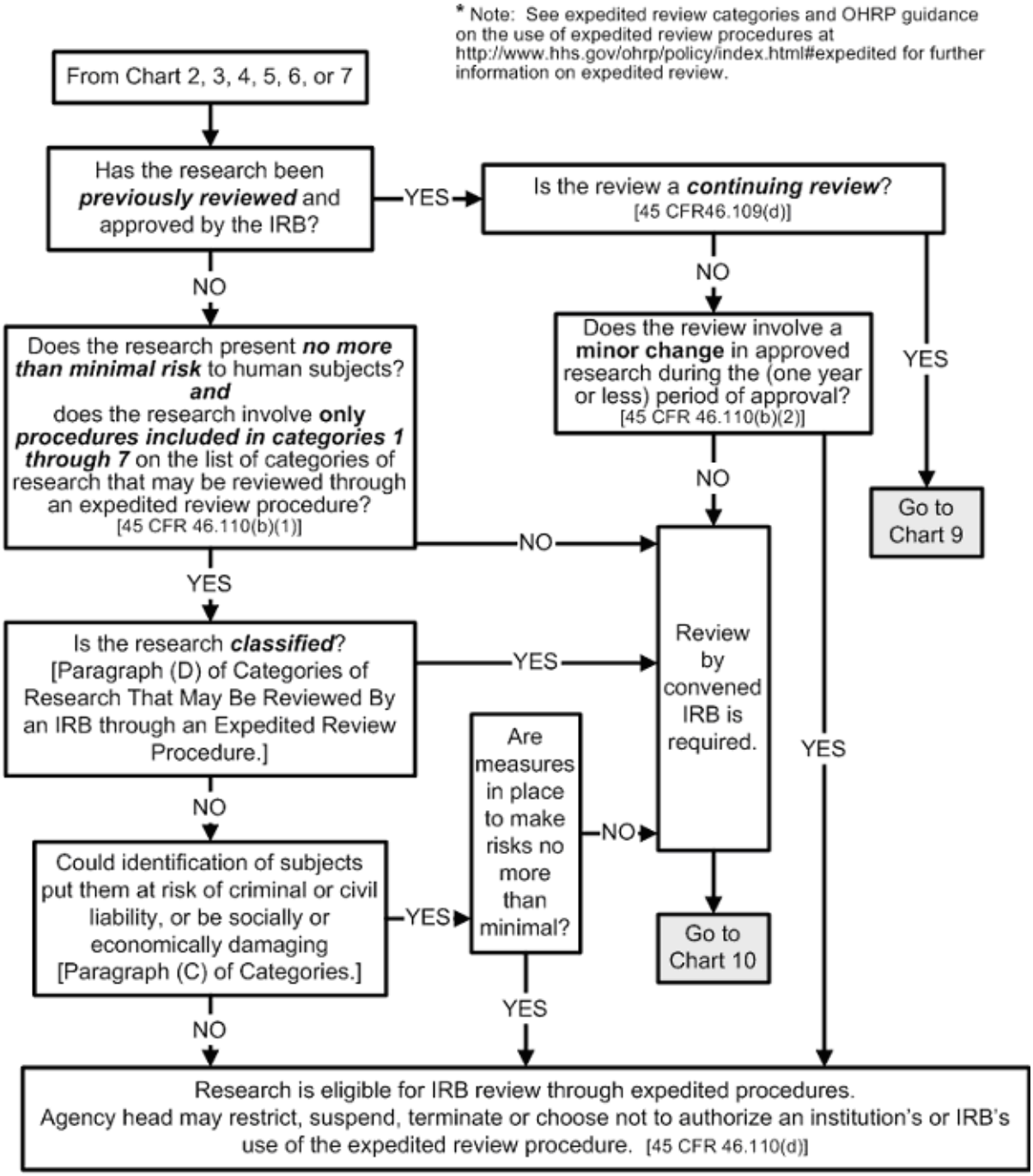
September 24, 2004

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



September 24 2004

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



September 24, 2004

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

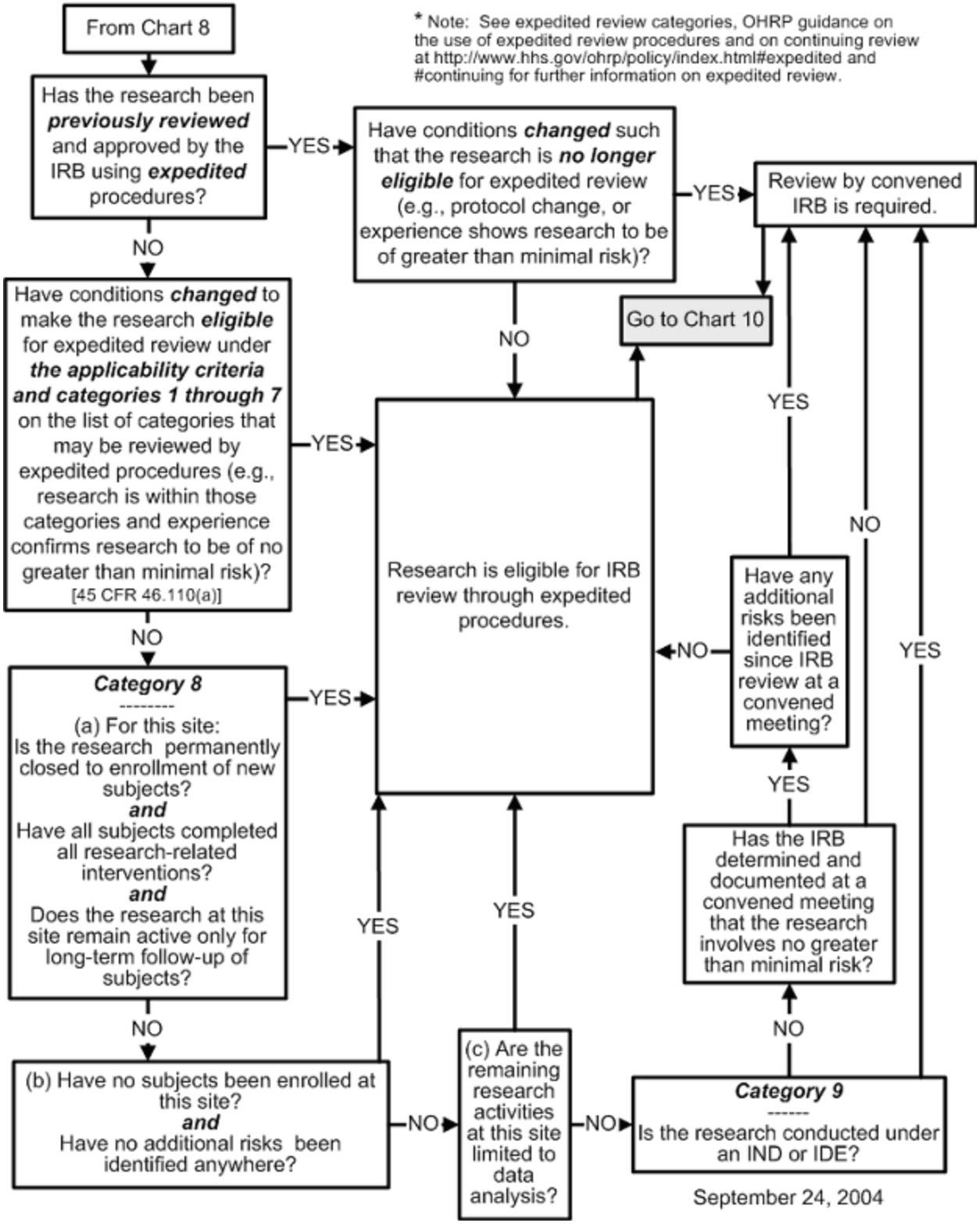
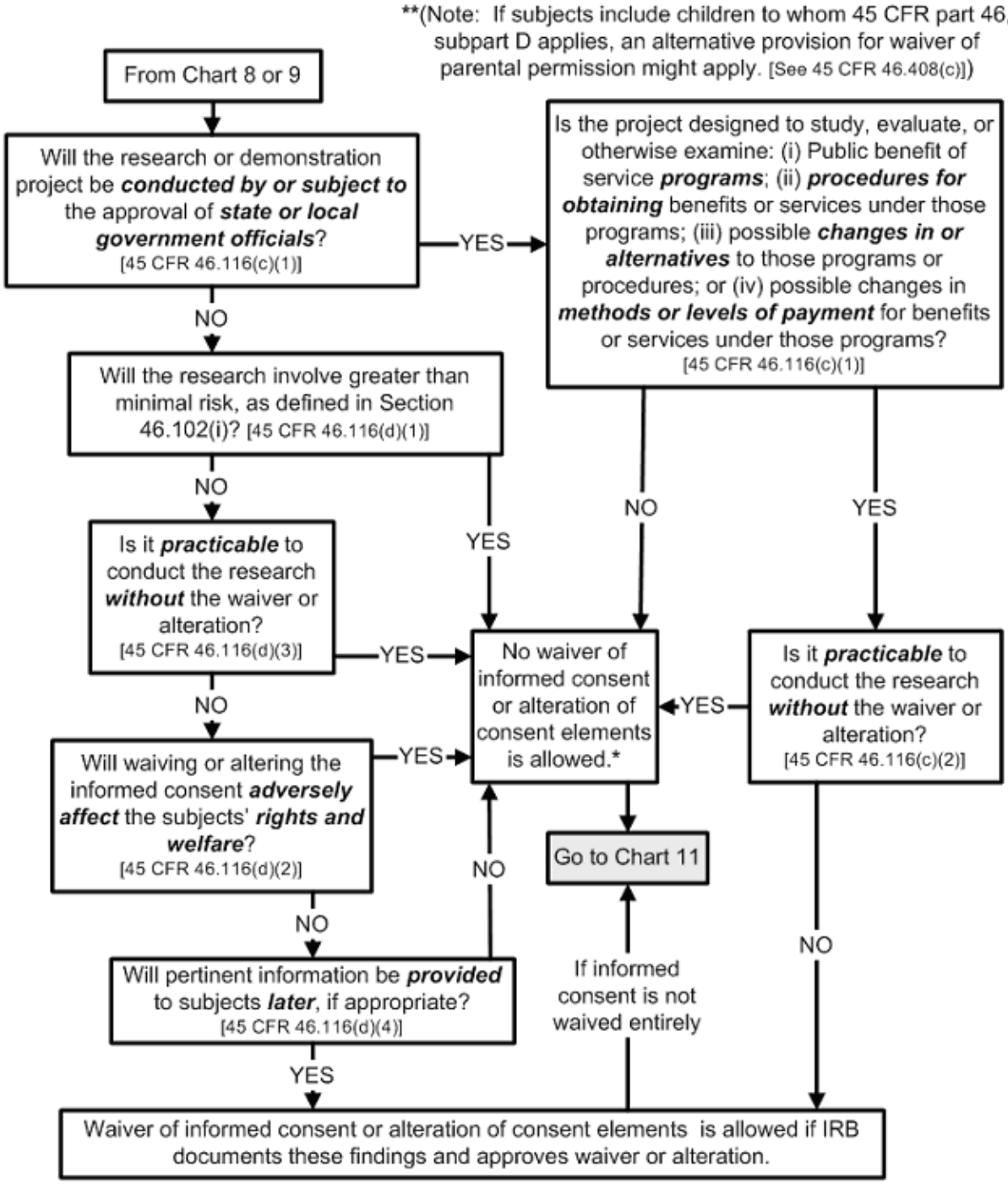


Chart 10: Can Informed Consent Be Waived or Consent Elements Be Altered Under 45 CFR 46.116(c) or (d)?**



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

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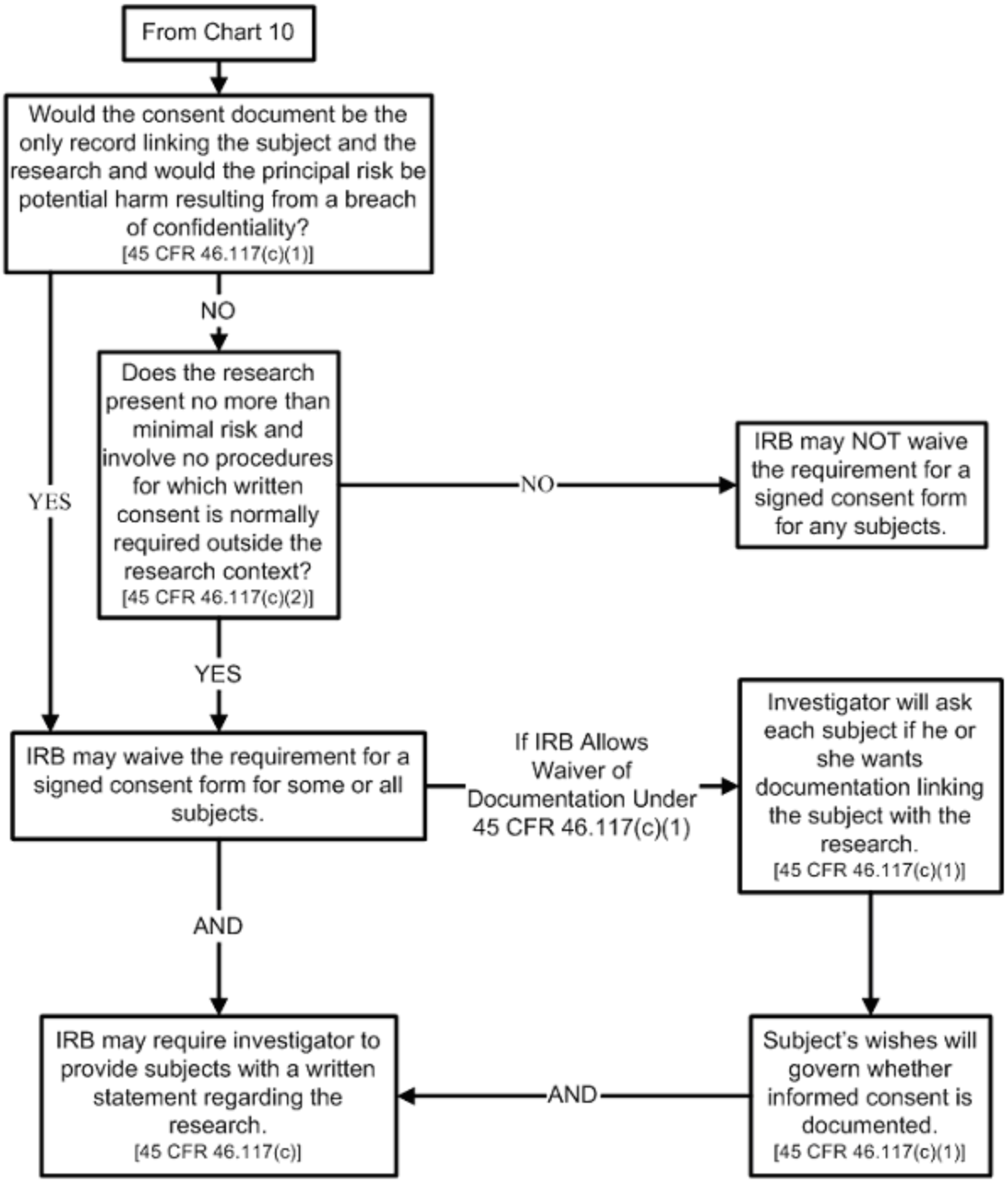
Chart 11: Can Documentation of Informed Consent Be Waived Under 45 CFR 46.117(c)?



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