

The enabling legislation for DAU, 10 USC Sec. 1746, lays out the requirement for defense acquisition research. It states that the Defense Acquisition University shall provide for: (1) the professional educational development and training of the acquisition workforce; and (2) research and analysis of defense acquisition policy issues from an academic perspective.

Defense acquisition research is defined as the range of activities aimed at creating, growing and disseminating new knowledge regarding the acquisition of defense-related materiel and services. The aim of this research is to create the broad body of knowledge that can produce actionable results and/or novel insights that can influence defense acquisition policy and/or practice. The insights and knowledge gained from defense acquisition research help program managers and senior leaders reach clarity on acquisition strategies, business practices, and technological concepts, all aimed at creating more favorable acquisition outcomes.

All research projects conducted by DAU faculty and staff shall be approved by the investigator's leadership chain (i.e., his/her immediate supervisor and/or dean or director). Any research conducted by or on behalf of DAU that involves human subjects (e.g., in surveys or interviews) must follow DoD Instruction 3216.2, Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research, November 8, 2011 (summarized in the Appendix, while the full Instruction is here: <http://www.dtic.mil/whs/directives/corres/pdf/321602p.pdf>). It is important that the investigator become familiar with this Instruction prior to engaging in the research activity.

The most important requirement of DoDI 3216.2 for research conducted under the auspices of DAU is noted on p. 12 (para 3.a.7), that the investigator shall rely on an Institutional Review Board (IRB) whose membership meets the requirements listed in that section. Briefly, that IRB

must be part of a Service or other DoD Component. However, the IRB may be of another organization which has been determined by the appropriate Service or other DoD Component to have the proper federal assurances (but that also requires approval by the Service or Component and may be subject to additional review). DAU itself does not have an IRB, so the investigator must select and coordinate with another Service or Component IRB.

The following flow charts explain how to determine whether the proposed research falls within the scope of this Directive, and what steps to take to ensure compliance. Given the nature of the policy- and process-related studies that would be conducted under the auspices of DAU, the following charts are most likely to be of specific use:

- Chart 1: Is an Activity Research Involving Human Subjects?

This leads to:

- Chart 2: Is the Human Subjects Research Eligible for Exemption?

The most common exemptions for DAU affiliated research will include:

Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as research on regular and special education instructional strategies, OR research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. This leads to:

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

Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: a. Information obtained is recorded in such a manner that human 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 subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation. This leads to:

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

Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic 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. This leads to:

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

Chart 1: Is an Activity Research Involving Human Subjects?

February 16, 2016

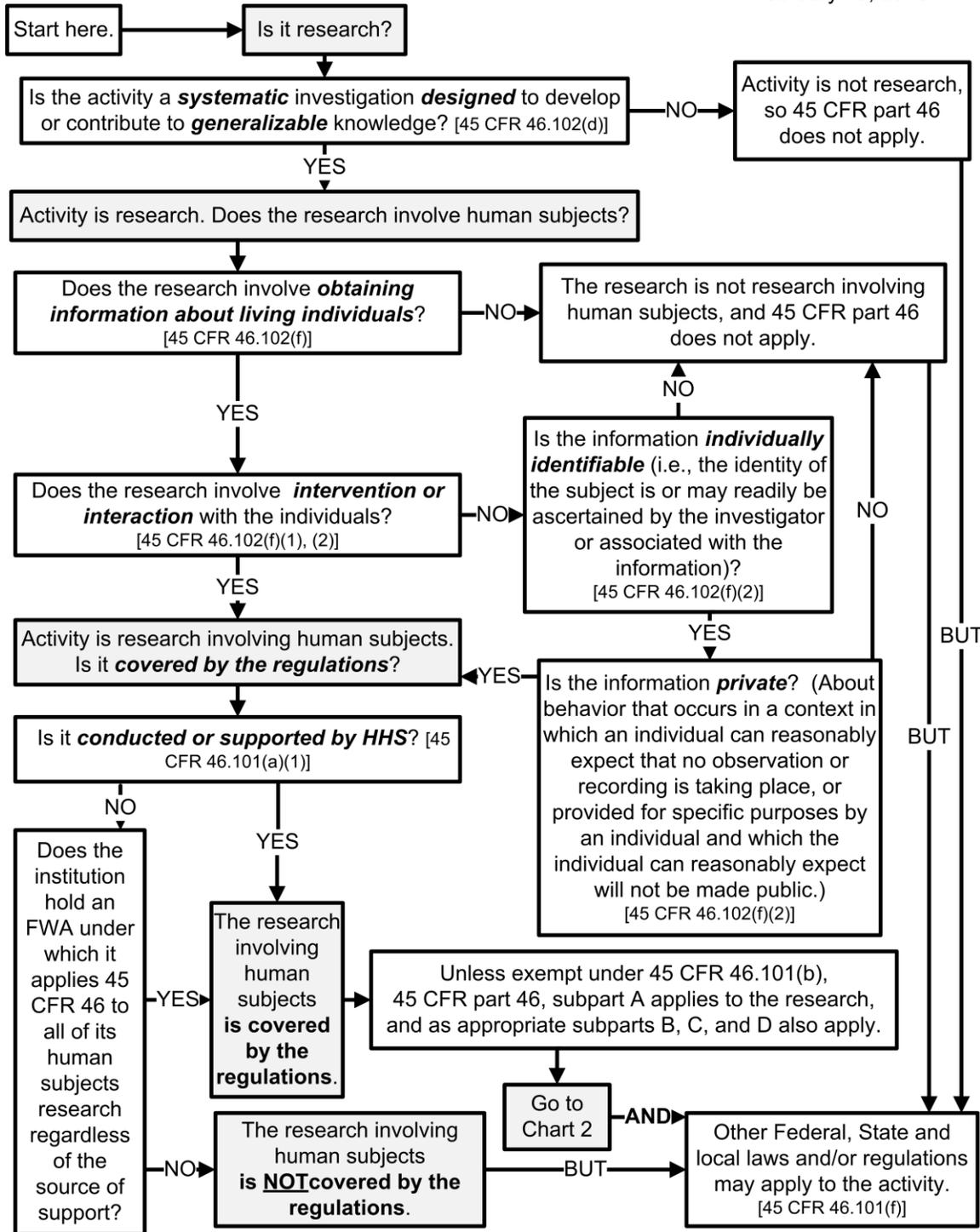


Chart 2: Is the Human Subjects Research Eligible for Exemption?

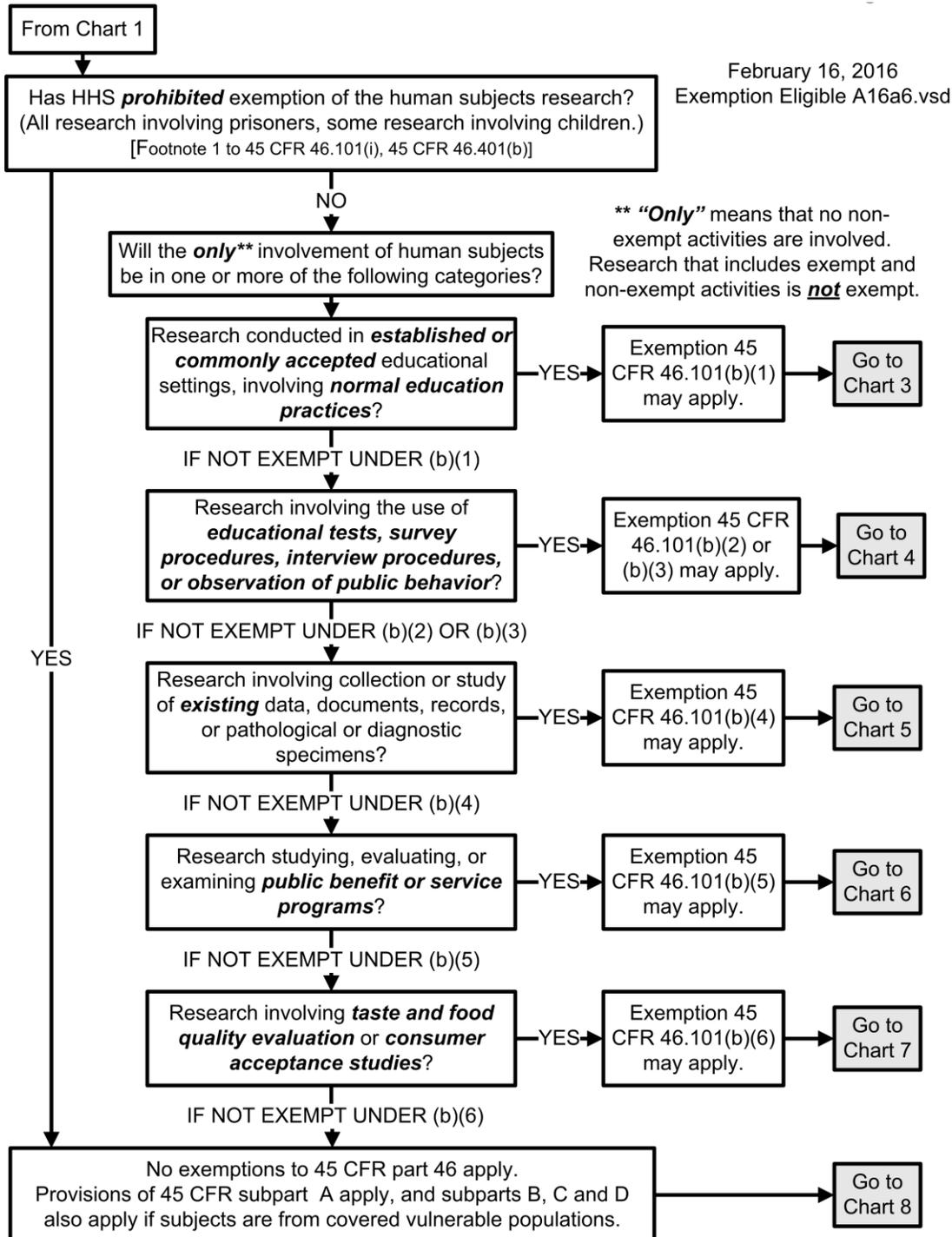
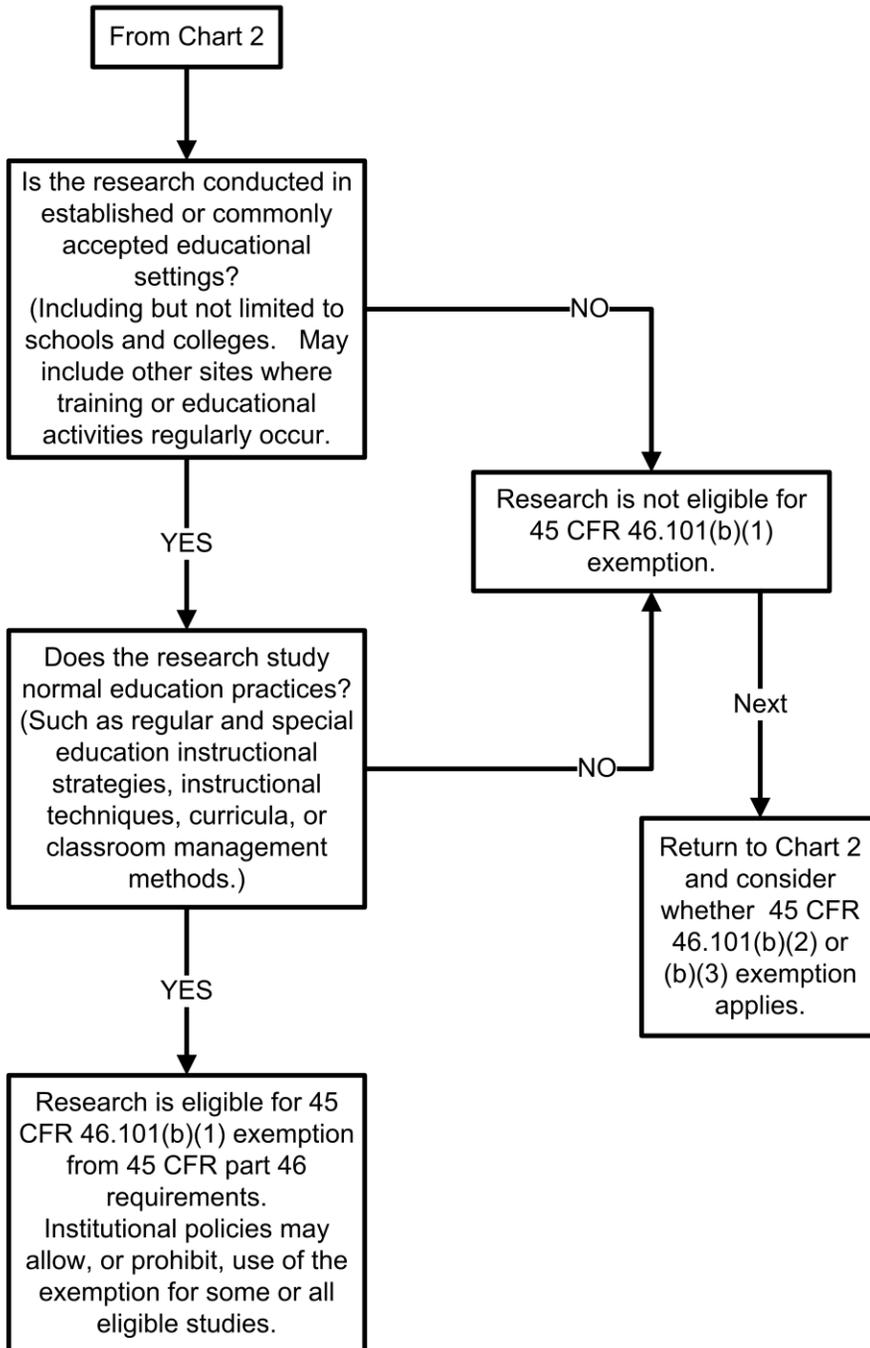


Chart 3: Does Exemption 45 CFR 46.101(b)(1) (for Educational Settings) Apply?



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Exemption Eligible (b)(1) 1a6.vsd

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

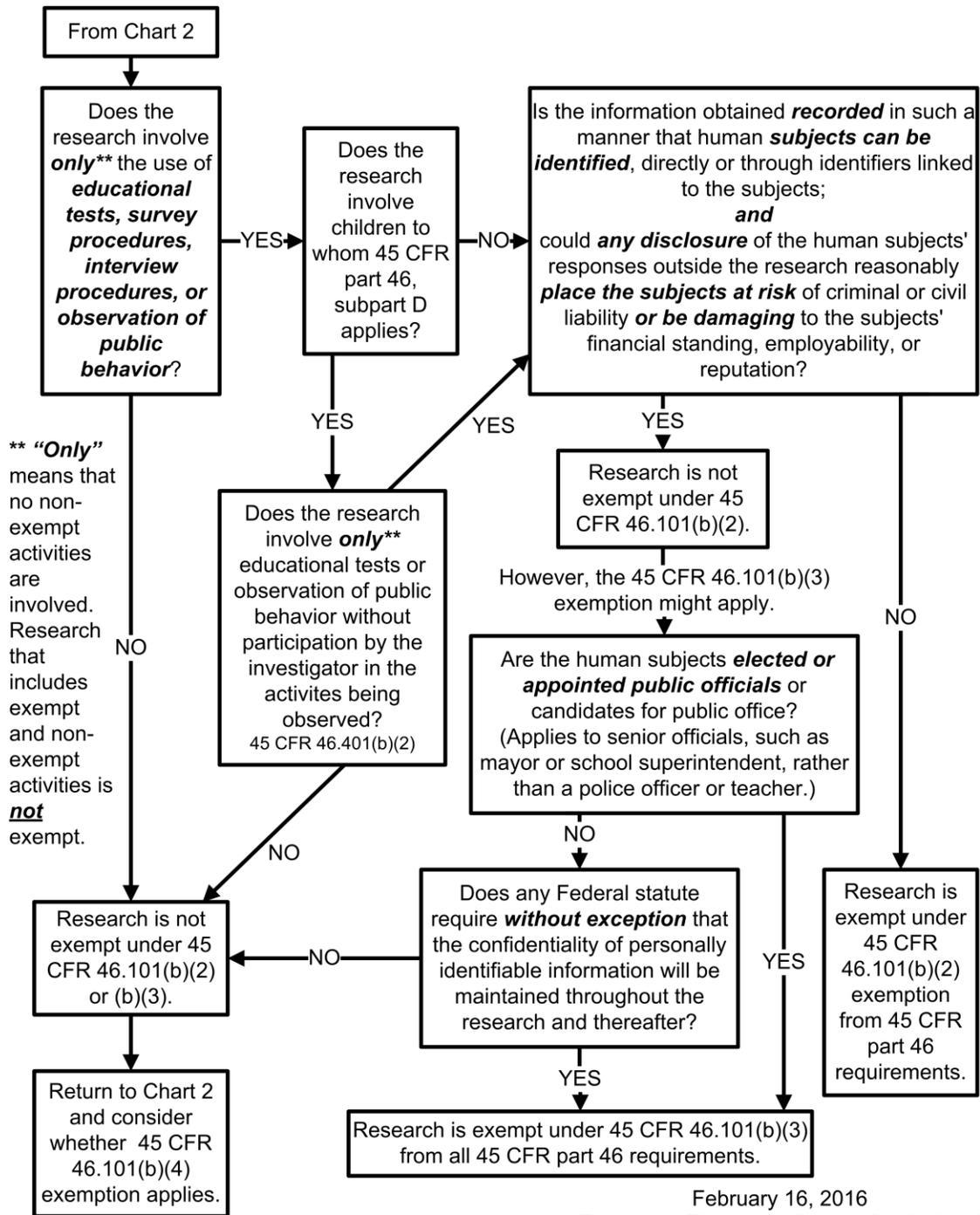
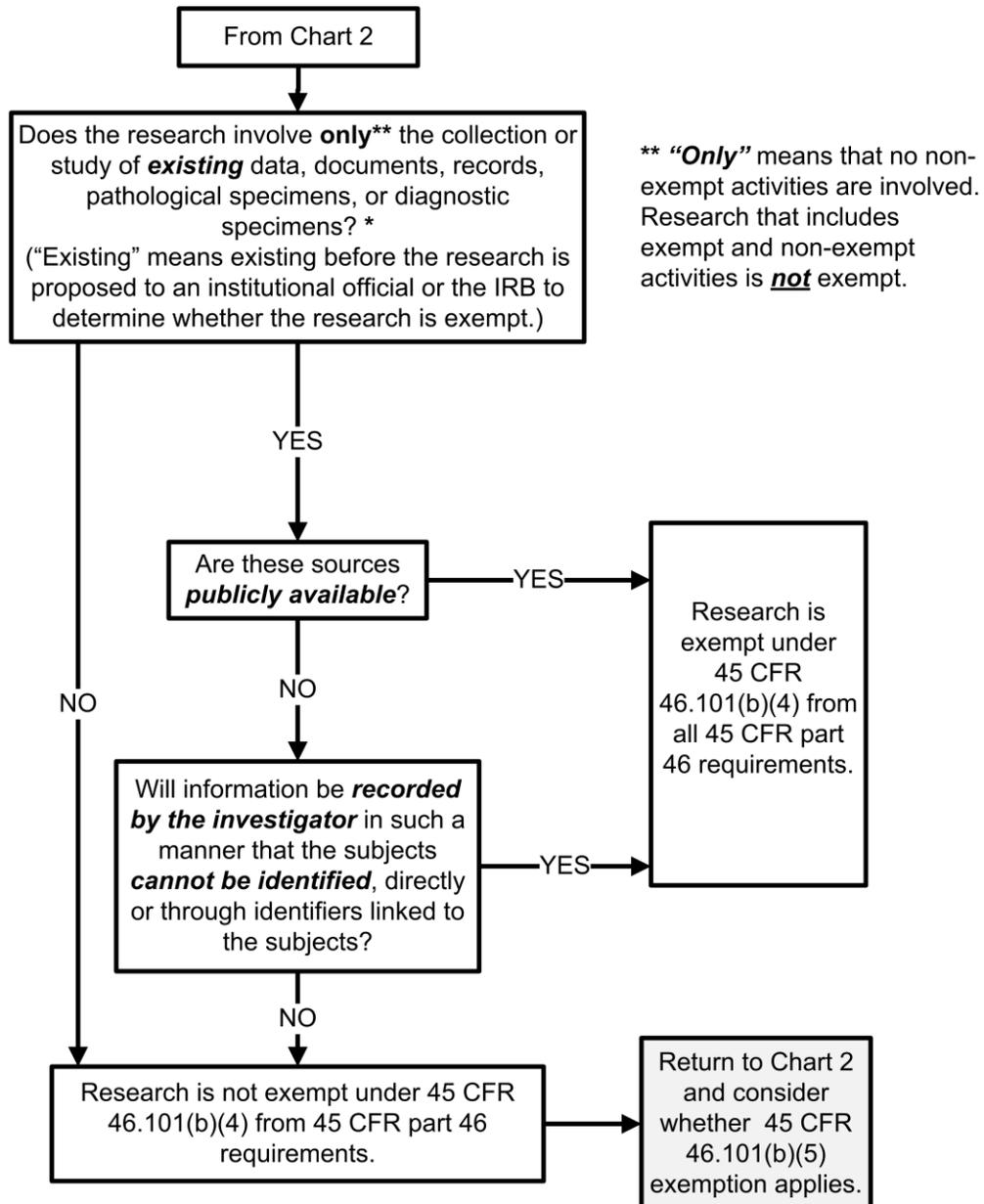


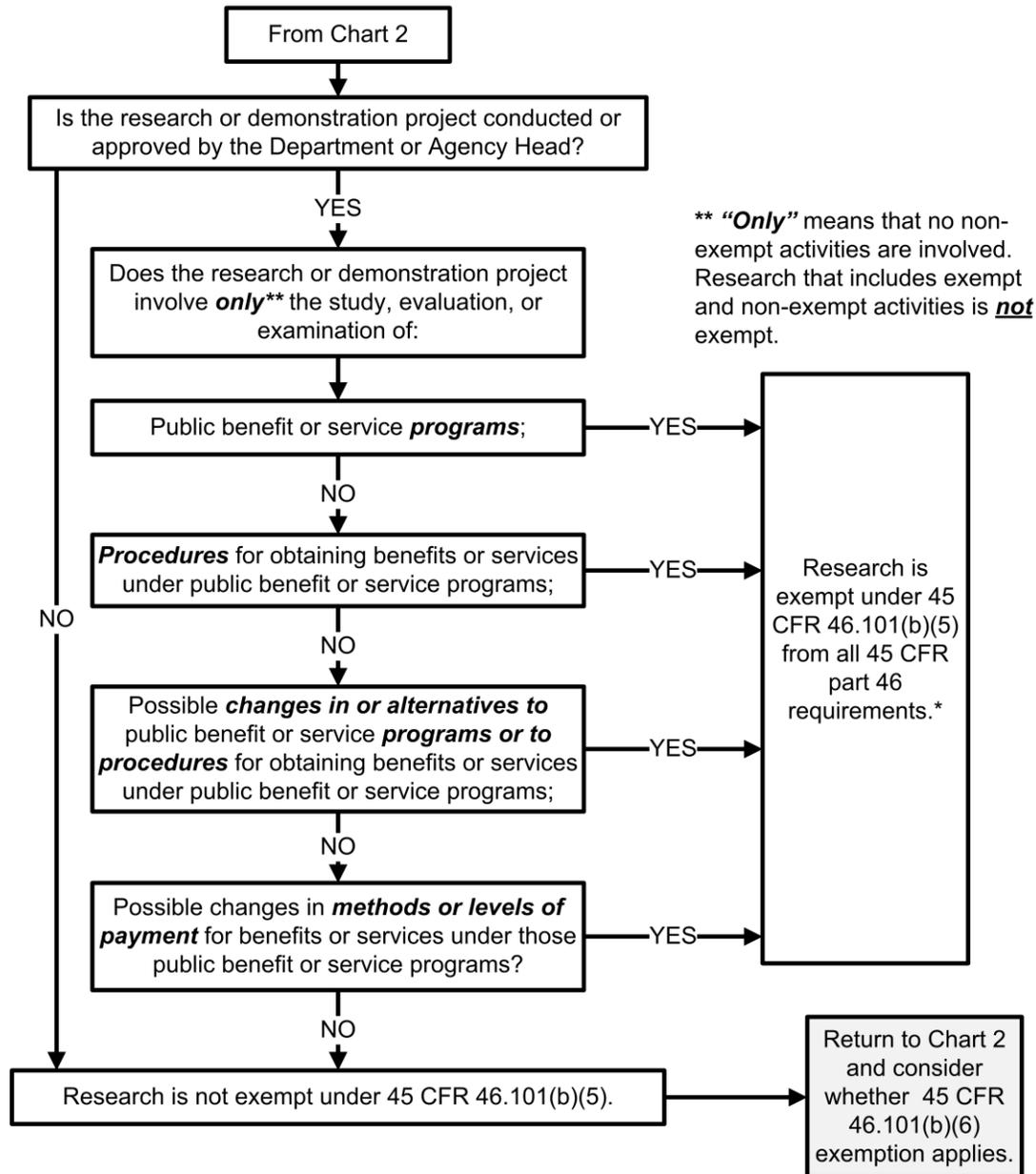
Chart 5: Does Exemption 45 CFR 46.101(b)(4) (for Existing Data, Documents, Records and Specimens) Apply?



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

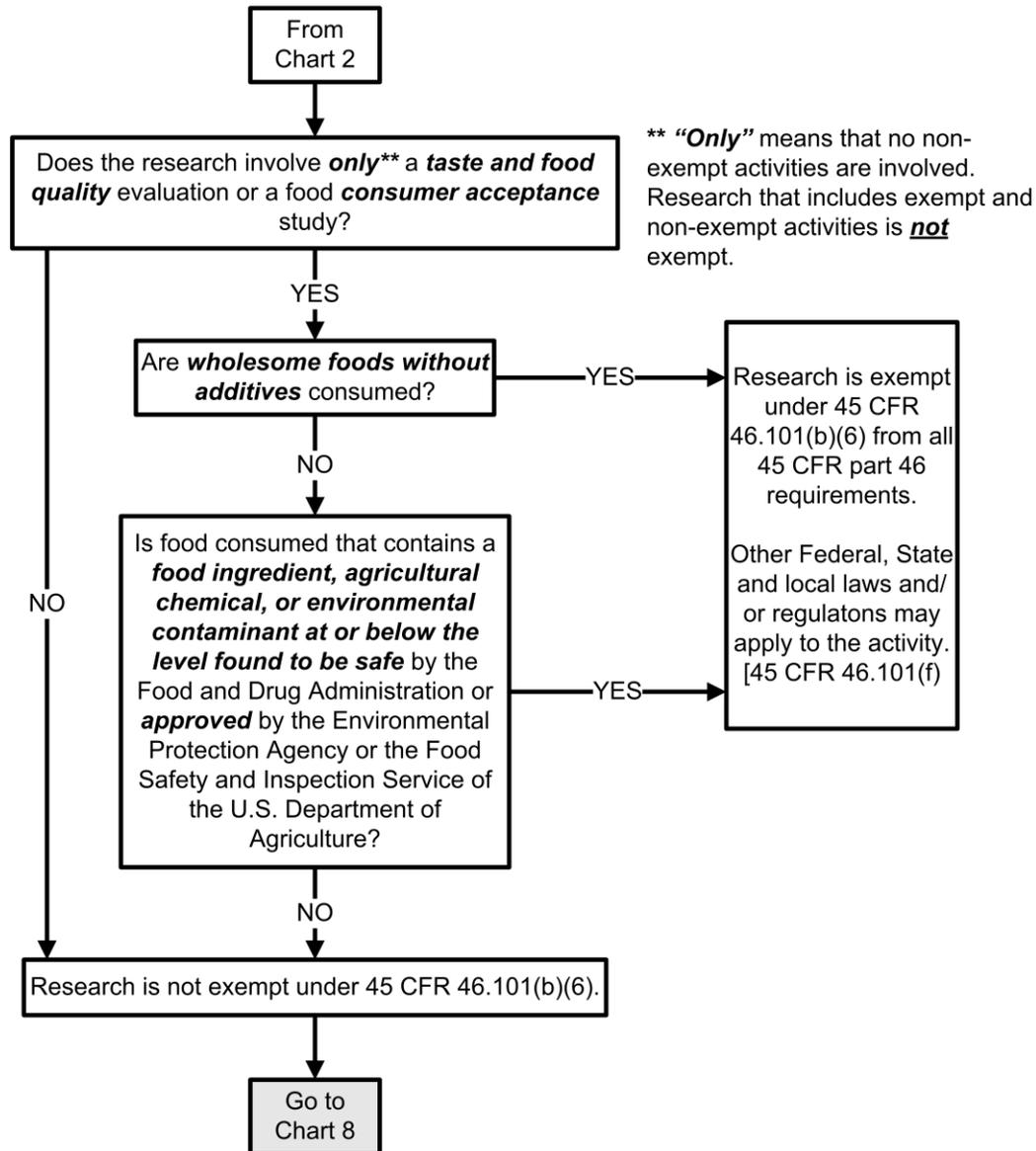
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Exemption Eligible (b)(4) 16a6.vsd

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



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

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



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Exemption Eligible (b)(6) 9a6.vsd

Chart 8: May the IRB Review Be Done by Expedited Procedures?

* Note: See expedited review categories at <http://www.hhs.gov/ohrp/policy/expedited98.html> and OHRP guidance on the use of expedited review procedures at <http://www.hhs.gov/ohrp/policy/exprev.html> for further information on expedited review.

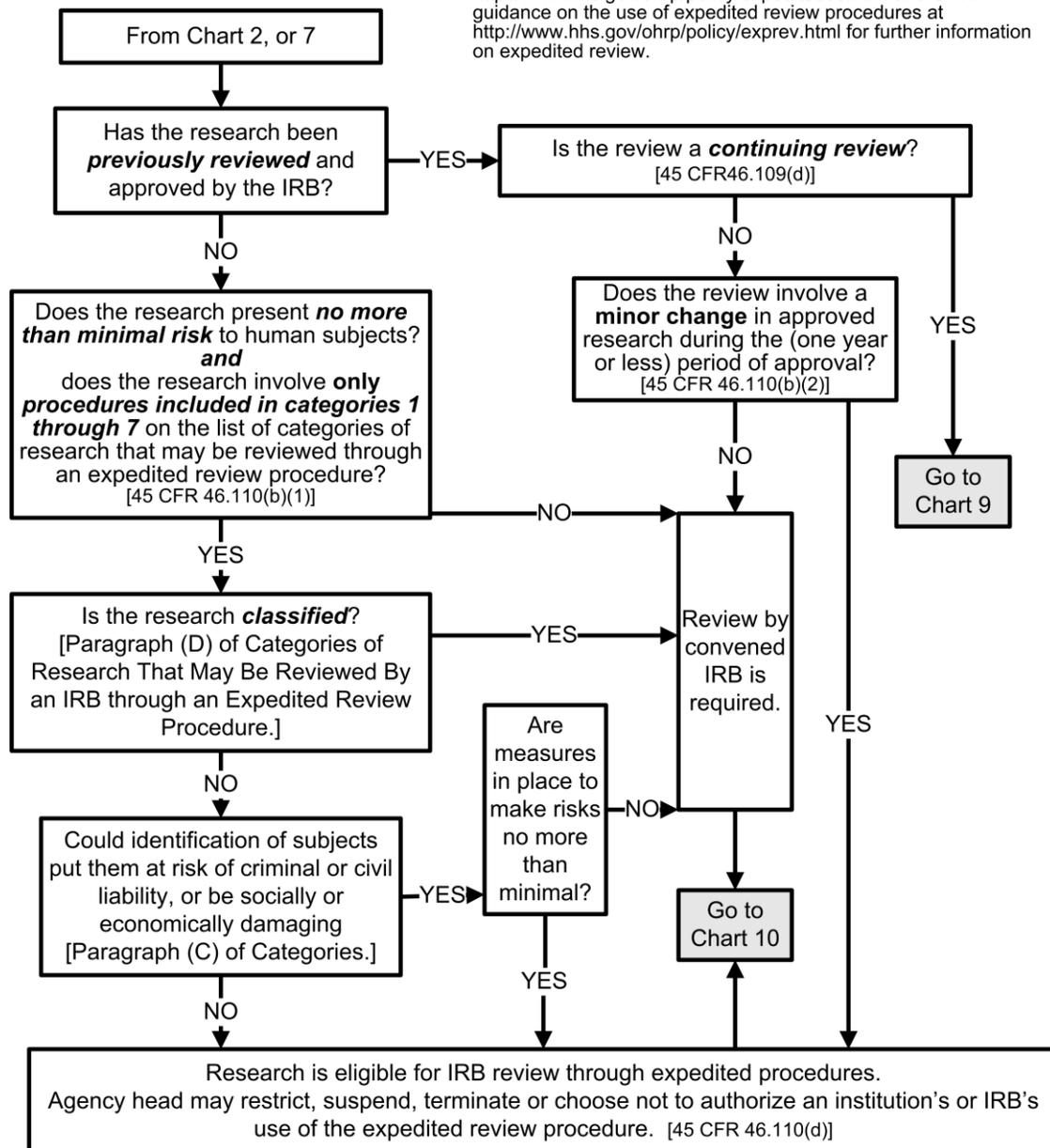


Chart 9: May the IRB Continuing Review Be Done by Expedited Procedures?

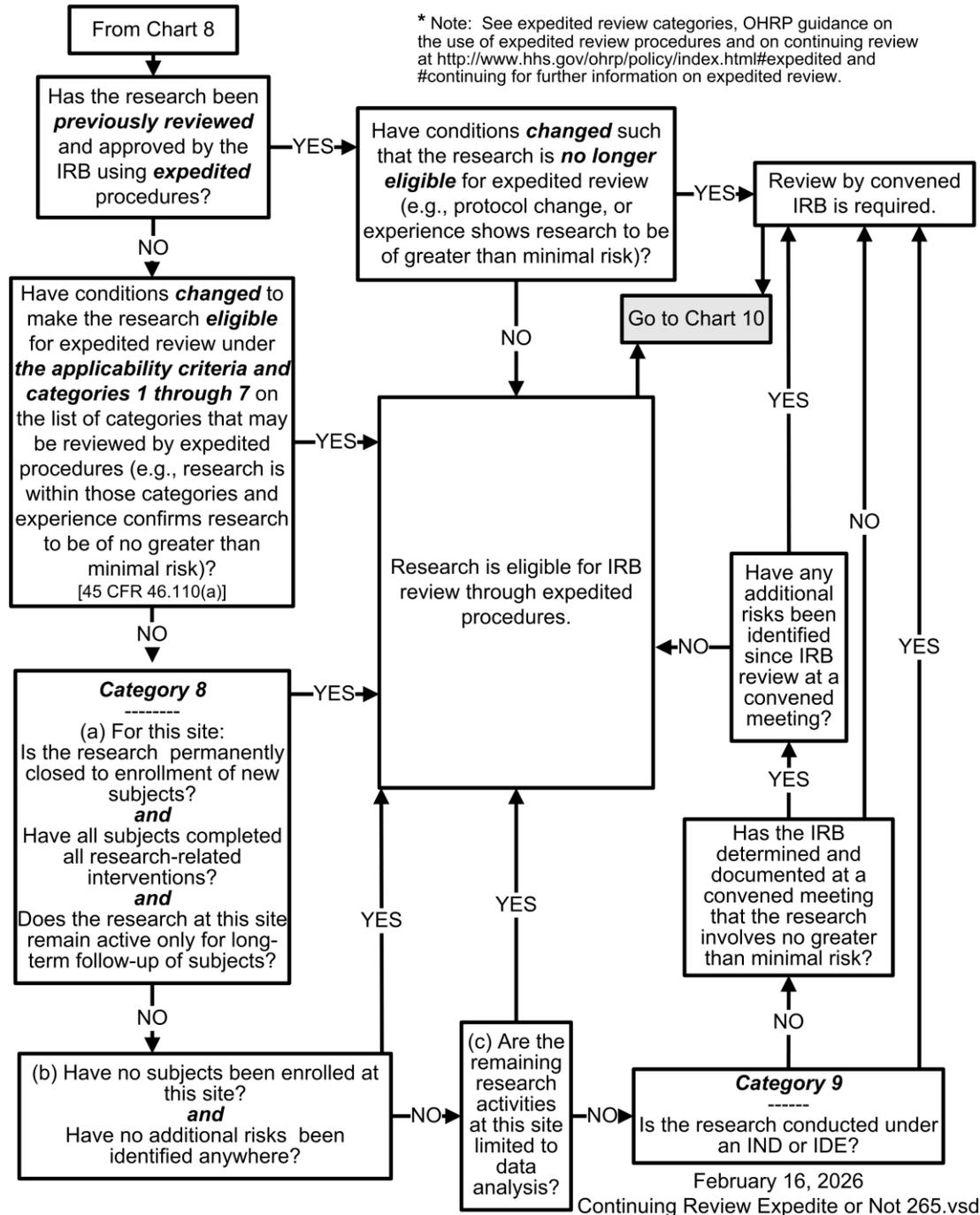
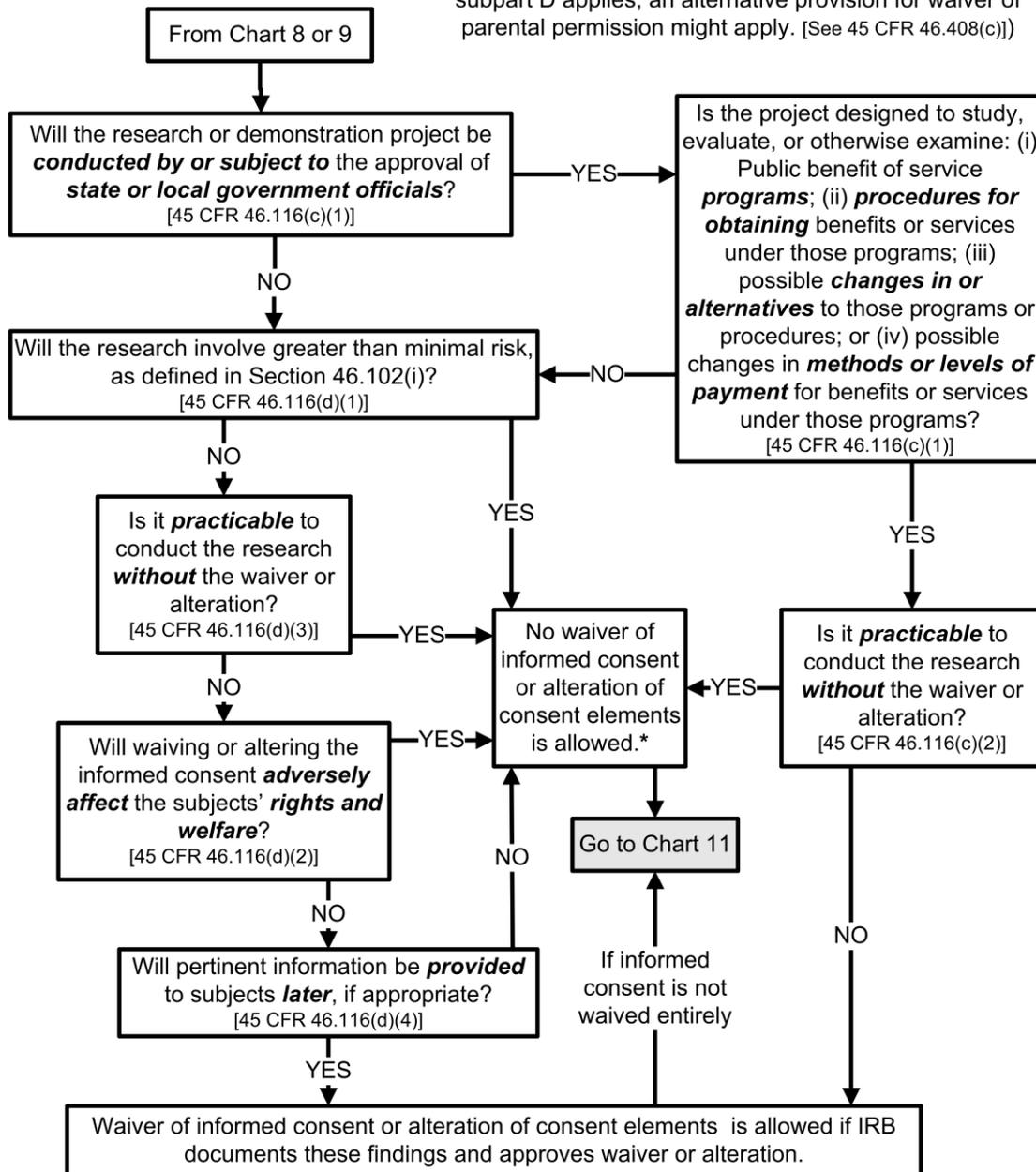


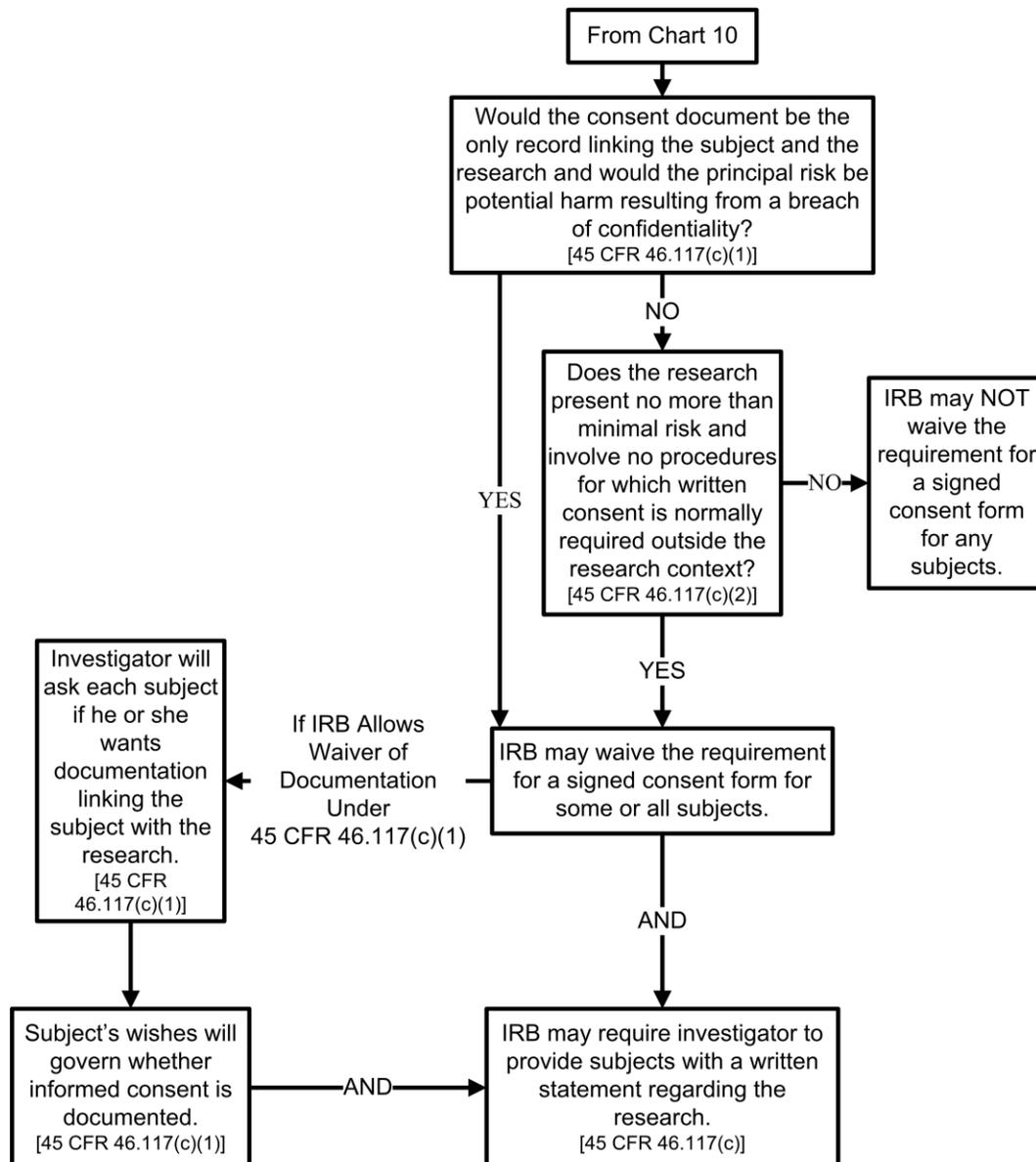
Chart 10: May Informed Consent Be Waived or Consent Elements Be Altered under 45 CFR 46.116(d)?

******(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/hsc97-01.html> for further information on emergency research informed consent waiver.

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



February 16, 2016
 Consent Documentation Waiver under 117c 10a6.vsd

DoD Instruction 3216.2, Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research

November 8, 2011



Department of Defense INSTRUCTION

NUMBER 3216.02
November 8, 2011

USD(AT&L)

SUBJECT: Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research

References: See Enclosure 1

1. **PURPOSE.** This Instruction reissues DoD Directive (DoDD) 3216.02 (Reference (a)) as a DoD Instruction in accordance with the authority in DoDD 5134.01 (Reference (b)) to establish policy and assign responsibilities for the protection of human subjects in DoD-supported programs to implement part 219 of title 32, Code of Federal Regulations (CFR) (also known and hereinafter referred to as "the Common Rule" (Reference (c))).

2. **APPLICABILITY**

a. This Instruction applies to:

(1) OSD, the Military Departments, the Office of the Chairman of the Joint Chiefs of Staff and the Joint Staff, the Combatant Commands, the Office of the Inspector General of the Department of Defense, the Defense Agencies, the DoD Field Activities, and all other organizational entities within the Department of Defense (hereinafter referred to collectively as the "DoD Components").

(2) All DoD-conducted or -supported research involving human subjects as defined in the Glossary. All such activities must include both systematic investigation designed to develop or contribute to generalizable knowledge AND involve a living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual or about whom identifiable private information is obtained. All activities meeting both of these conditions will hereinafter be referred to as "research involving human subjects" in this Instruction.

(3) Activities such as research, development, testing, and evaluation (RDT&E) that meet the definition of research involving human subjects (as defined in the Glossary), as well as clinical investigations or medical activities regulated by the Food and Drug Administration (FDA) in parts 50, 56, 312, 600, and 812 of title 21, CFR (Reference (d)).

b. Applicability is not dependent upon the budget activities funding the research, the mission of the DoD organization conducting or supporting the research, the security classification of the research, the location of the research in the United States or a foreign country, or whether the research is conducted or supported under a program that is not considered research for other purposes.

3. DEFINITIONS. See Glossary.

4. POLICY. It is DoD policy that:

a. All research involving human subjects that is conducted or supported by the Department of Defense shall comply with part 219 of Reference (c), which incorporates the ethical principles of respect for persons, beneficence, and justice, as codified in page 23192 of the Federal Register (also known as "The Belmont Report" (Reference (e))).

b. Certain categories of human subjects in research are recognized as vulnerable populations, groups, or individuals and are afforded additional protections as specified in section 7 of Enclosure 3 of this Instruction.

c. Research involving human subjects for testing of chemical or biological warfare agents is generally prohibited by section 1520a of title 50, United States Code (U.S.C.) (Reference (f)), subject to possible exceptions for research for prophylactic, protective, or other peaceful purposes.

d. DoD-appropriated funds shall not be used to support research involving a human being as an experimental subject, as defined in this Instruction, without the prior informed consent of the experimental subject or in accordance with section 980 of title 10, U.S.C. (Reference (g)) and this Instruction (see section 9 of Enclosure 3 of this Instruction for details). The definitions of research involving a human being as an experimental subject and research involving human subjects are different; see the Glossary for an explanation.

e. Research involving human subjects covered under this Instruction shall also comply with applicable Federal and State laws and regulations. When the research is conducted outside of the United States, it must also comply with applicable requirements of the foreign country and its national laws and requirements. In the event of an unresolved conflict between this Instruction, including its references, and other applicable laws and requirements such that compliance with both is impossible, the requirements most protective of the human subjects shall be followed. When there is an unresolved conflict, DoD Components shall consult with legal counsel and seek guidance from the Assistant Secretary of Defense for Research and Engineering (ASD(R&E)).

6. PROCEDURES. See Enclosure 3.

7. RELEASABILITY. UNLIMITED. This Instruction is approved for public release and is available on the Internet from the DoD Issuances Website at <http://www.dtic.mil/whs/directives>.

8. EFFECTIVE DATE. This Instruction is effective upon its publication to the DoD Issuances Website.



Frank Kendall
Acting Under Secretary of Defense
for Acquisition, Technology, and Logistics

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Glossary

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