Chart 1: Is an activity research involving human subjects covered by 45 CFR 46?

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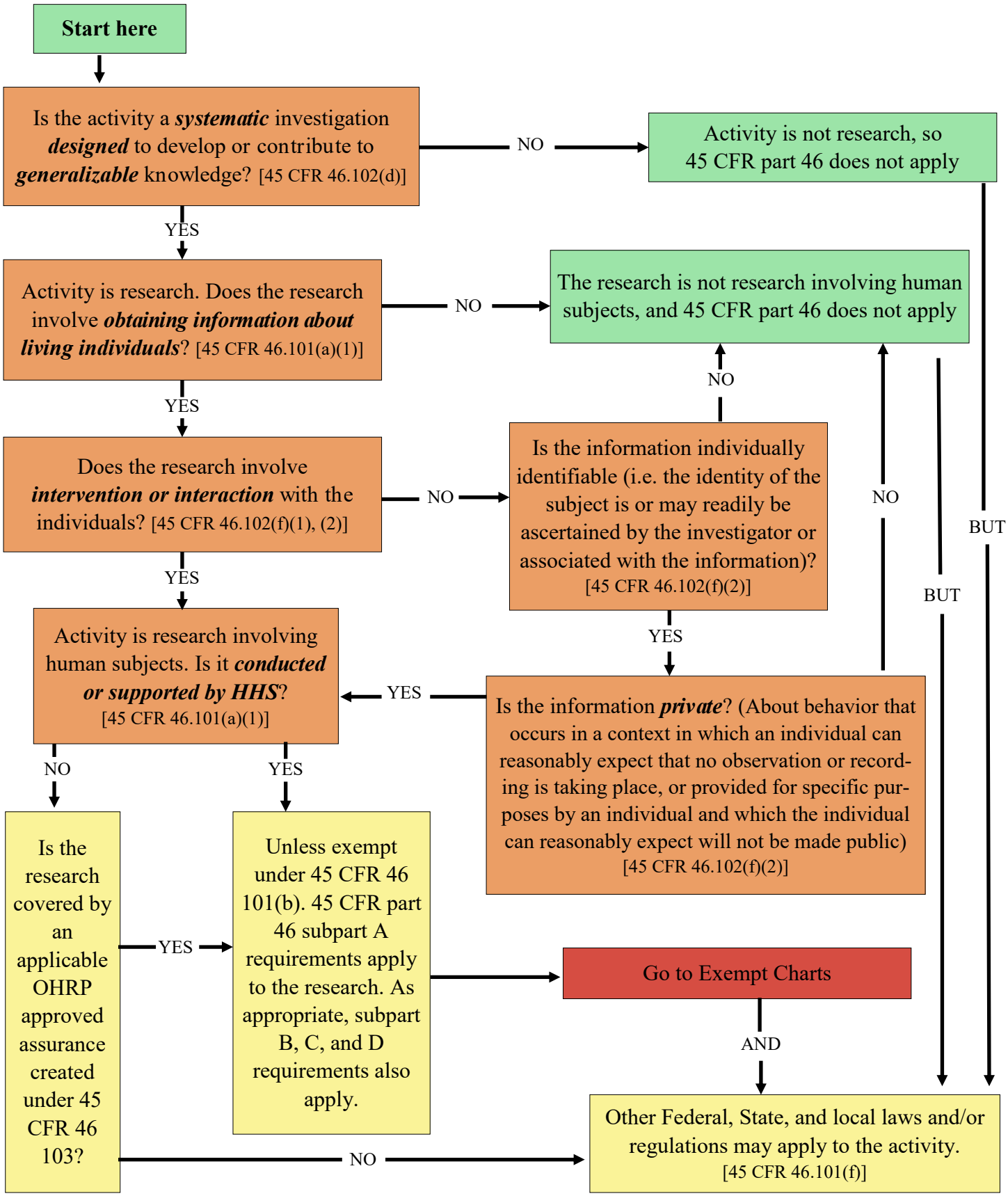
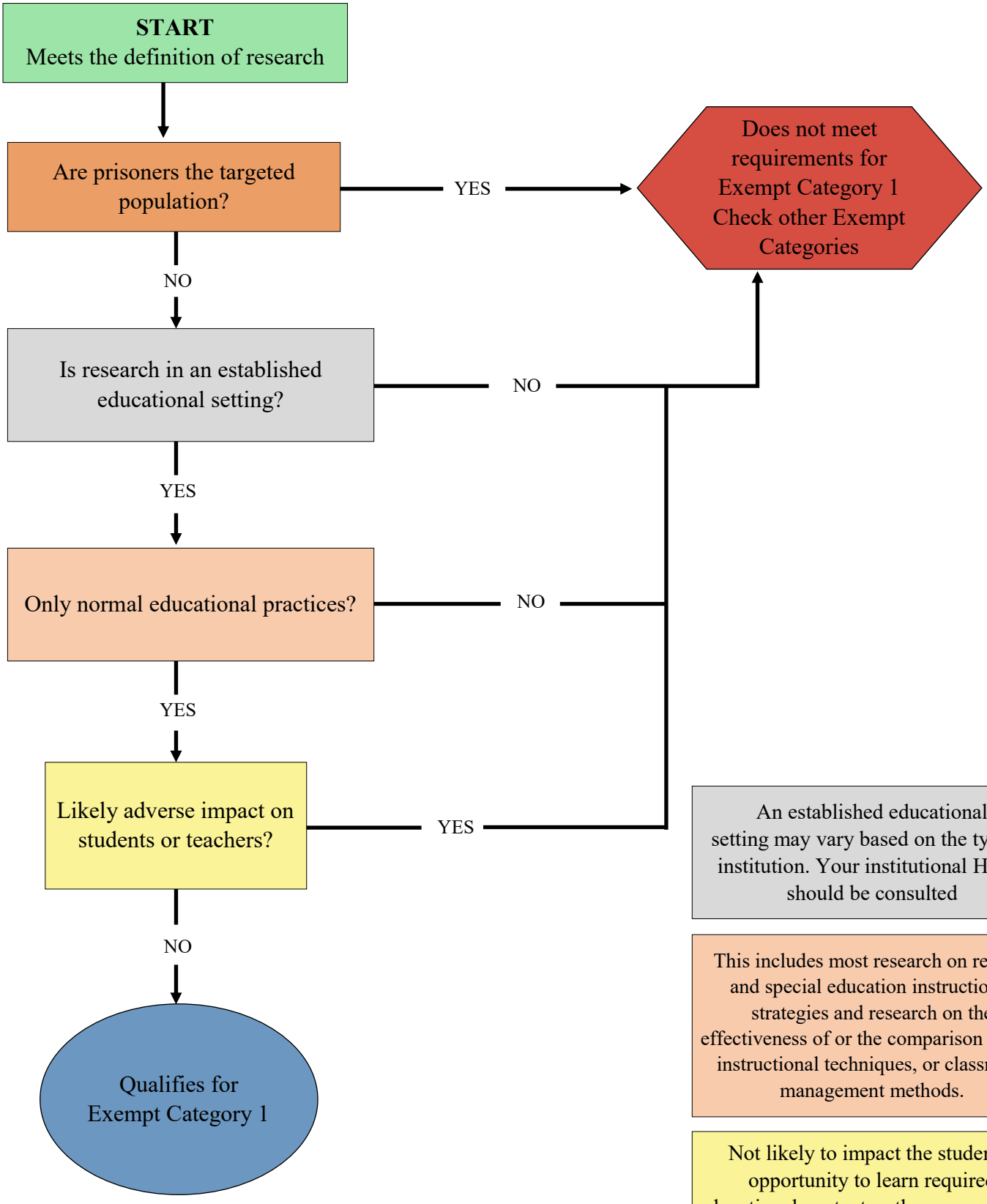


Chart 2: 2019 Exempt Category 1 Educational Setting

Revised 02-2019



An established educational setting may vary based on the type of institution. Your institutional HRPP should be consulted

This includes most research on regular and special education instructional strategies and research on the effectiveness of or the comparison among instructional techniques, or classroom management methods.

Not likely to impact the student's opportunity to learn required educational content or the assessment of educators who provide instruction.

Chart 3: 2019 Exempt Category 2 Educational Tests, Surveys, Interviews, Observations of Public Behavior

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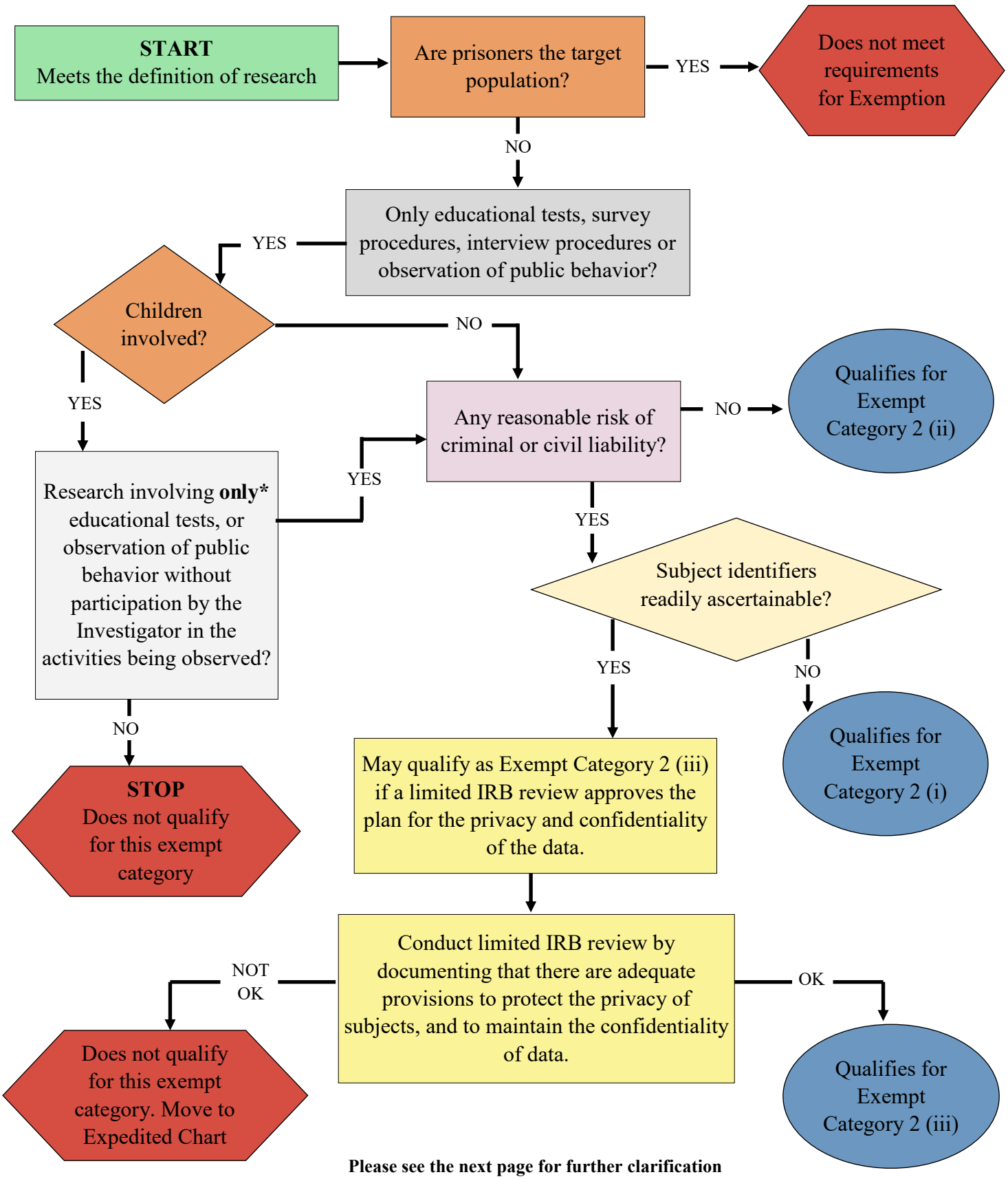

Please see the next page for further clarification

2019 Exempt Category 2
Educational Tests, Surveys,
Interviews, Observations of Public Behavior
Clarification for Chart Questions

Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording).

Identifiers: The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects.

Any disclosure of the human subjects' responses outside of the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation.

The exempt category does not apply if the investigator participates in the activities involved in the educational test or the public behavior being observed.

A protocol need only meet **ONE** of the requirements to meet the exemption

Chart 4: 2019 Exempt Category 3 Benign Behavioral Interventions Use

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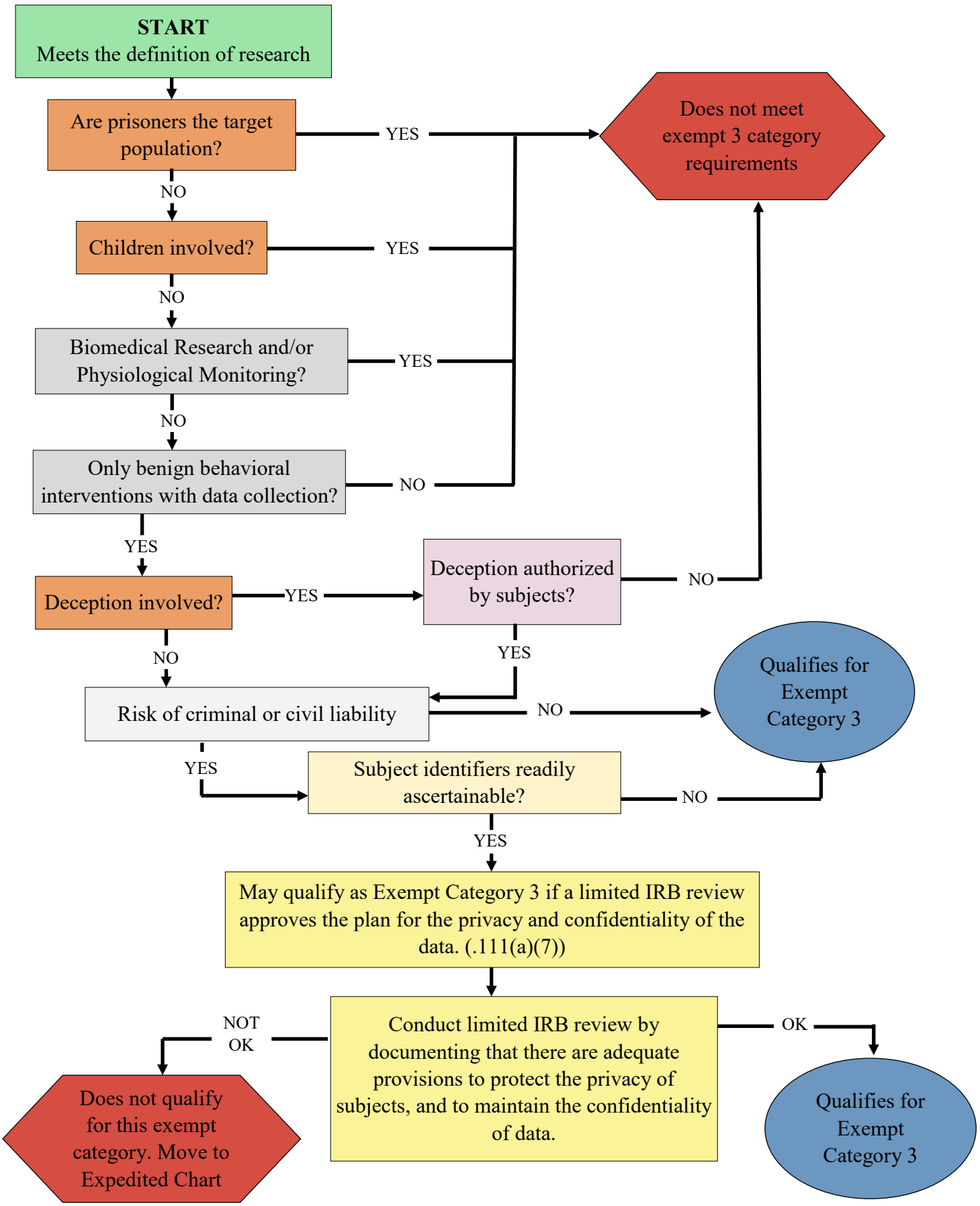


Please see the next page for further clarification

2019 Exempt Category 3
Benign Behavioral Interventions Use
Clarification for Chart Questions

Benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the intervention offensive or embarrassing.

Identifiers: The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects.

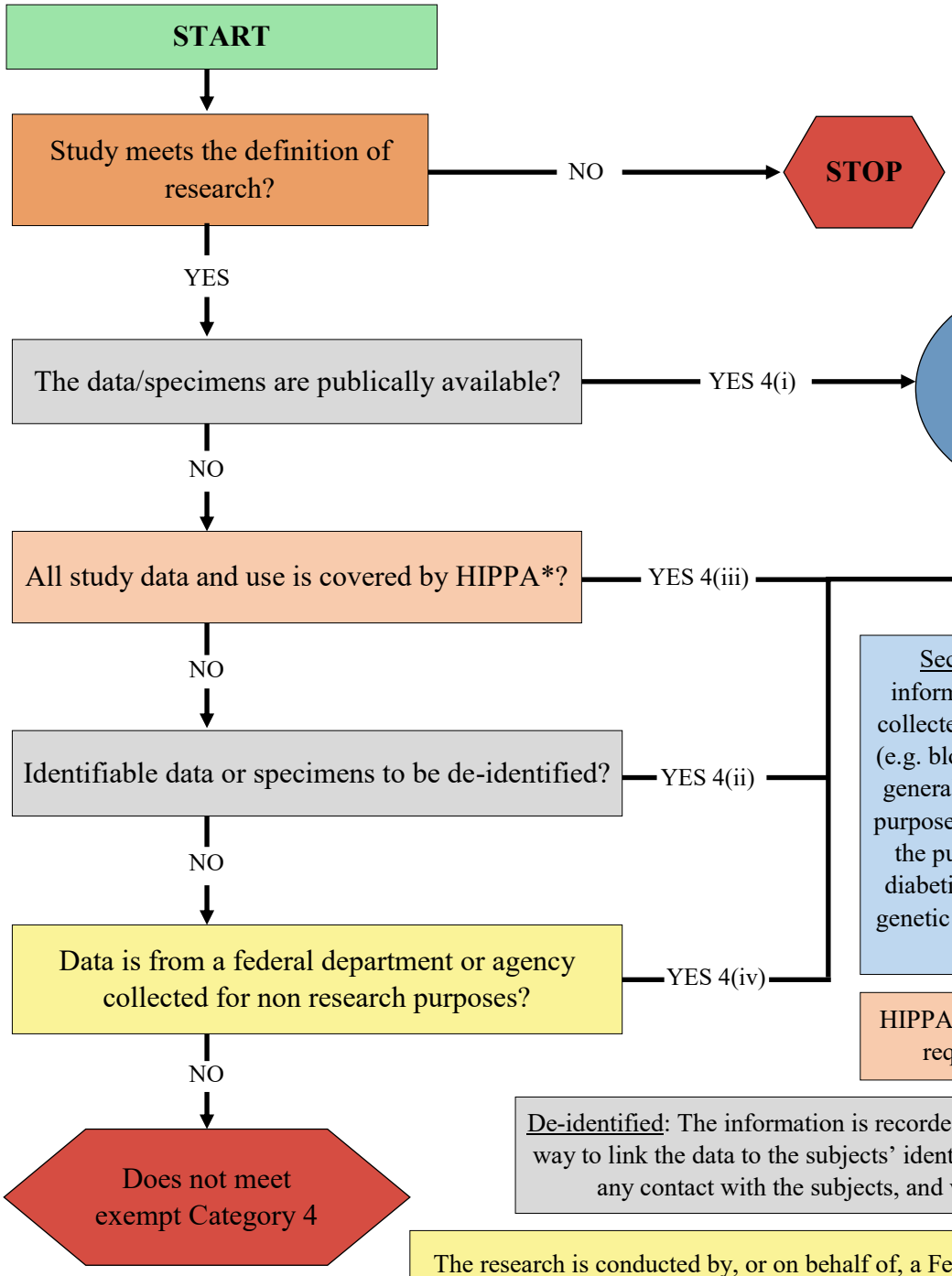
104.(d)(2)(ii) Any disclosure of the human subjects responses outside the research would not reasonably place the subject at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation.

The subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature of purposes of the research.

Physiologic monitoring is not included in this exemption

Chart 5: 2019 Exempt Category 4: Secondary Use of Identifiable Data or Specimens

Revised 02-2019



Secondary Data: Research use of information or bio specimen originally collected for: (a) Non– research purposes (e.g. blood left from routine clinical tests, general information collected for census purposes); (b) Research studies other than the purposed one (e.g. evaluating new diabetic drug to conduct a new study on genetic predisposition of diabetic patients to Alzheimer's disease)

HIPPA Rules apply and study must meet requirements for HIPPA waiver.

De-identified: The information is recorded in a way that there is no possible way to link the data to the subjects' identities, the researcher does not have any contact with the subjects, and will not re-identify the data.

The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C.3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in system of records subjet to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

Chart 6: 2019 Exempt Category 5: Research and Demonstration Projects

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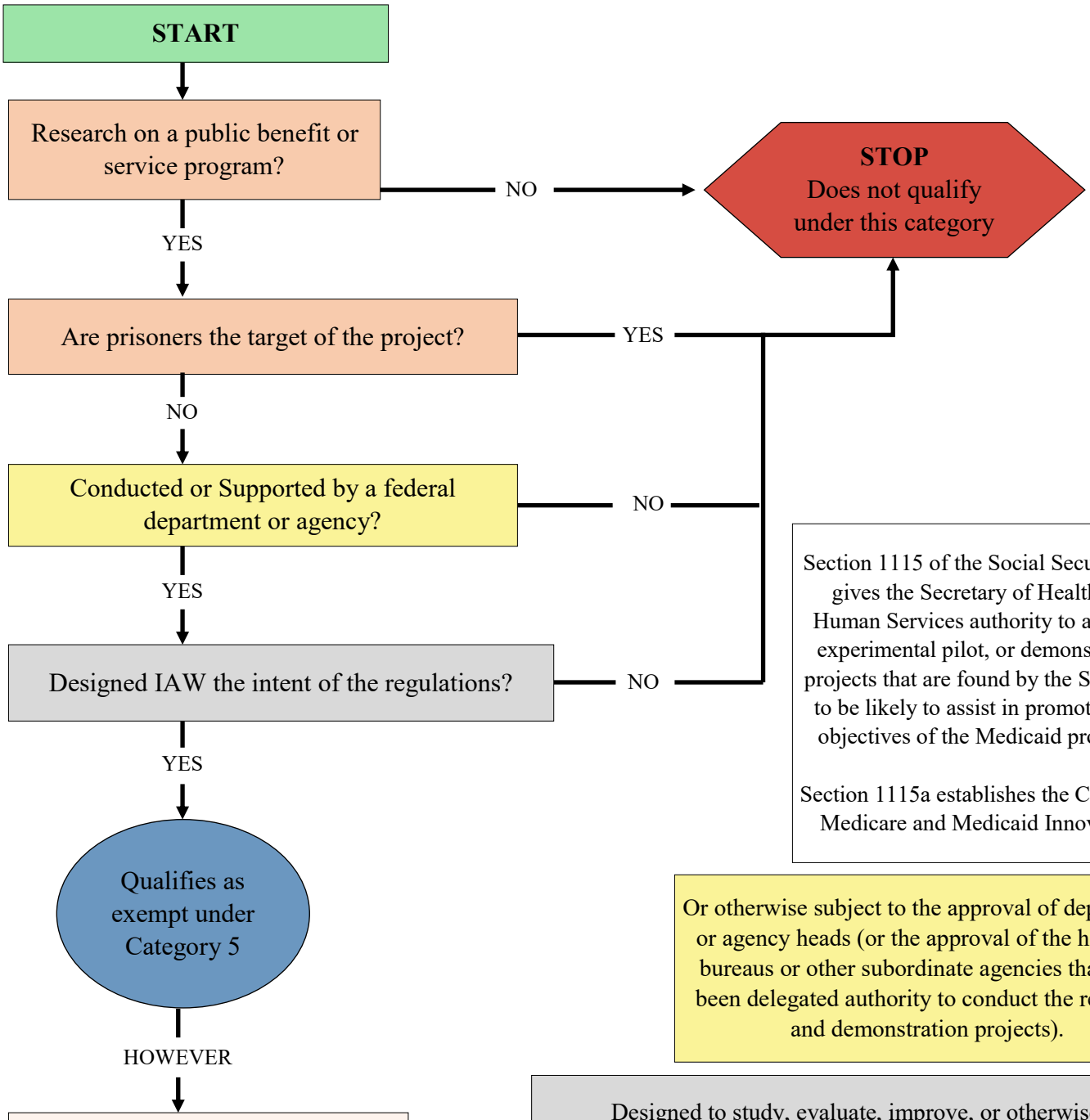


Section 1115 of the Social Security Act gives the Secretary of Health and Human Services authority to approve experimental pilot, or demonstration projects that are found by the Secretary to be likely to assist in promoting the objectives of the Medicaid program.

Section 1115a establishes the Center for Medicare and Medicaid Innovation.

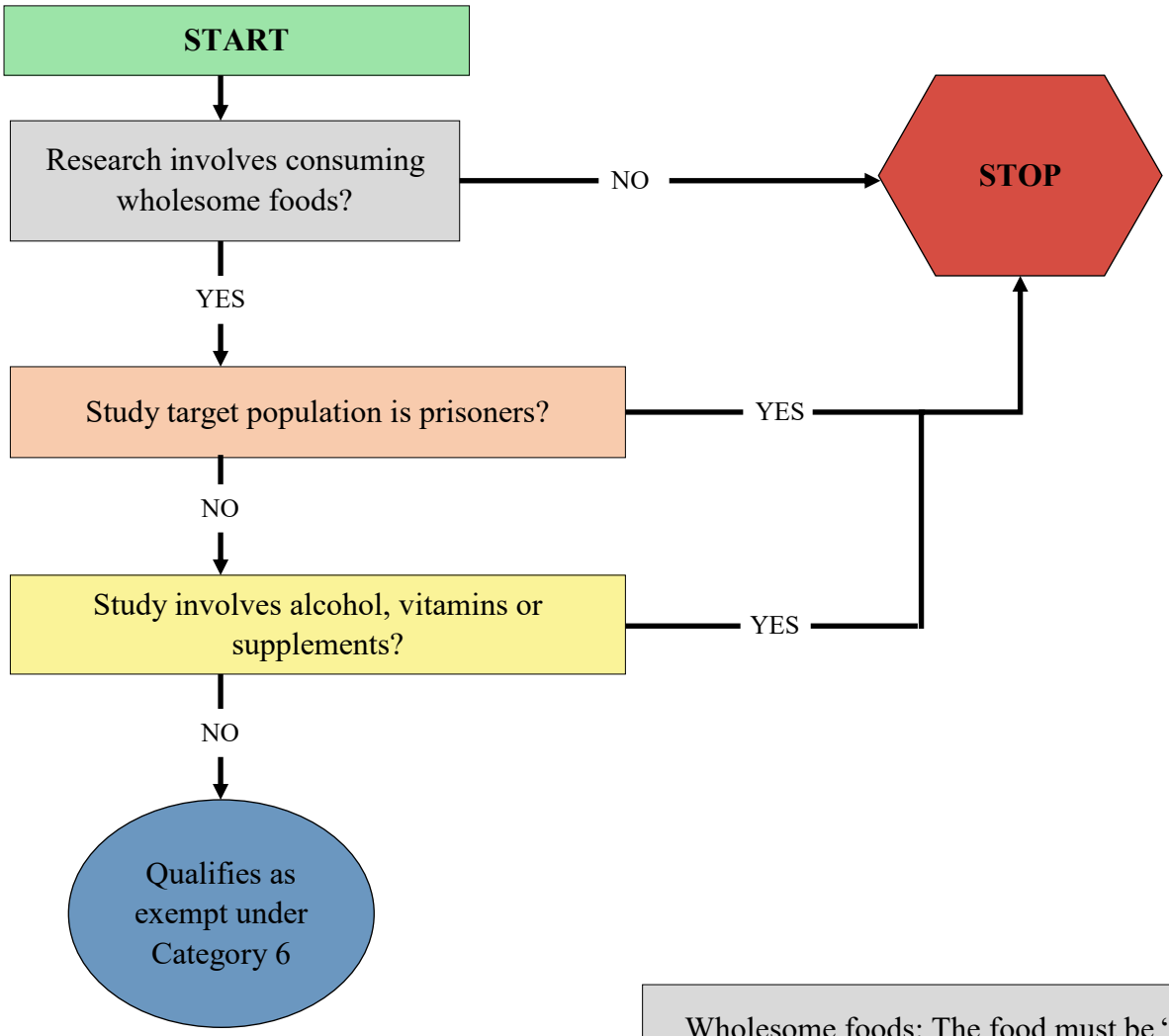
Or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects).

Designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs.

Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants.

Chart 7: 2019 Exempt Category 6: Taste and Food Quality

Revised 02-2019

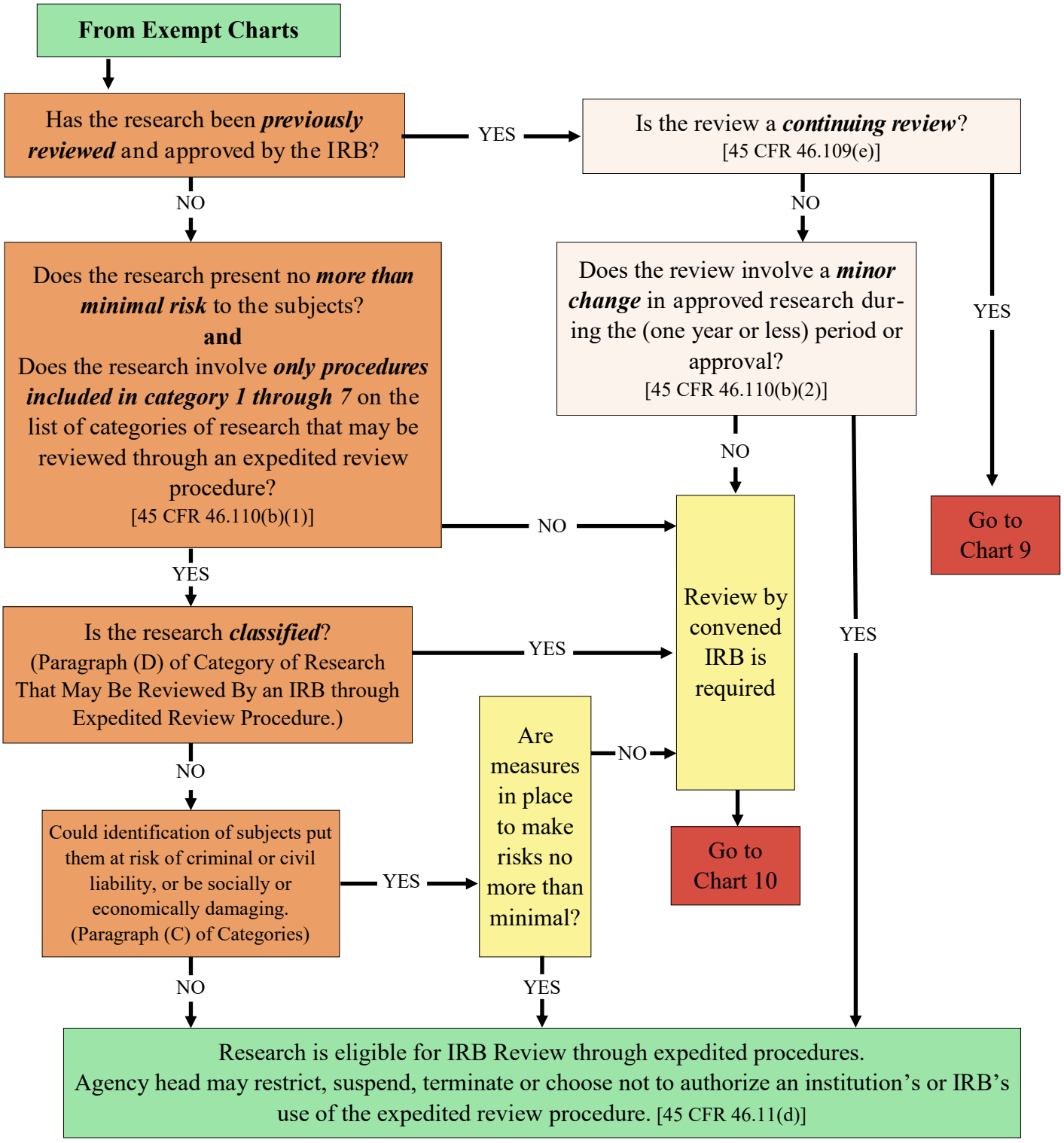


Wholesome foods: The food must be "wholesome" (no additives), or if it involves plants or animals raised for food products, the level of chemical additives or environmental contaminants must be at or below the levels approved by the FDA, EPA, or USDA.

Studies involving the consumption of alcohol, vitamins, and other supplements do not qualify for exempt status.

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

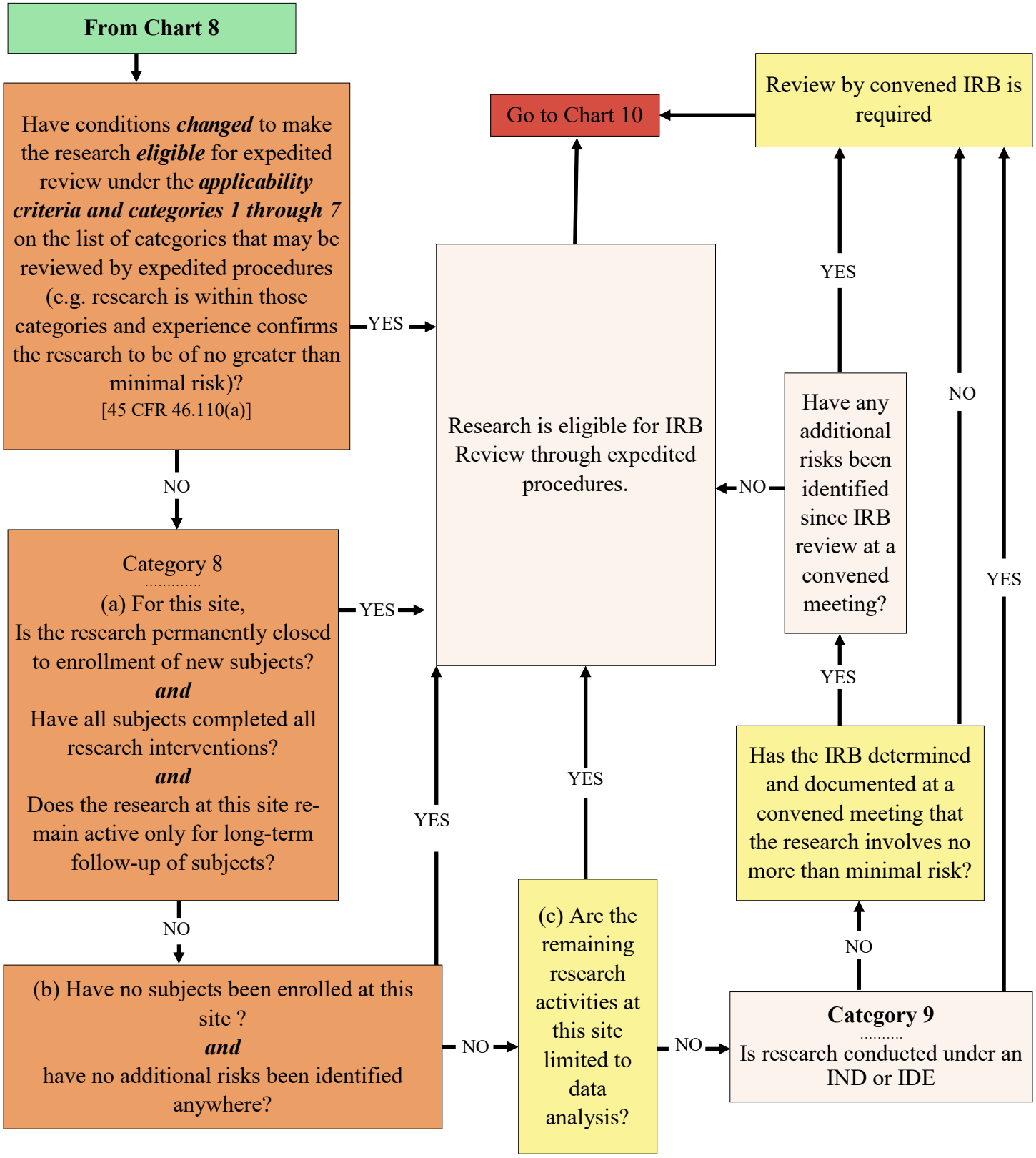
Revised 02-2019



Note: See expedited review categories 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: Can Full Board Review be Done by Expedited Procedures Under 45 CFR 46.110?

Revised 02-2019



Note: See expedited review categories 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 10: Can Informed Consent be Waived or Consent Elements Be Altered Under 45 CFR 46.116(c) or (d)?

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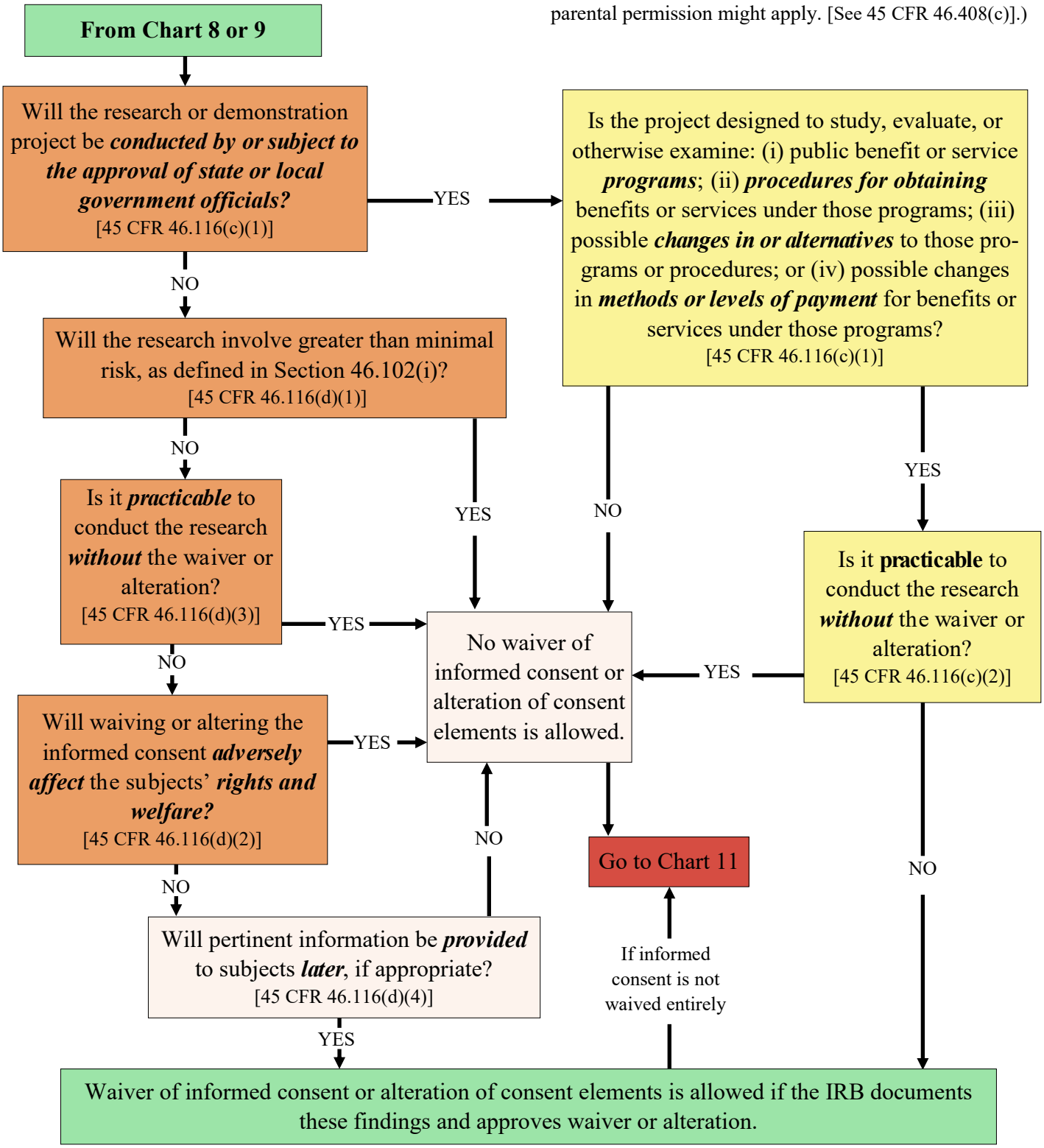
**(Note: If subjects include children to whom 45 CFR part 46, subpart D applies, an alternative provision for waiver of parental permission might apply. [See 45 CFR 46.408(c)].)



Note: See expedited review categories 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 11: Can Documentation of Informed Consent Be Waived Under 45 CFR 46.117(c)?

Revised 02-2019