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Human Subject Regulations Decision Charts: 2018 Requirements

DATE: June 23, 2020

NOTE: These decision charts are consistent with the 2018 Requirements (i.e., the revised Common Rule).

Scope:

The following graphic charts are intended to aid those who need to decide if an activity is research involving human subjects that must be reviewed by an institutional review board (IRB) and whether informed consent or the documentation of informed consent can be waived under the 2018 Requirements found for the U.S. Department of Health and Human Services (HHS) at 45 CFR part 46, Subpart A.

Target Audience:

IRBs, institutions, investigators, and others

Considerations:

These charts are necessarily generalizations and may not be specific enough for particular situations. Other documents are available related to specific topics at [<https://www.hhs.gov/ohrp/regulations-and-policy/guidance/index.html>](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/index.html). OHRP cautions that the full text of an applicable regulatory provision should be considered in making final decisions. The charts do not address requirements that may be imposed by other organizations, such as the Food and Drug Administration, the National Institutes of Health, other sponsors, or state or local governments.

- Chart 01: Is an Activity Human Subjects Research Covered by 45 CFR Part 46?
- Chart 02: Is the Research Involving Human Subjects Eligible for Exemption Under 45 CFR 46.104(d)?
- Chart 03: Does Exemption 45 CFR 46.104(d)(1) for Educational Practices Apply?
- Chart 04: Does Exemption 45 CFR 46.104(d)(2) for Educational Tests, Surveys, Interviews, or Observation of Public Behavior Apply?
- Chart 05: Does Exemption 45 CFR 46.104(d)(3) for Benign Behavioral Interventions Apply?
- Chart 06: Does Exemption 45 CFR 46.104(d)(4) for Secondary Research that Does Not Require Consent Apply?
- Chart 07: Does Exemption 45 CFR 46.104(d)(5) for Public Benefit or Service Programs Apply?
- Chart 08: Does Exemption 45 CFR 46.104(d)(6) for Food Taste and Acceptance Studies Apply?
- Chart 09: Does Exemption 45 CFR 46.104(d)(7), Storage for Secondary Research for Which Broad Consent Is Required, Apply?
- Chart 10: Does Exemption 45 CFR 46.104(d)(8) for Secondary Research for Which Broad Consent Is Required Apply?
- Chart 11: Is Continuing Review Required Under 45 CFR 46.109(f)?

- Chart 12: Waiver or Alteration of Informed Consent in Research Involving Public Benefit and Service Programs Conducted by or Subject to the Approval of State or Local Government Officials (45 CFR 46.116(e))
- Chart 13: When Can Informed Consent Be Waived or Altered Under 45 CFR 46.116(f)?
- Chart 14: Can Documentation of Informed Consent Be Waived Under 45 CFR 46.117(c)?

Download Decision Charts in PDF format - PDF

</ohrp/sites/default/files/human-subject-regulations-decision-charts-2018-requirements.pdf>

Chart 01: Is an Activity Human Subjects Research Covered by 45 CFR Part 46?

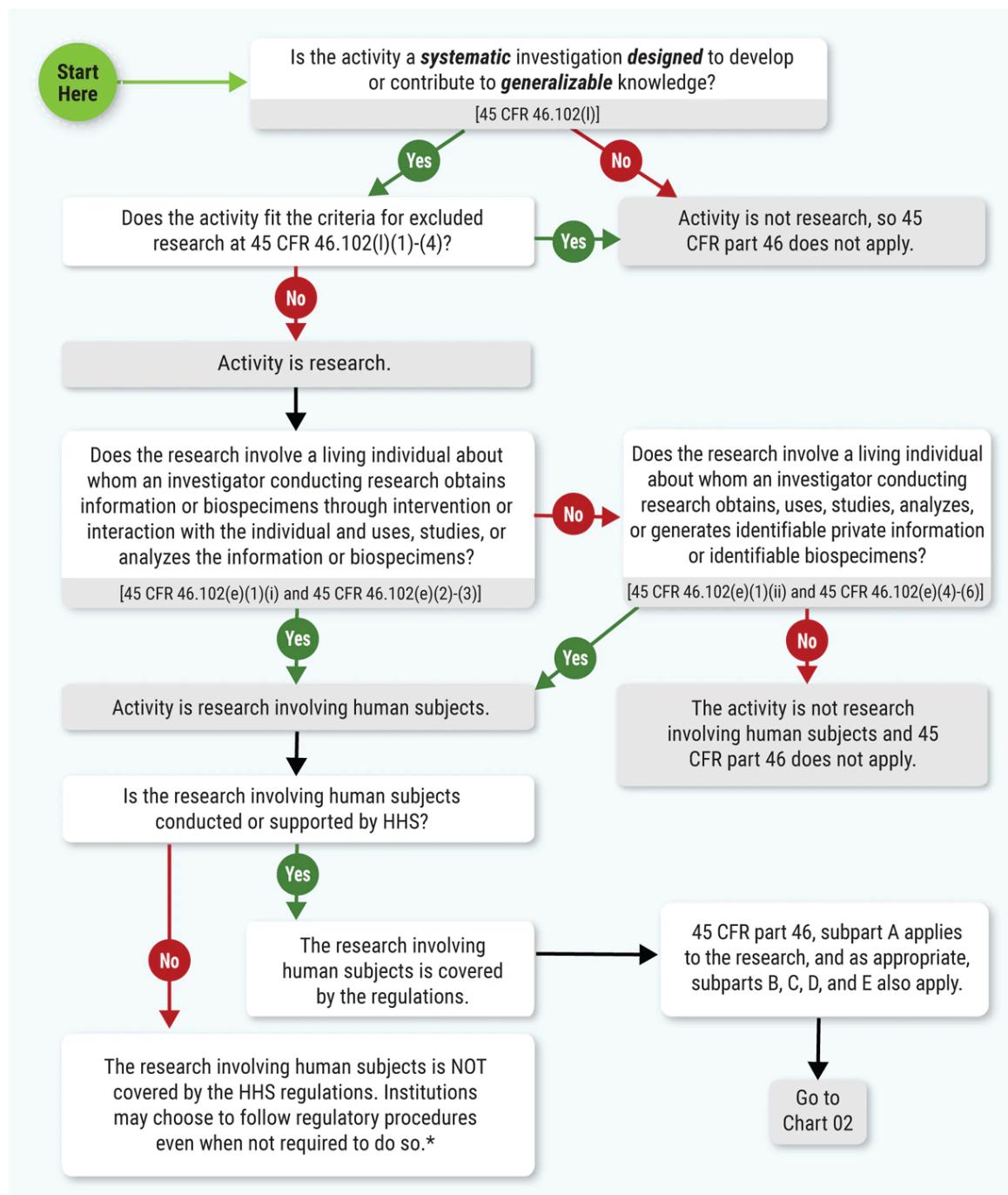


Chart 02: Is the Research Involving Human Subjects Eligible for Exemption Under 45 CFR 46.104(d)?

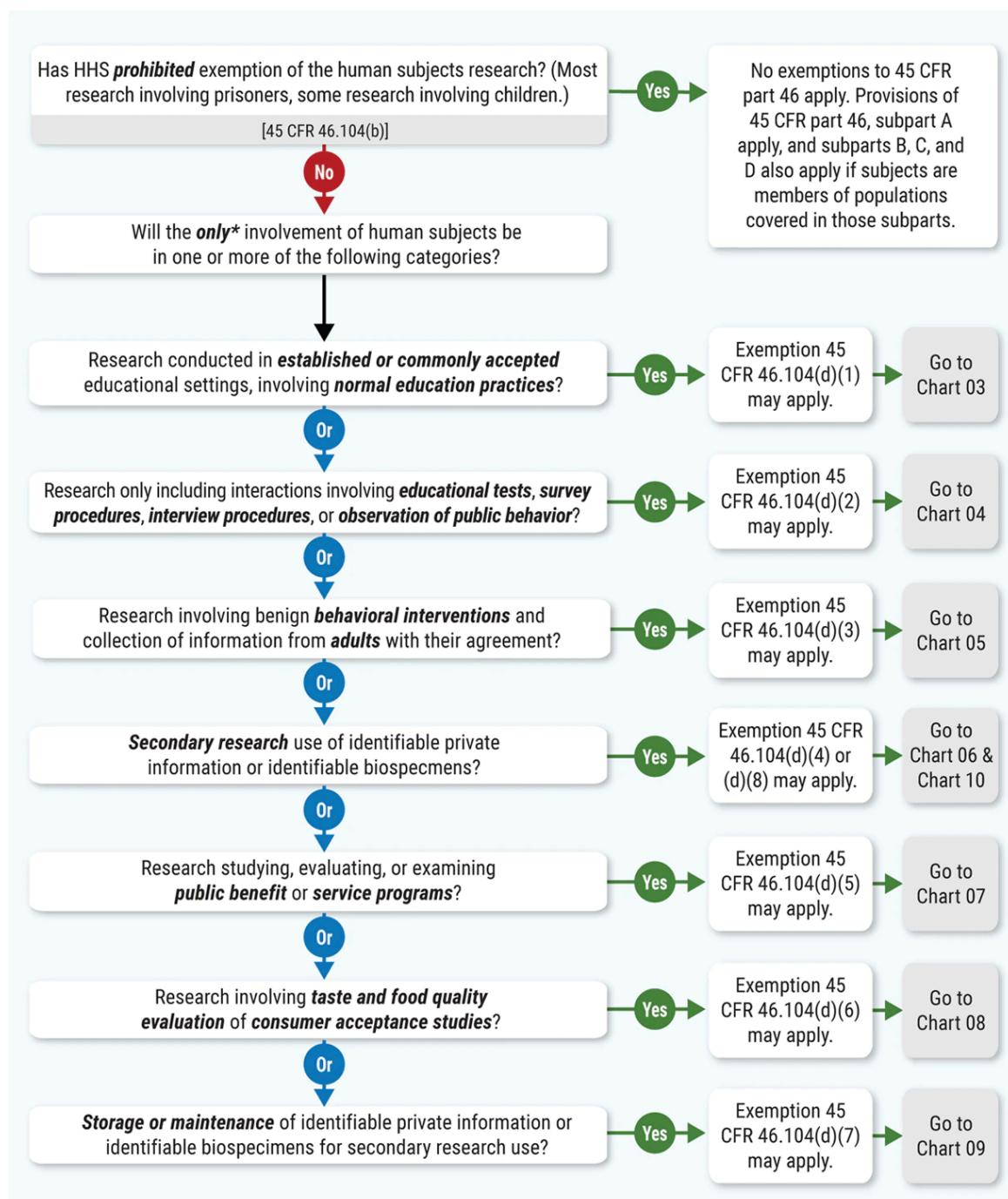


Chart 03: Does Exemption 45 CFR 46.104(d)(1) for Educational Practices Apply?

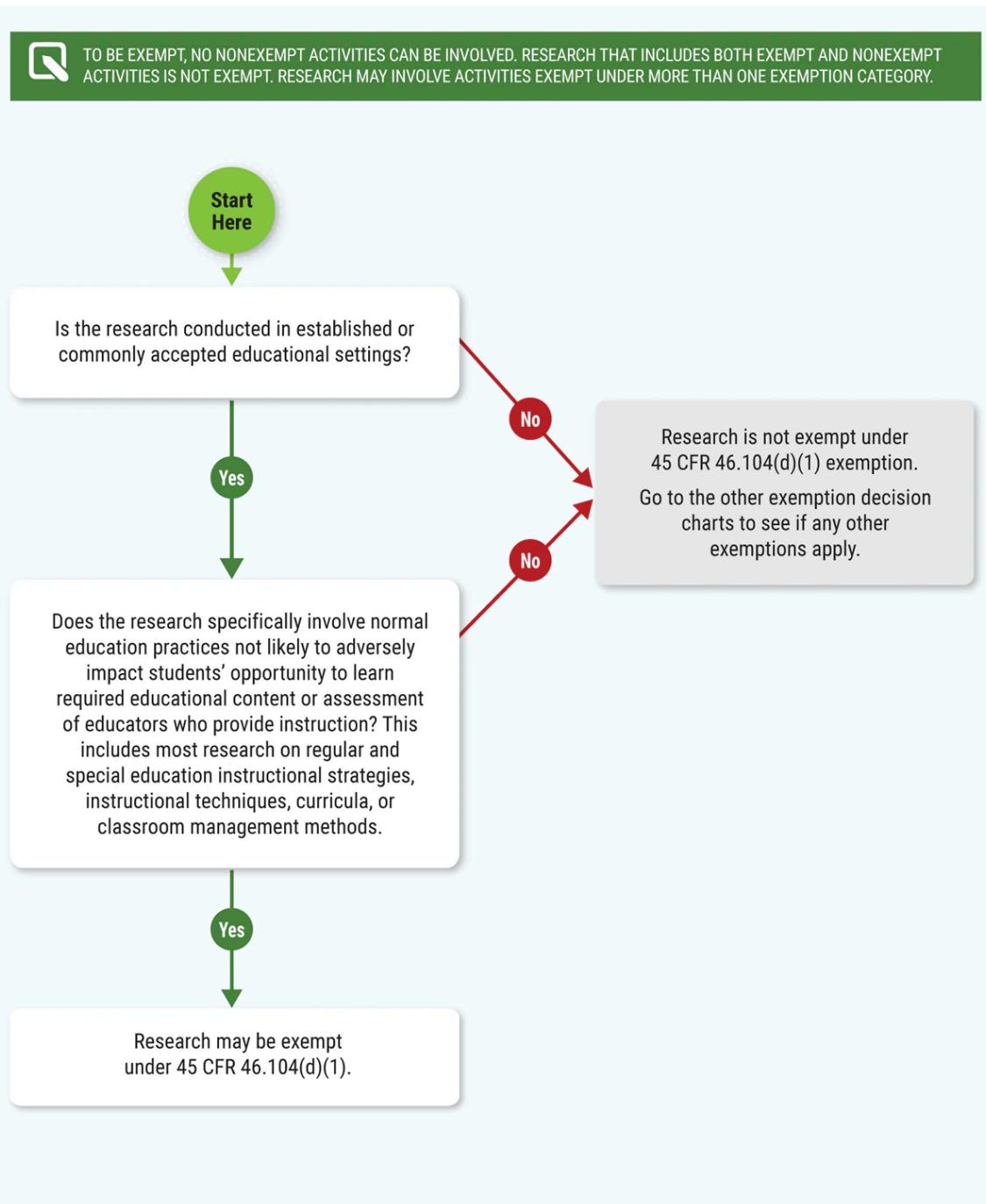


Chart 04: Does Exemption 45 CFR 46.104(d)(2) for Educational Tests, Surveys, Interviews, or Observation of Public Behavior Apply?

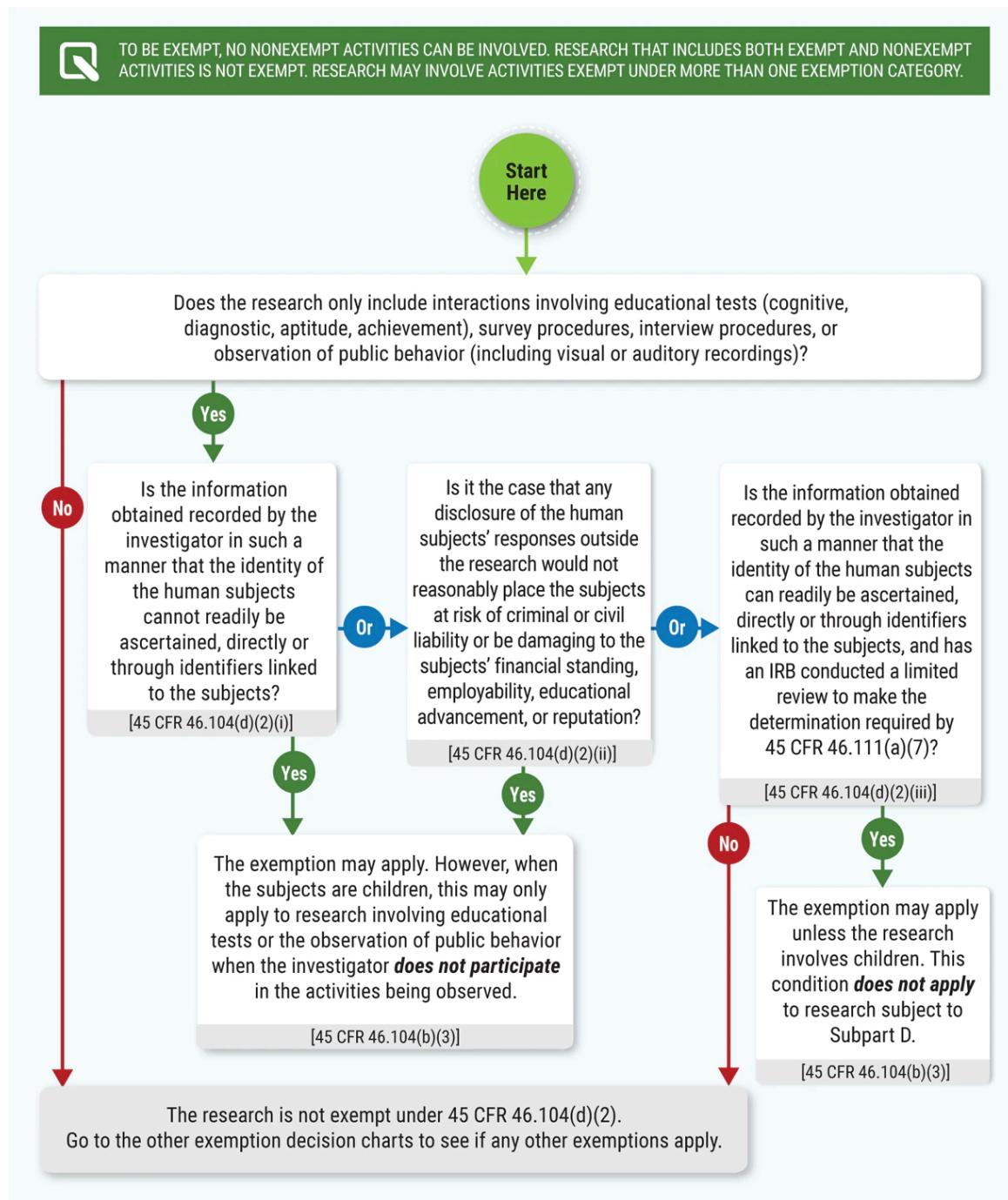


Chart 05: Does Exemption 45 CFR 46.104(d)(3) for Benign Behavioral Interventions Apply?

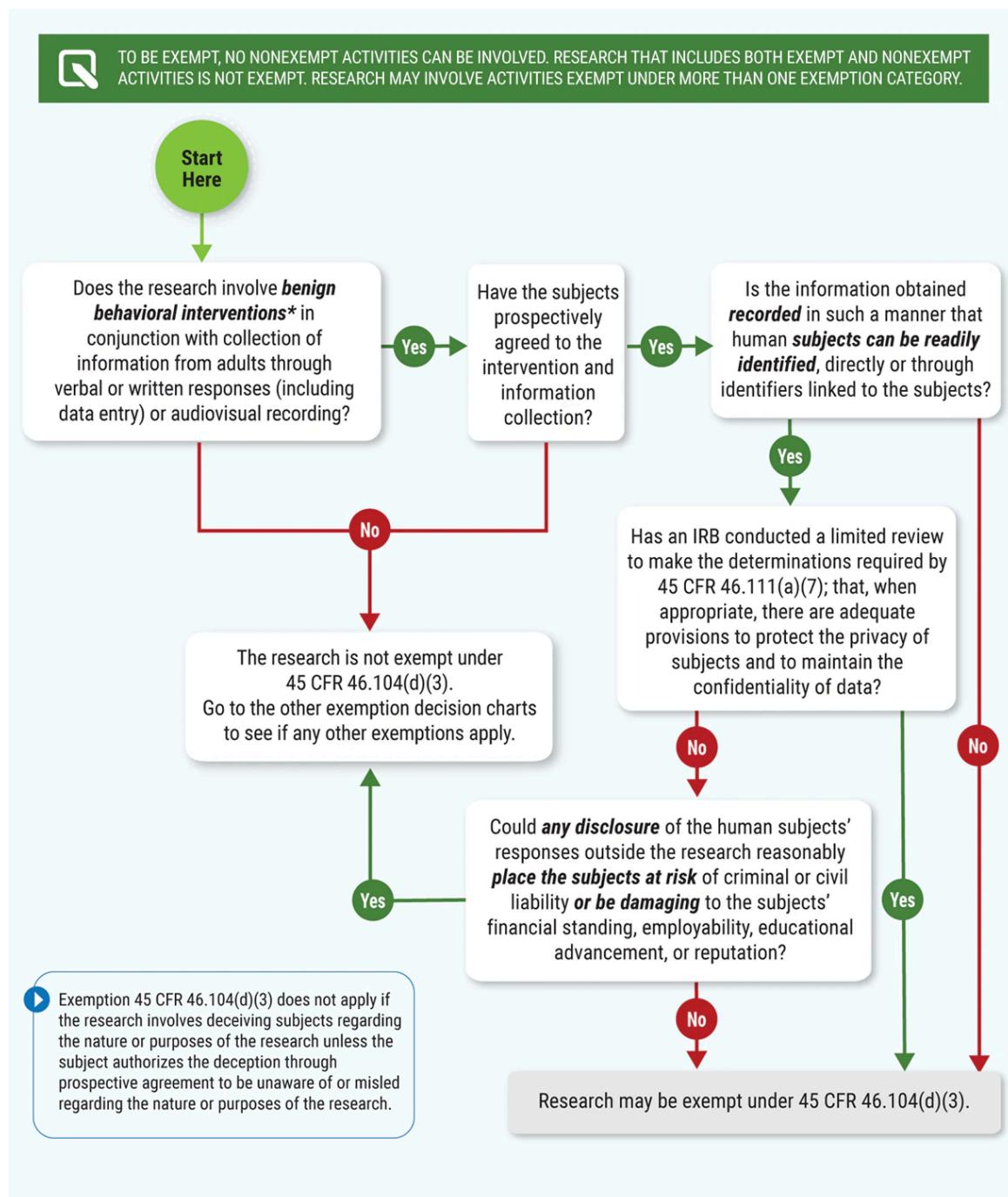


Chart 06: Does Exemption 45 CFR 46.104(d)(4) for Secondary Research that Does Not Require Consent Apply?

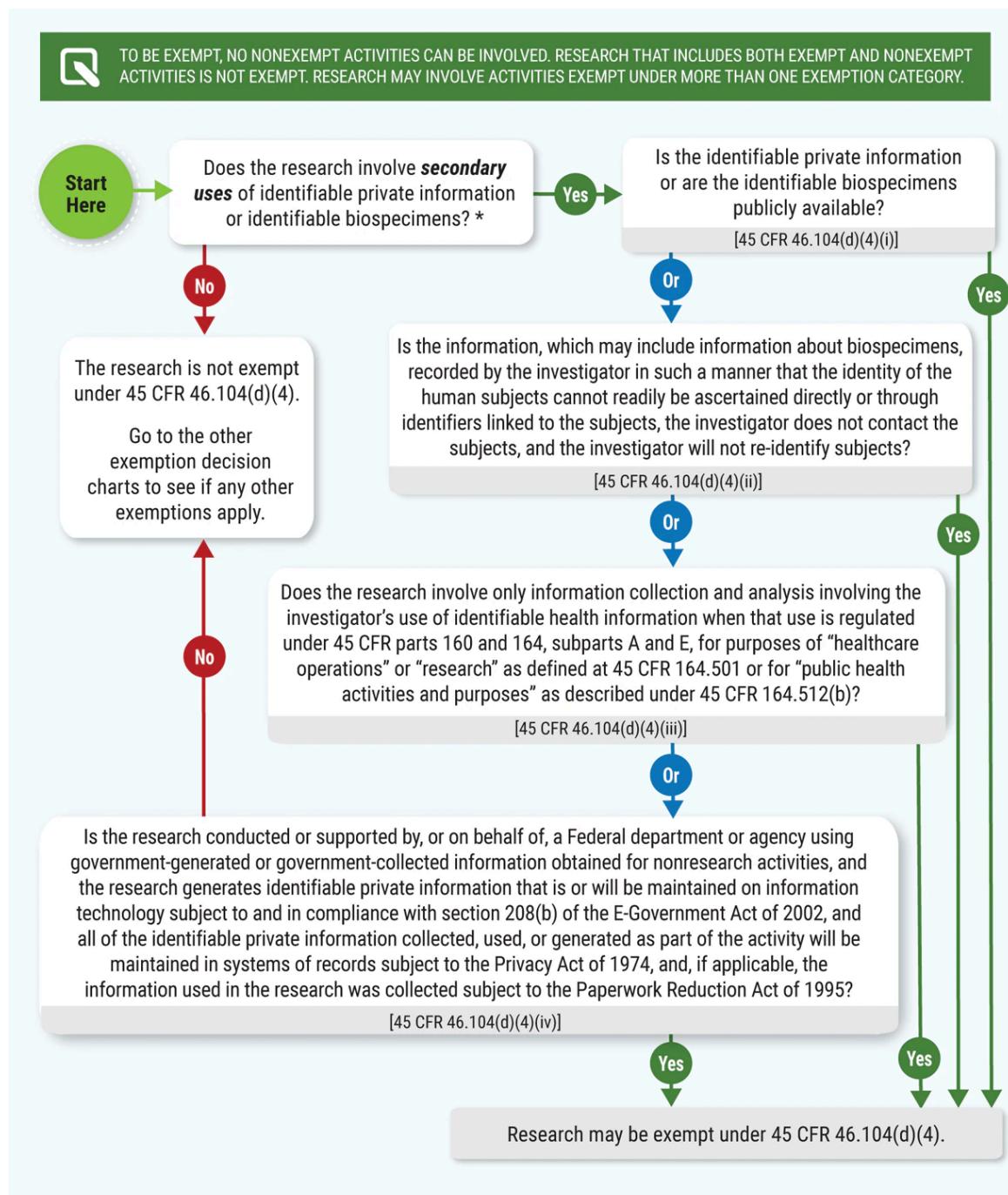


Chart 07: Does Exemption 45 CFR 46.104(d)(5) for Public Benefit or Service Programs Apply?

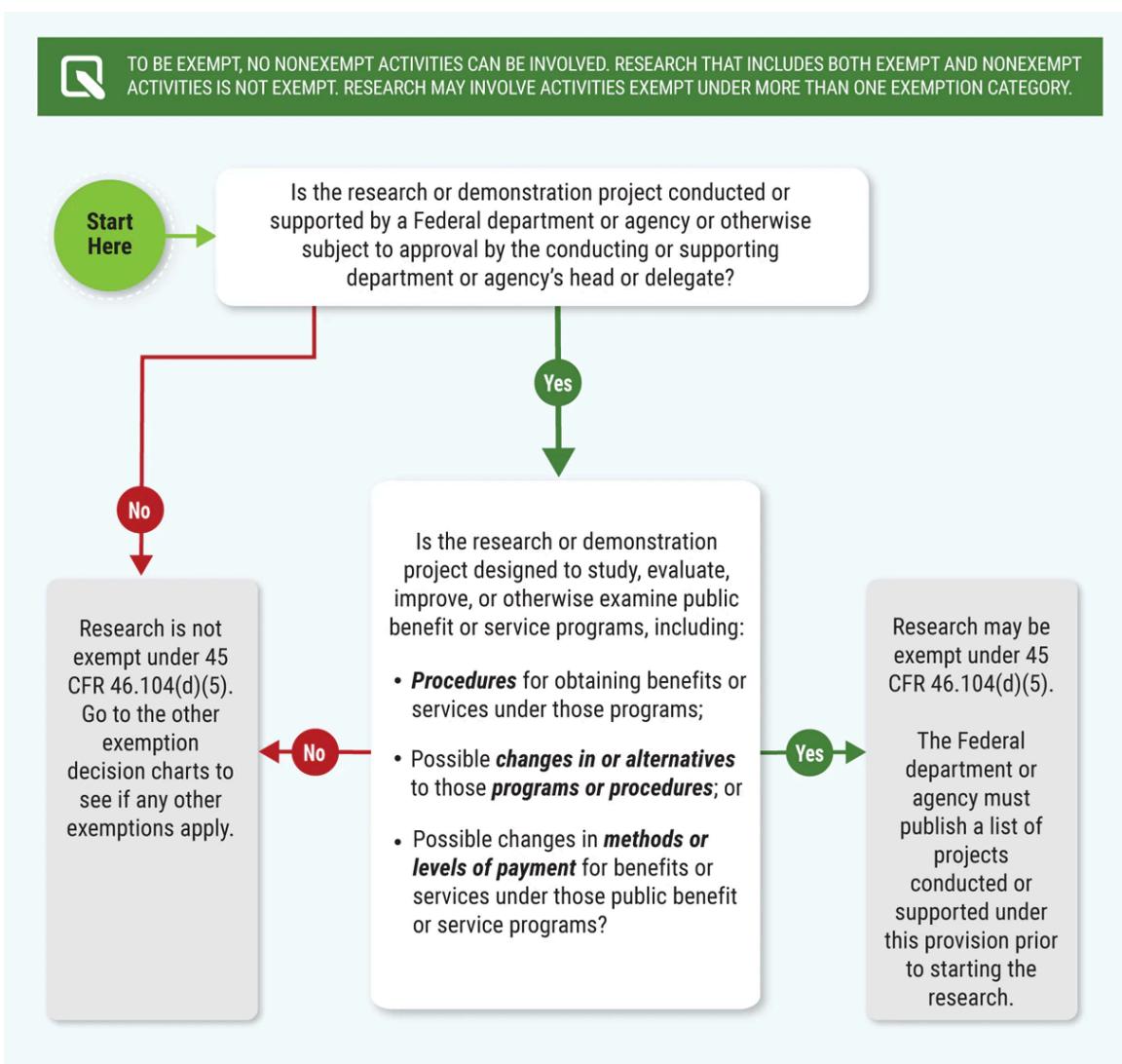


Chart 08: Does Exemption 45 CFR 46.104(d)(6) for Food Taste and Acceptance Studies Apply?



TO BE EXEMPT, NO NONEXEMPT ACTIVITIES CAN BE INVOLVED. RESEARCH THAT INCLUDES BOTH EXEMPT AND NONEXEMPT ACTIVITIES IS NOT EXEMPT. RESEARCH MAY INVOLVE ACTIVITIES EXEMPT UNDER MORE THAN ONE EXEMPTION CATEGORY.

Does the research involve a **taste and food quality** evaluation or a **consumer acceptance** study?

Yes

Are **wholesome foods without additives** consumed?

Yes

Research may be exempt under 45 CFR 46.104(d)(6).

Or

Is a food 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?

Yes

No

No

Research is not exempt under 45 CFR 46.104(d)(6). Go to the other exemption decision charts to see if any other exemptions apply.

Chart 09: Does Exemption 45 CFR 46.104(d)(7), Storage for Secondary Research for Which Broad Consent Is Required, Apply?

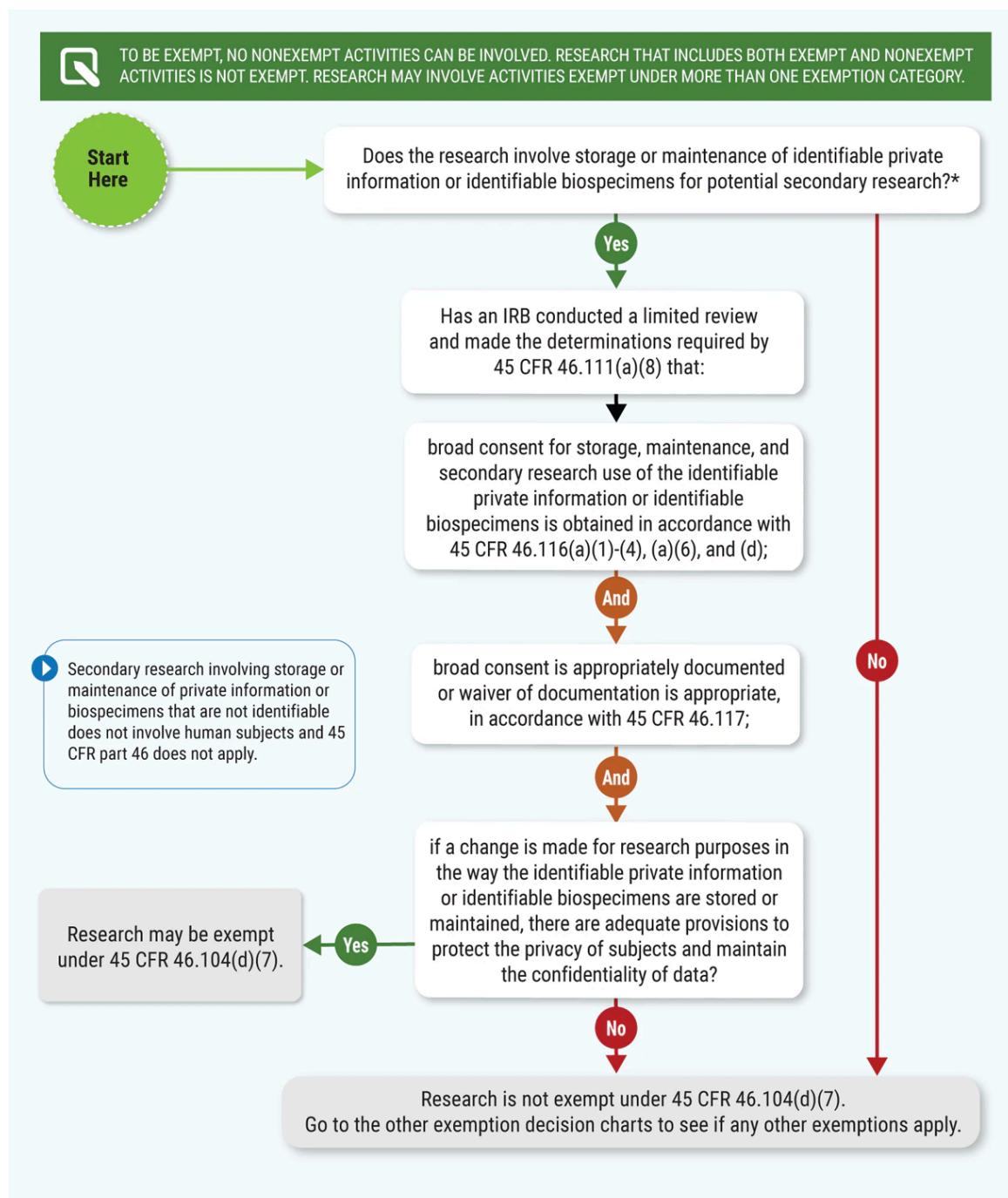


Chart 10: Does Exemption 45 CFR 46.104(d)(8) for Secondary Research for Which Broad Consent Is Required Apply?

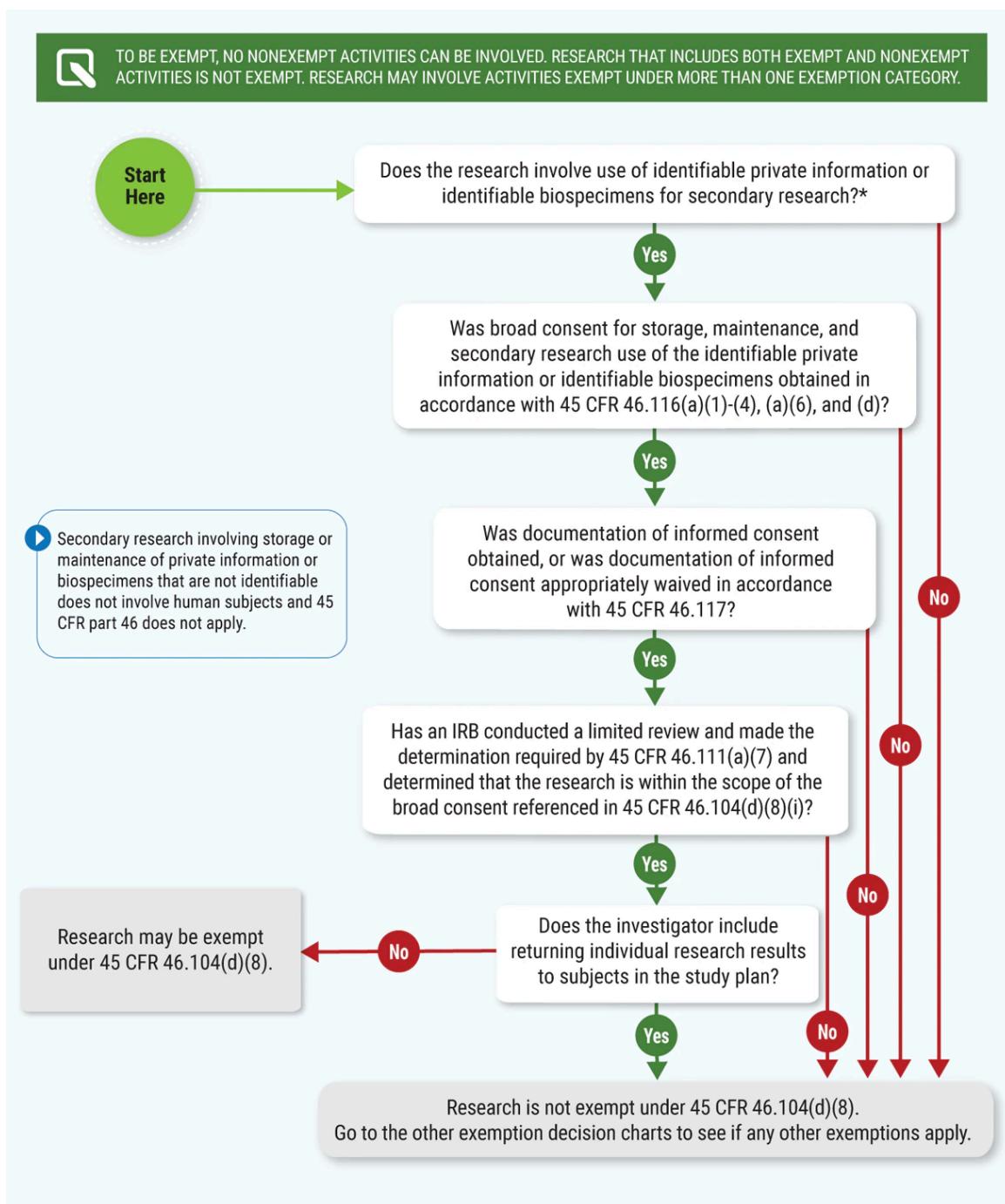


Chart 11: Is Continuing Review Required Under 45 CFR 46.109(f)?

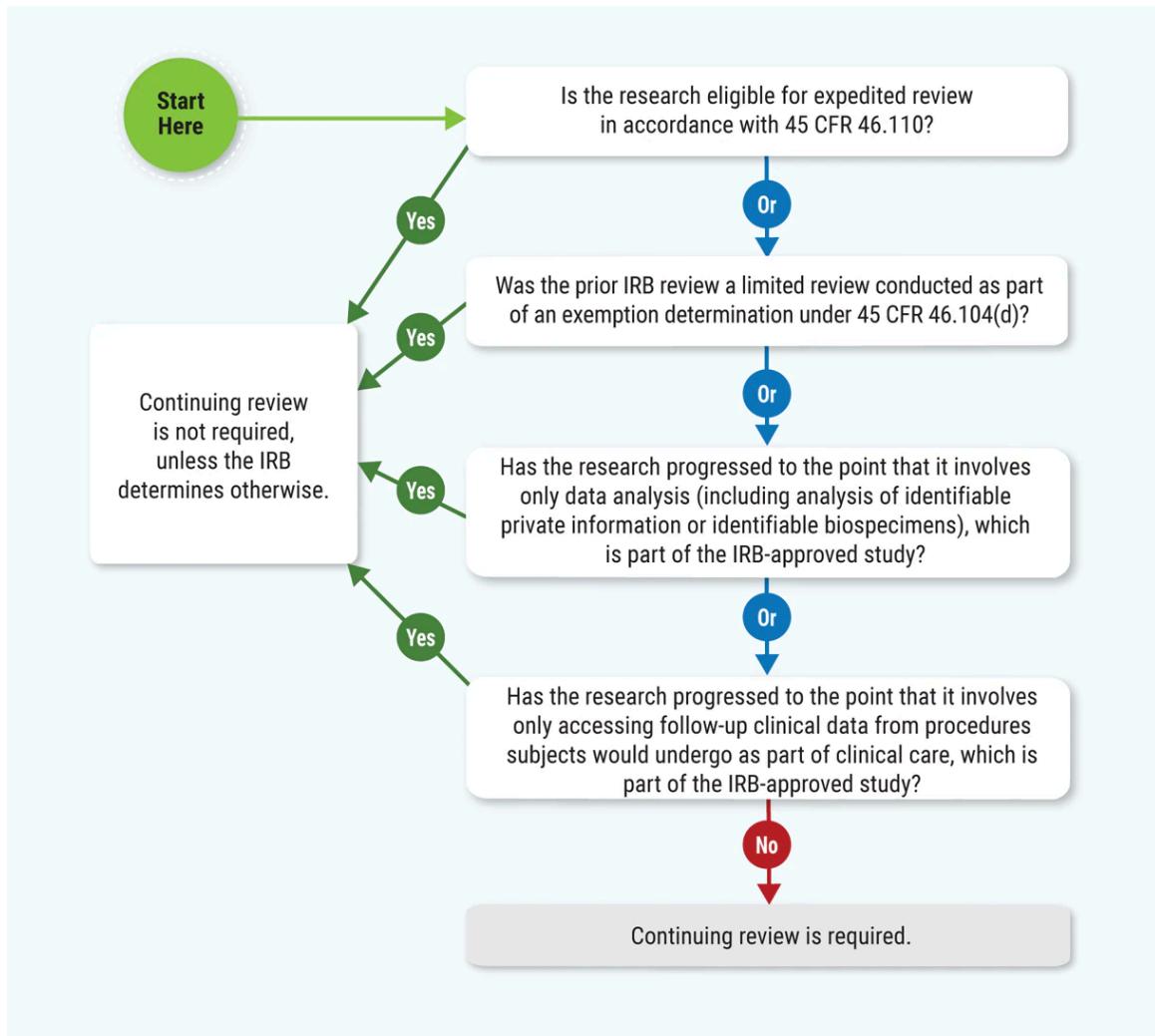


Chart 12: Waiver or Alteration of Informed Consent in Research Involving Public Benefit and Service Programs Conducted by or Subject to

the Approval of State or Local Government Officials (45 CFR 46.116(e))

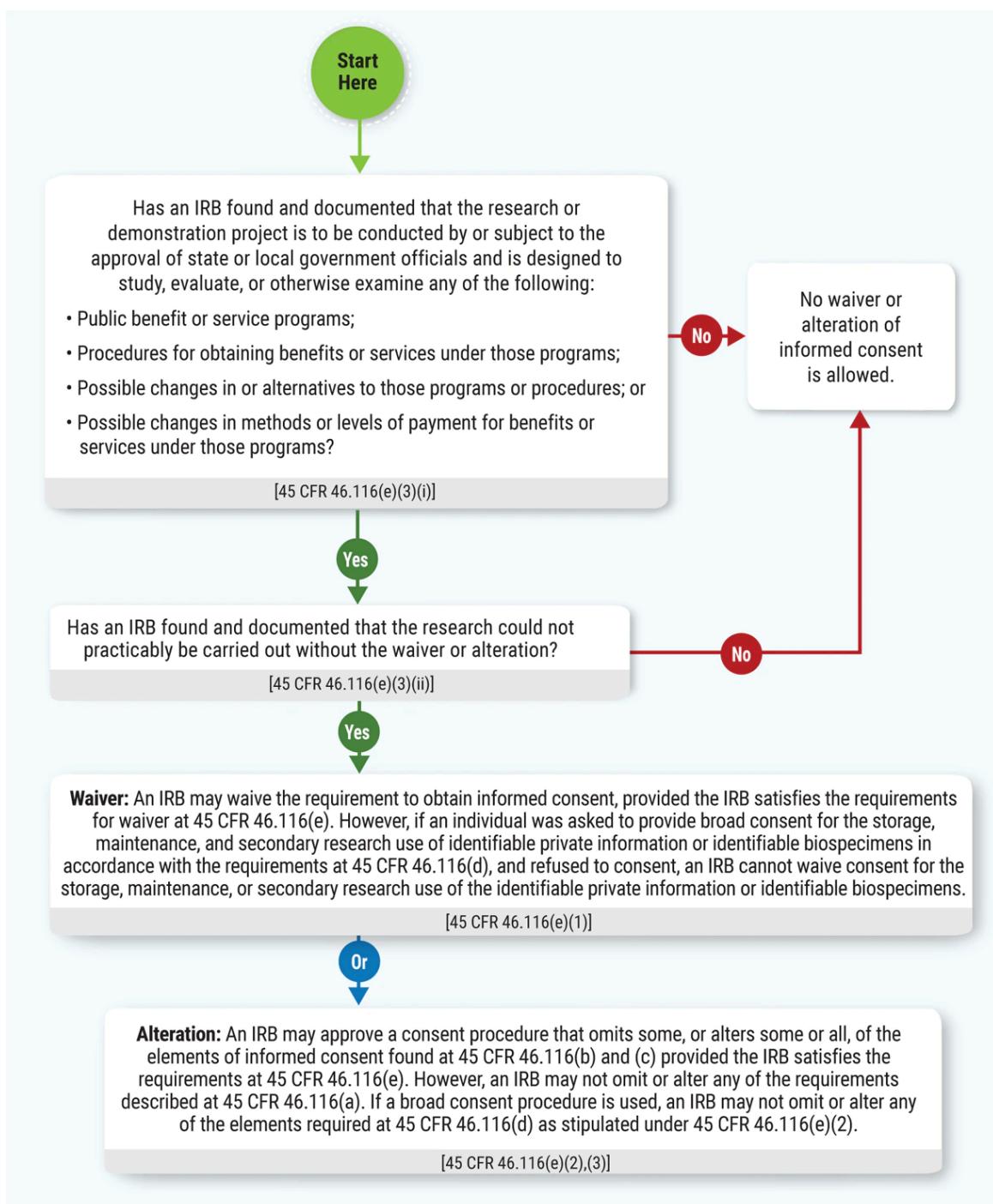


Chart 13: When Can Informed Consent Be Waived or Altered Under 45 CFR 46.116(f)?

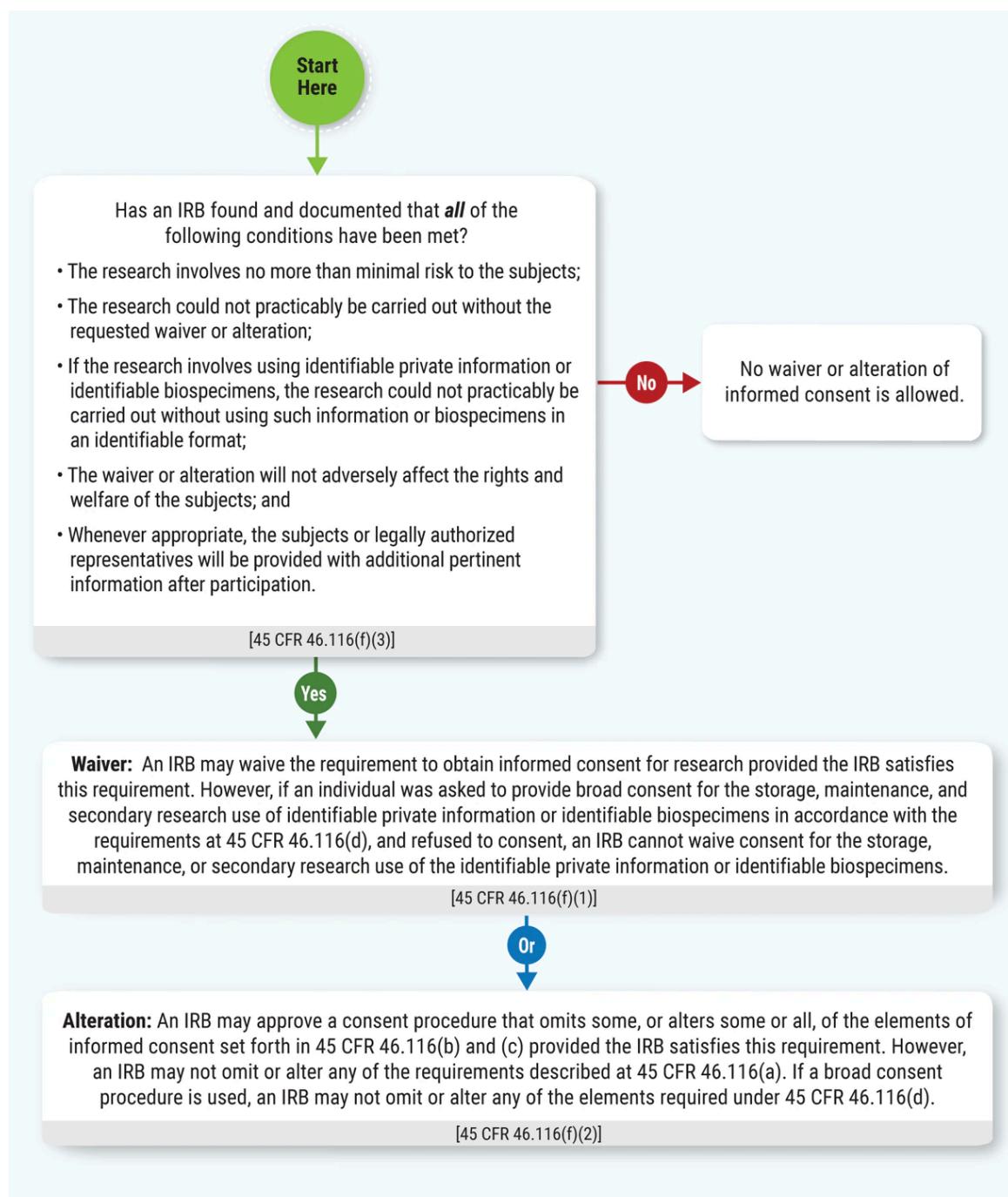
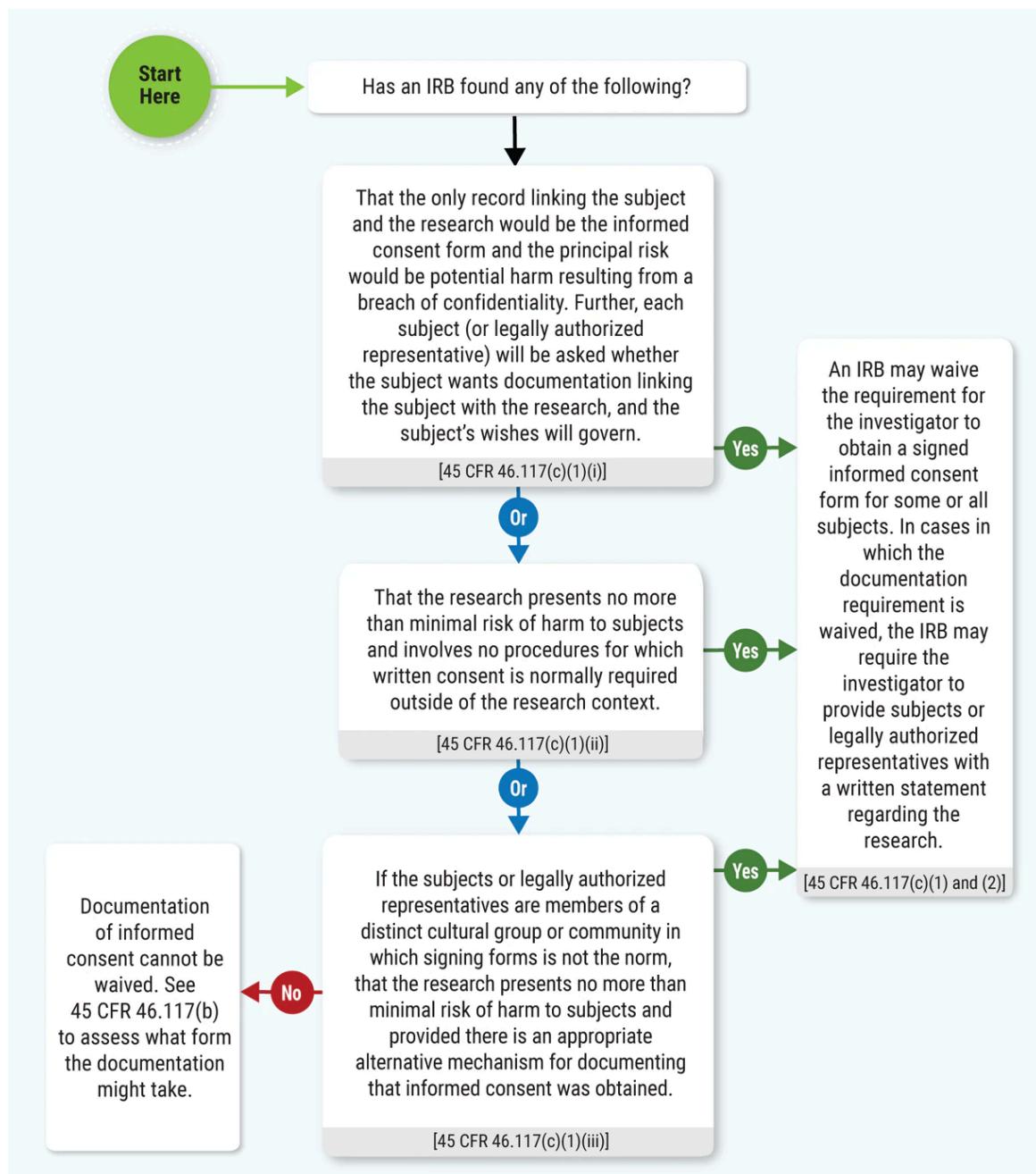


Chart 14: Can Documentation of Informed Consent Be Waived Under 45 CFR 46.117(c)?



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Content last reviewed June 30, 2020

