

HUMAN SUBJECT REGULATIONS DECISION CHARTS:

2018 REQUIREMENTS



OHRP
Office for Human
Research Protections

NOTE: This guidance is consistent with the 2018 Requirements (i.e., the revised Common Rule).

For use after January 20, 2019

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 guidance documents are available related to specific topics at <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.

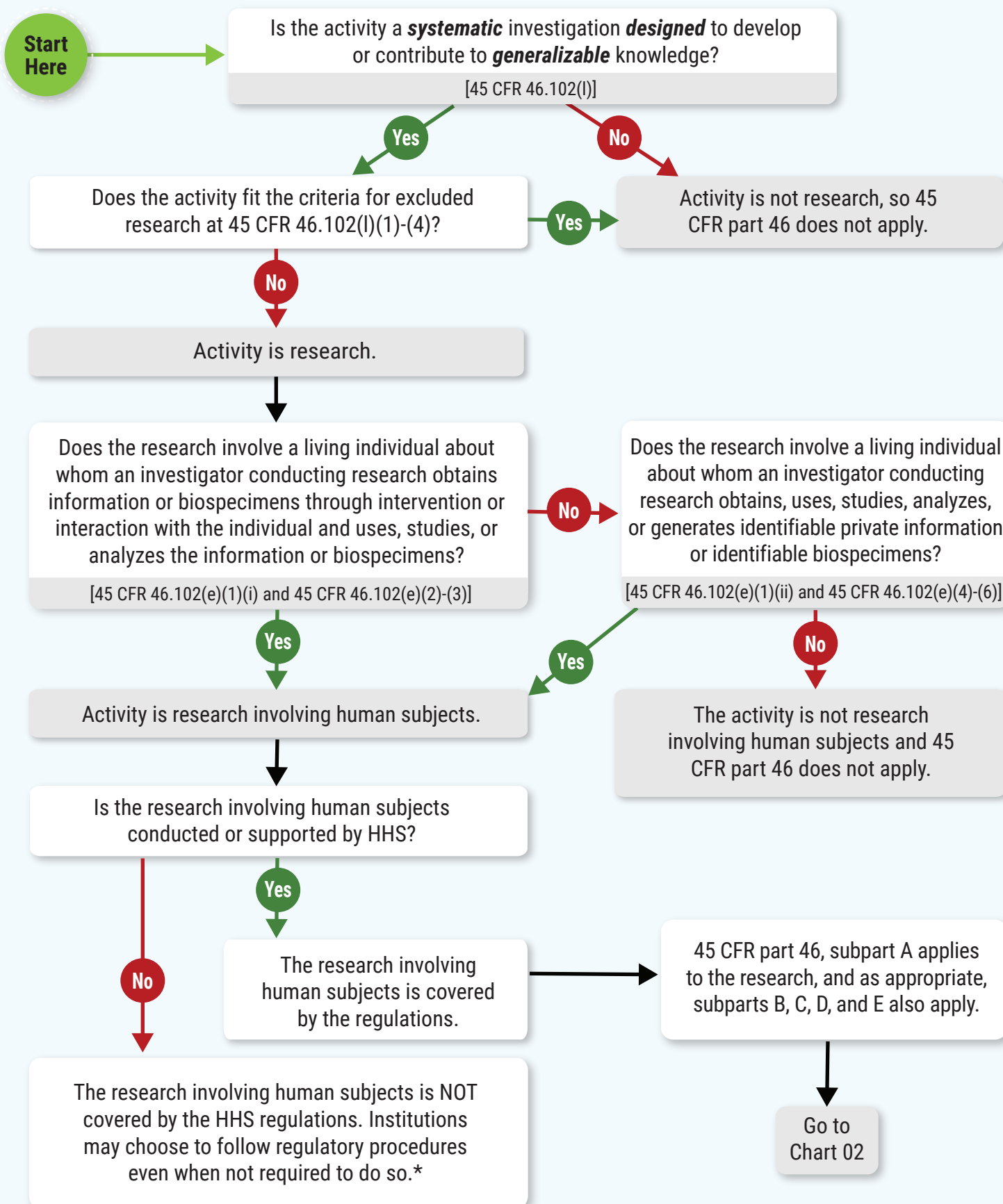
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| CHART 01: | IS AN ACTIVITY HUMAN SUBJECTS RESEARCH COVERED BY 45 CFR PART 46? |
| CHART 02: | IS THE RESEARCH INVOLVING HUMAN SUBJECTS ELIGIBLE FOR EXEMPTION UNDER 45 CFR 46.104(d)? |
| CHART 03: | DOES EXEMPTION 45 CFR 46.104(d)(1) FOR EDUCATIONAL PRACTICES APPLY? |
| CHART 04: | DOES EXEMPTION 45 CFR 46.104(d)(2) FOR EDUCATIONAL TESTS, SURVEYS, INTERVIEWS, OR OBSERVATION OF PUBLIC BEHAVIOR APPLY? |
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| CHART 06: | DOES EXEMPTION 45 CFR 46.104(d)(4) FOR SECONDARY RESEARCH THAT DOES NOT REQUIRE CONSENT APPLY? |
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| 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)? |
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IS AN ACTIVITY HUMAN SUBJECTS RESEARCH COVERED BY 45 CFR PART 46?



NOTE: This chart is consistent with the 2018 Requirements (i.e., the revised Common Rule)

For use after January 20, 2019



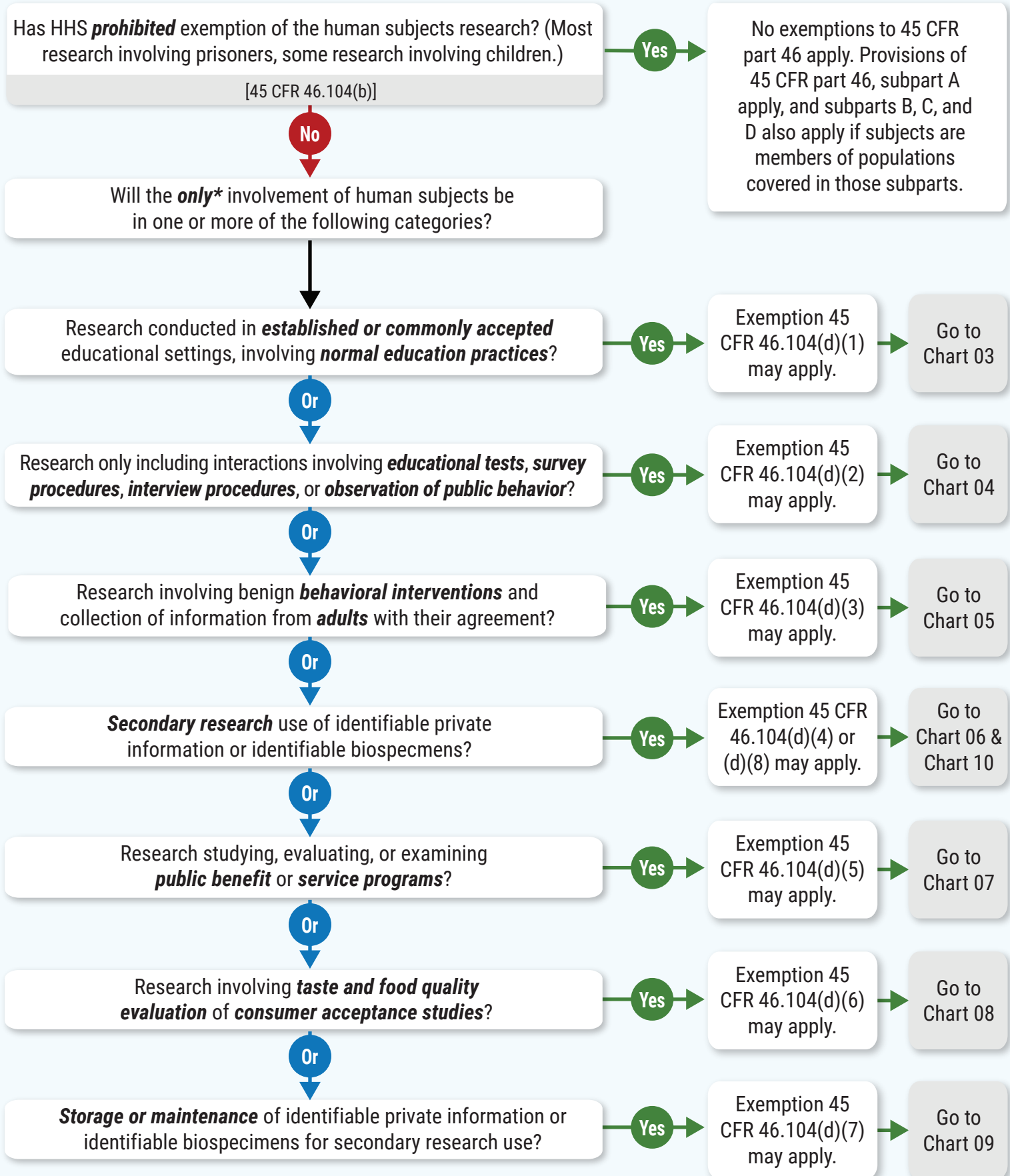
*For information on whether an institution needs to revise its FWA because of the 2018 Requirements, see, <https://www.hhs.gov/ohrp/education-and-outreach/revised-common-rule/revised-common-rule-q-and-a/index.html>

IS THE RESEARCH INVOLVING HUMAN SUBJECTS ELIGIBLE FOR EXEMPTION UNDER 45 CFR 46.104(d)?

NOTE: This chart is consistent with the 2018 Requirements (i.e., the revised Common Rule)



For use after January 20, 2019



*Only means that no nonexempt activities are involved. Research that excludes both exempt and nonexempt activities is **not** exempt. Research may involve activities exempt under more than one exemption category.

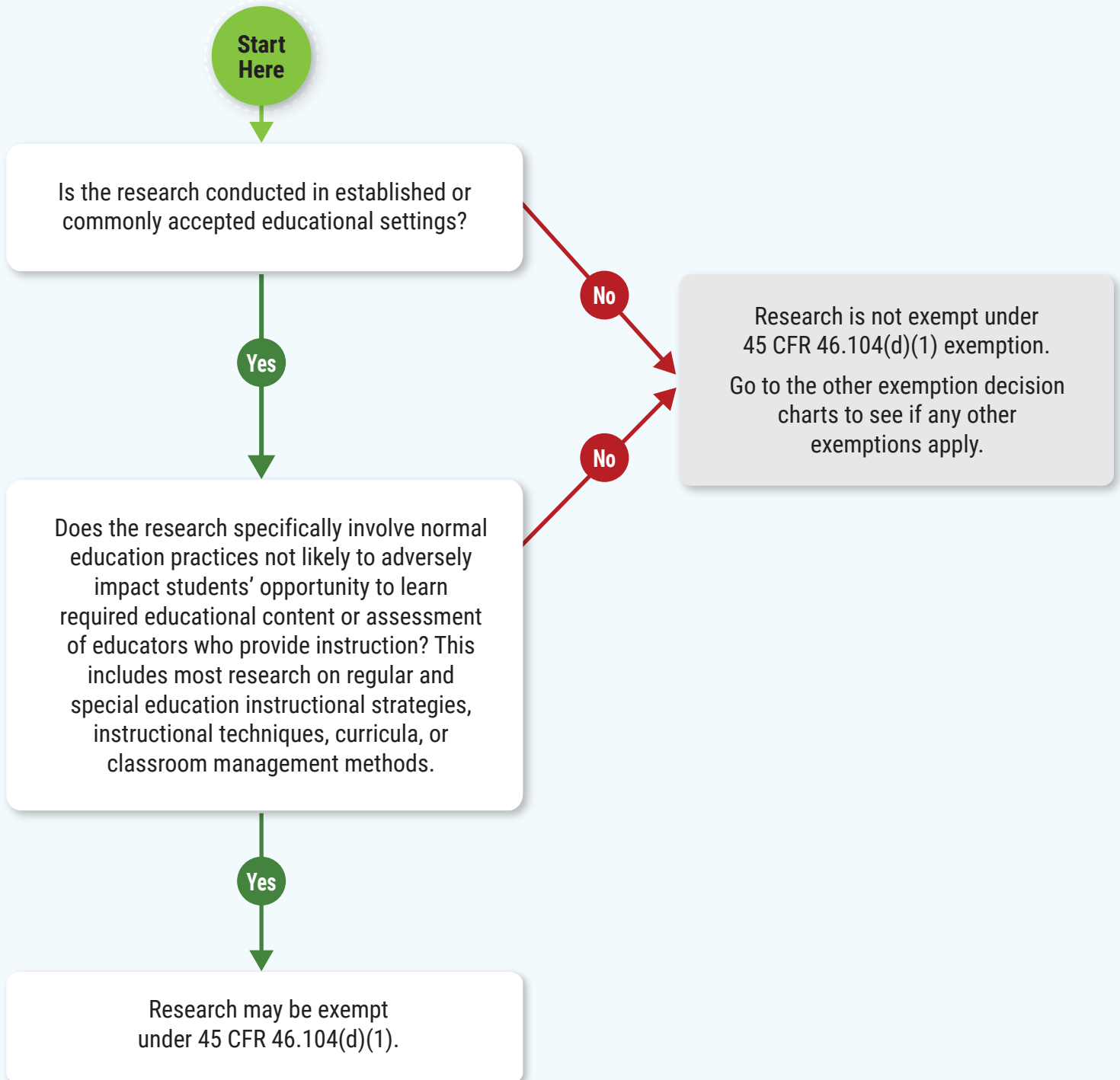
DOES EXEMPTION 45 CFR 46.104(d)(1) FOR EDUCATIONAL PRACTICES APPLY?

NOTE: This chart is consistent with the 2018 Requirements (i.e., the revised Common Rule)

For use after January 20, 2019



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DOES EXEMPTION 45 CFR 46.104(d)(2) FOR EDUCATIONAL TESTS, SURVEYS, INTERVIEWS, OR OBSERVATION OF PUBLIC BEHAVIOR APPLY?



NOTE: This chart is consistent with the 2018 Requirements (i.e., the revised Common Rule)

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Start
Here

Does the research only include interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recordings)?

Yes

No

Is the information obtained recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects?

[45 CFR 46.104(d)(2)(i)]

Or

Is it the case that any disclosure of the human subjects' responses outside 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?

[45 CFR 46.104(d)(2)(ii)]

Or

Is the information obtained 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, and has an IRB conducted a limited review to make the determination required by 45 CFR 46.111(a)(7)?

[45 CFR 46.104(d)(2)(iii)]

Yes

The exemption may apply. However, when the subjects are children, this may only apply to research involving educational tests or the observation of public behavior when the investigator **does not participate** in the activities being observed.

[45 CFR 46.104(b)(3)]

Yes

No

Yes

The exemption may apply unless the research involves children. This condition **does not apply** to research subject to Subpart D.

[45 CFR 46.104(b)(3)]

The research is not exempt under 45 CFR 46.104(d)(2).
Go to the other exemption decision charts to see if any other exemptions apply.

DOES EXEMPTION 45 CFR 46.104(d)(3) FOR BENIGN BEHAVIORAL INTERVENTIONS APPLY?

NOTE: This chart is consistent with the 2018 Requirements (i.e., the revised Common Rule)

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Start
Here

Does the research involve **benign behavioral interventions*** in conjunction with collection of information from adults through verbal or written responses (including data entry) or audiovisual recording?

Yes

Have the subjects prospectively agreed to the intervention and information collection?

Yes

Is the information obtained **recorded** in such a manner that human **subjects can be readily identified**, directly or through identifiers linked to the subjects?

Yes

Has an IRB conducted a limited review to make the determinations required by 45 CFR 46.111(a)(7); that, when appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data?

No

Could **any disclosure** of the human subjects' responses outside the research reasonably **place the subjects at risk** of criminal or civil liability **or be damaging** to the subjects' financial standing, employability, educational advancement, or reputation?

No

Yes

No

The research is not exempt under 45 CFR 46.104(d)(3).
Go to the other exemption decision charts to see if any other exemptions apply.

Yes

Research may be exempt under 45 CFR 46.104(d)(3).



Exemption 45 CFR 46.104(d)(3) does not apply if the research involves deceiving subjects regarding the nature or purposes of the research unless the subject authorizes the deception through prospective agreement to be unaware of or misled regarding the nature or purposes of the research.



***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 interventions offensive or embarrassing.

DOES EXEMPTION 45 CFR 46.104(d)(4) FOR SECONDARY RESEARCH THAT DOES NOT REQUIRE CONSENT APPLY?

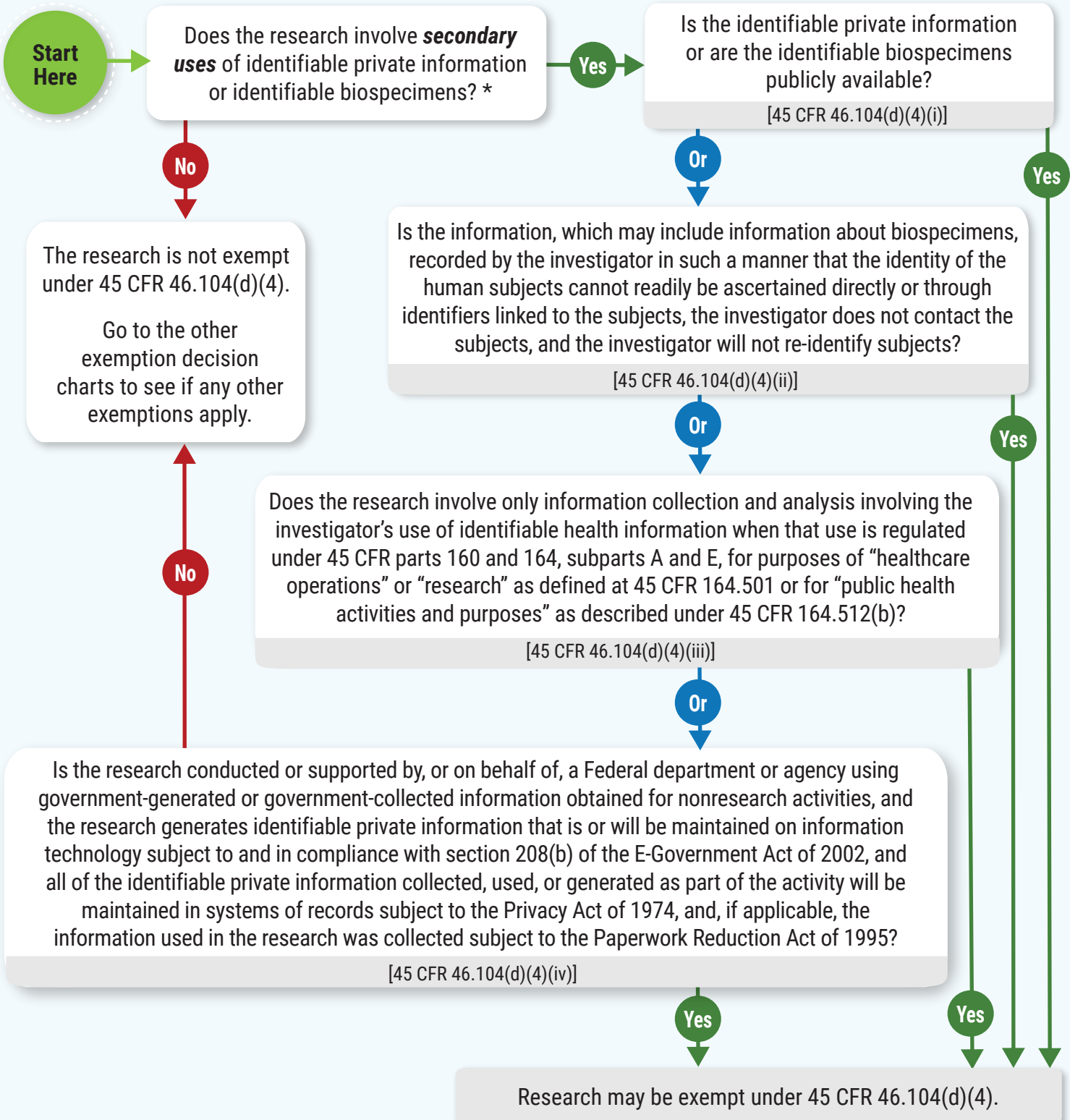


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*Research use of identifiable private information or identifiable biospecimens collected for either research studies other than the proposed research, or for nonresearch purposes.

DOES EXEMPTION 45 CFR 46.104(d)(5) FOR PUBLIC BENEFIT OR SERVICE PROGRAMS APPLY?

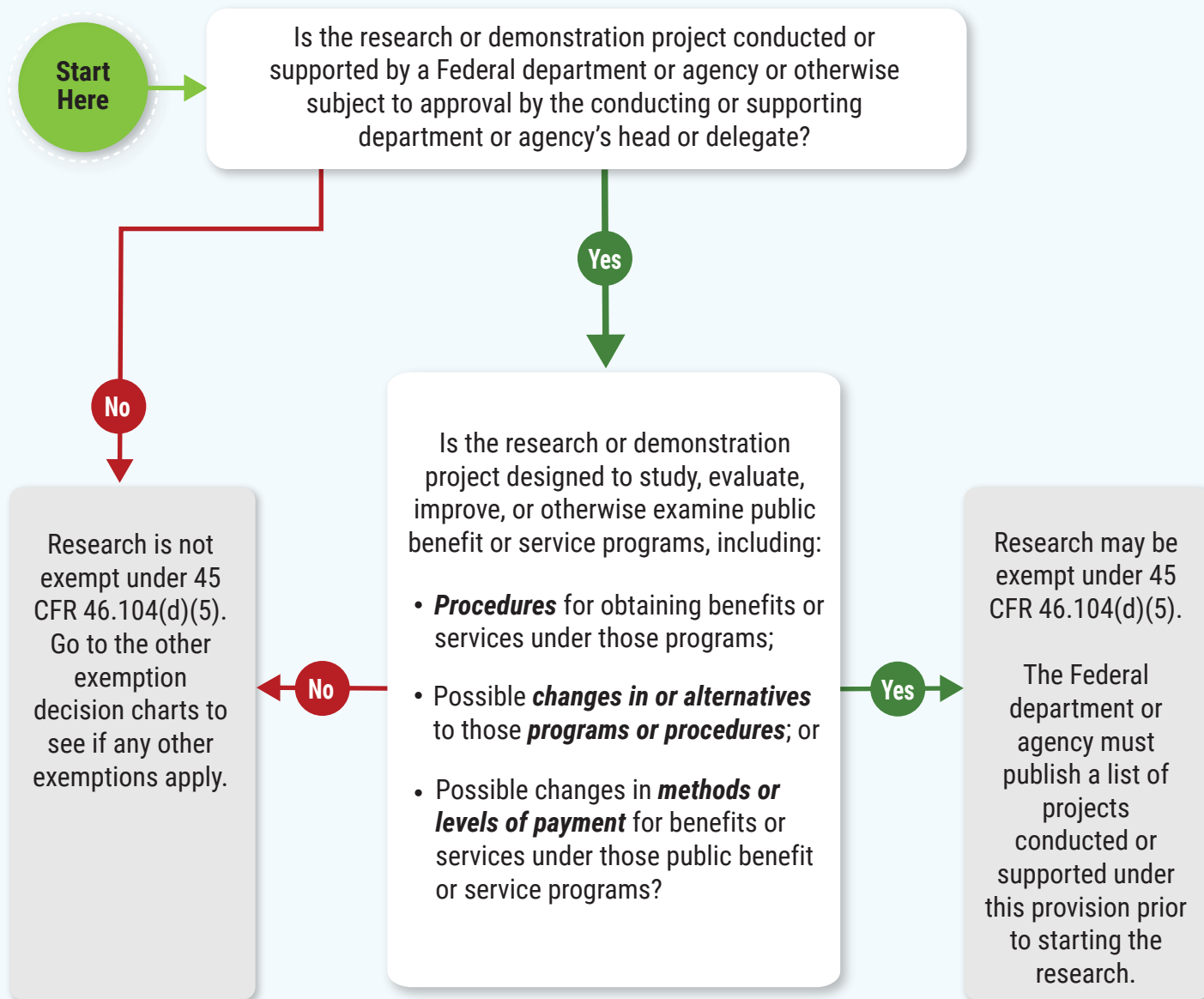
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DOES EXEMPTION 45 CFR 46.104(d)(6) FOR FOOD, TASTE, AND ACCEPTANCE STUDIES APPLY?

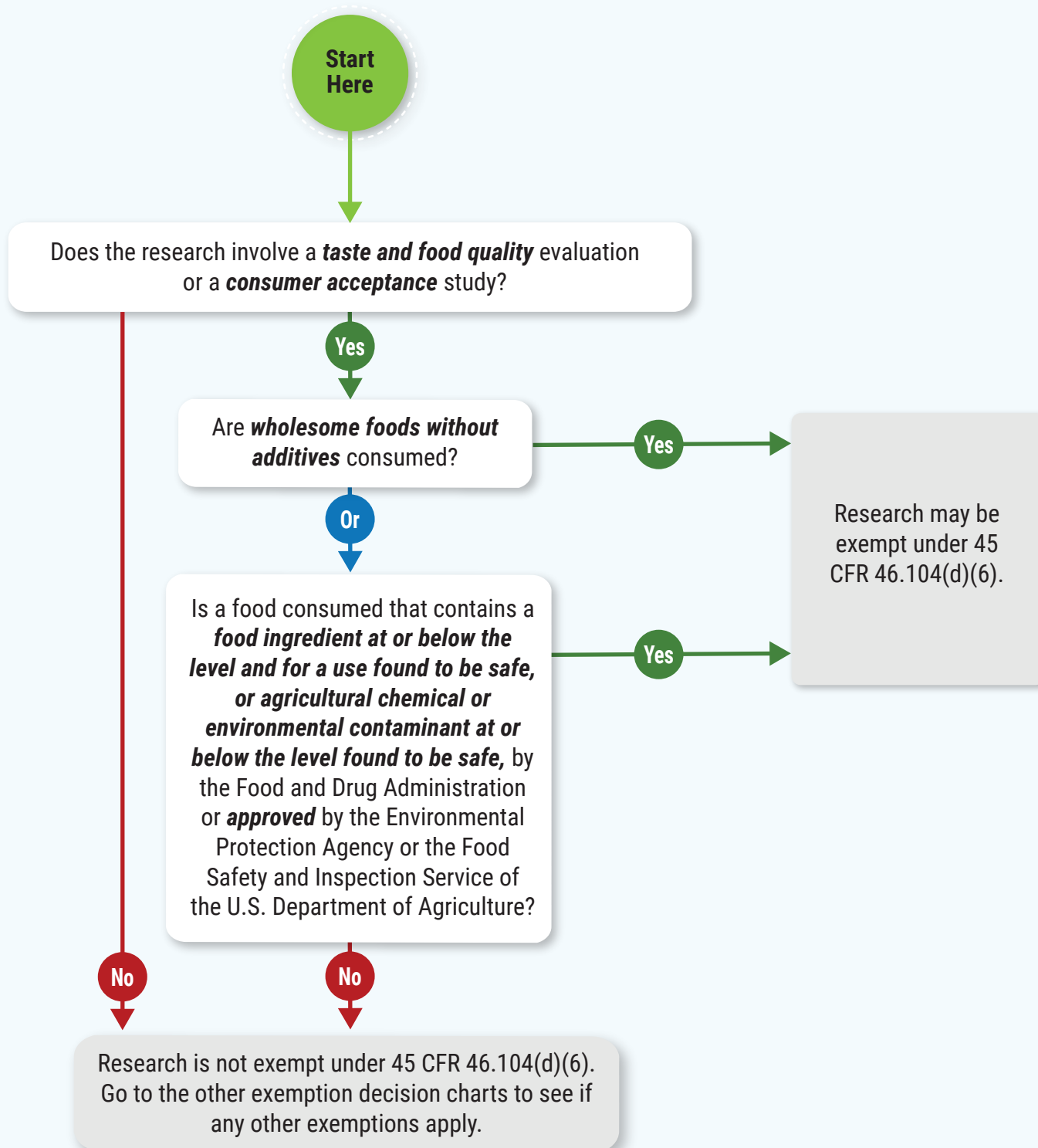
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DOES EXEMPTION 45 CFR 46.104(d)(7), STORAGE FOR SECONDARY RESEARCH FOR WHICH BROAD CONSENT IS REQUIRED, APPLY?



NOTE: This chart is consistent with the 2018 Requirements (i.e., the revised Common Rule)

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Start
Here

Does the research involve storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research?*

Yes

Has an IRB conducted a limited review and made the determinations required by 45 CFR 46.111(a)(8) that:

broad consent for storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens is obtained in accordance with 45 CFR 46.116(a)(1)-(4), (a)(6), and (d);

And

broad consent is appropriately documented or waiver of documentation is appropriate, in accordance with 45 CFR 46.117;

And

if a change is made for research purposes in the way the identifiable private information or identifiable biospecimens are stored or maintained, there are adequate provisions to protect the privacy of subjects and maintain the confidentiality of data?

Yes

Research may be exempt under 45 CFR 46.104(d)(7).

No

No

Research is not exempt under 45 CFR 46.104(d)(7).
Go to the other exemption decision charts to see if any other exemptions apply.



Secondary research involving storage or maintenance of private information or biospecimens that are not identifiable does not involve human subjects and 45 CFR part 46 does not apply.



*Research use of identifiable private information or identifiable biospecimens collected for either research studies other than the proposed research, or for nonresearch purposes.

DOES EXEMPTION 45 CFR 46.104(d)(8) FOR SECONDARY RESEARCH FOR WHICH BROAD CONSENT IS REQUIRED APPLY?



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Start
Here

Does the research involve use of identifiable private information or identifiable biospecimens for secondary research?*

Yes

Was broad consent for storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens obtained in accordance with 45 CFR 46.116(a)(1)-(4), (a)(6), and (d)?

Yes

Was documentation of informed consent obtained, or was documentation of informed consent appropriately waived in accordance with 45 CFR 46.117?

Yes

Has an IRB conducted a limited review and made the determination required by 45 CFR 46.111(a)(7) and determined that the research is within the scope of the broad consent referenced in 45 CFR 46.104(d)(8)(i)?

Yes

Does the investigator include returning individual research results to subjects in the study plan?

Yes

Research may be exempt under 45 CFR 46.104(d)(8).

No

No

No

No

No

Research is not exempt under 45 CFR 46.104(d)(8).
Go to the other exemption decision charts to see if any other exemptions apply.

▶ Secondary research involving storage or maintenance of private information or biospecimens that are not identifiable does not involve human subjects and 45 CFR part 46 does not apply.

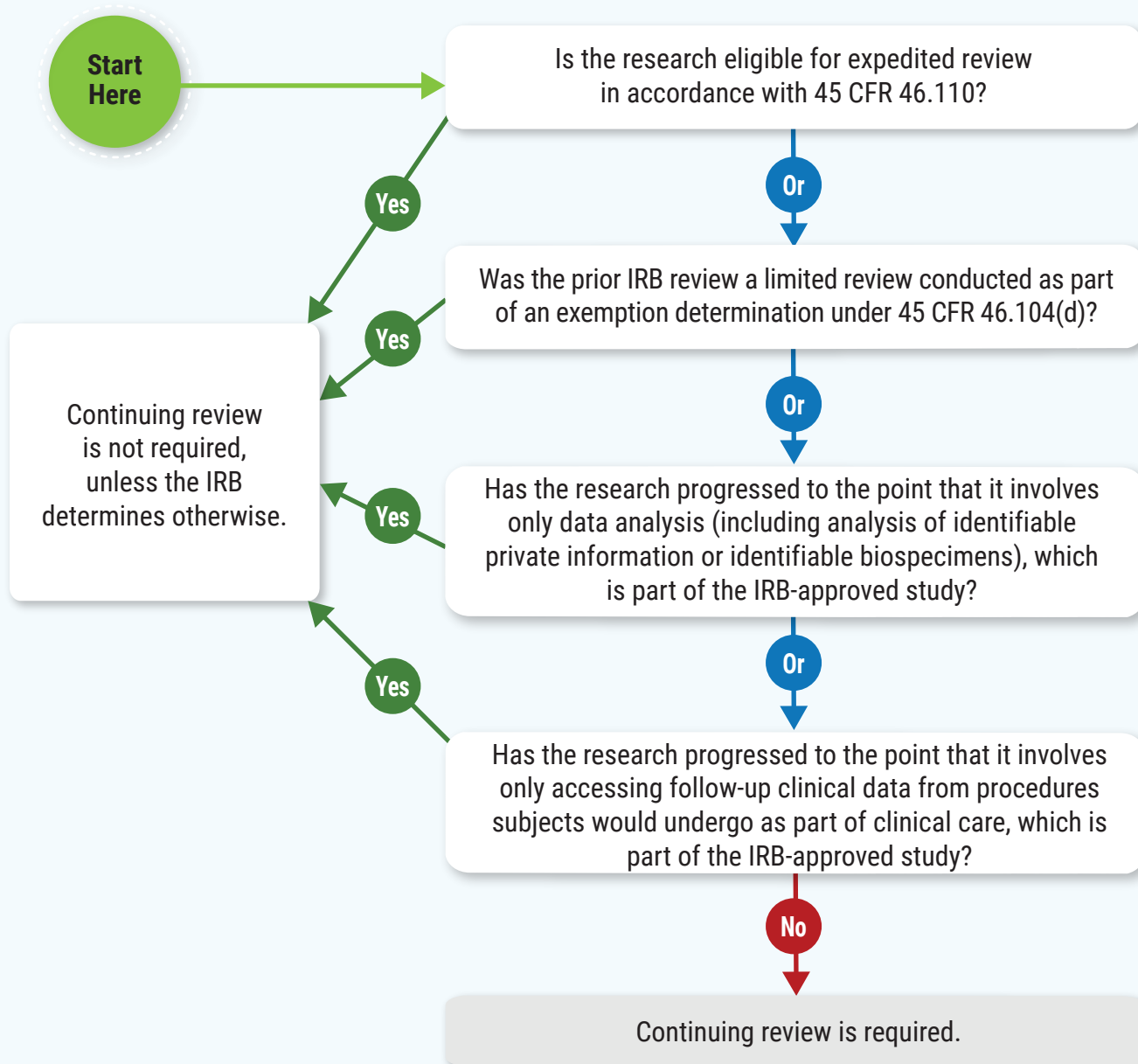


*Research use of identifiable private information or identifiable biospecimens collected for either research studies other than the proposed research, or for nonresearch purposes.

IS CONTINUING REVIEW REQUIRED UNDER 45 CFR 46.109(f)?

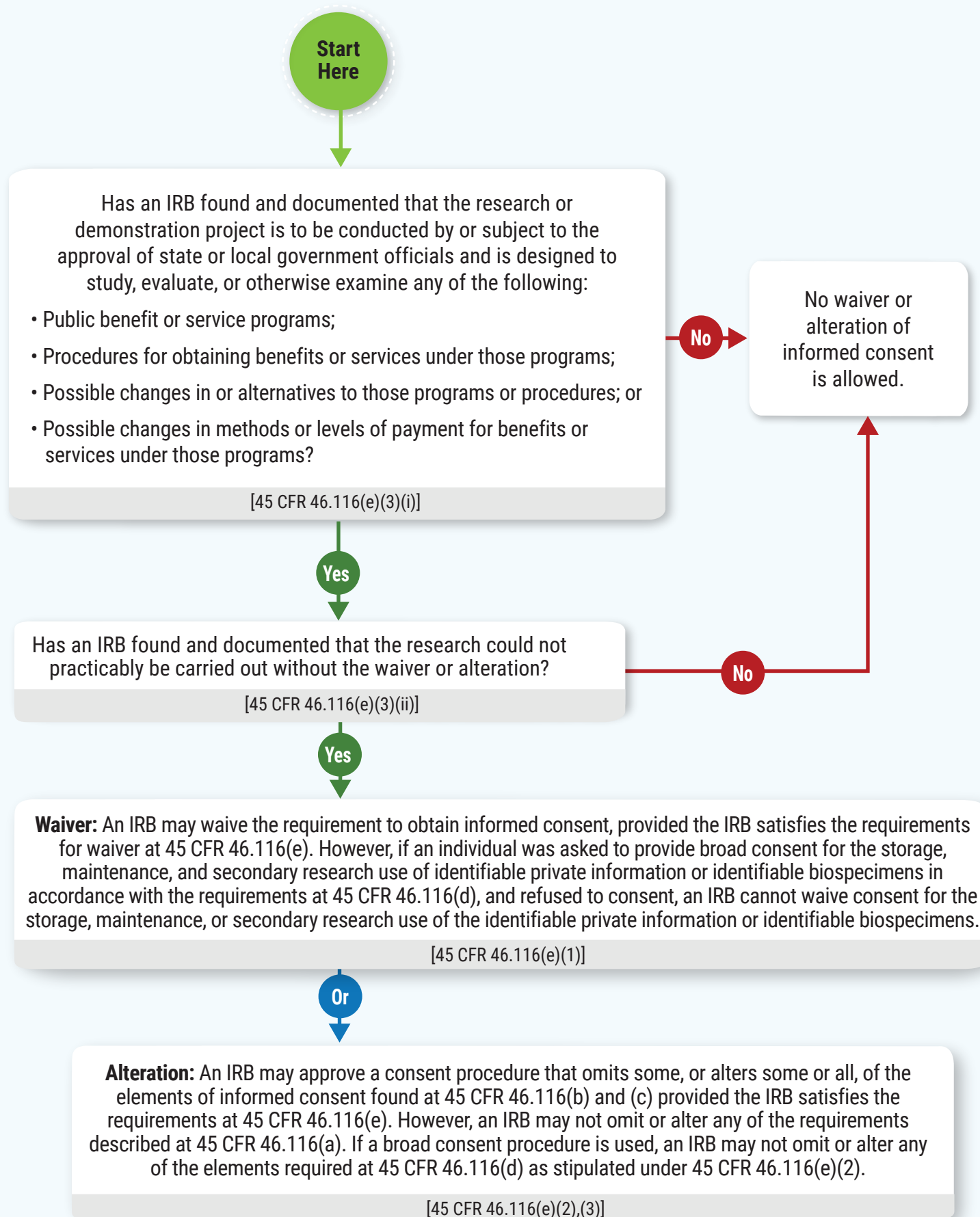
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WHEN CAN INFORMED CONSENT BE WAIVED OR ALTERED UNDER 45 CFR 46.116(f)?

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Start
Here

Has an IRB found and documented that **all** of the following conditions have been met?

- The research involves no more than minimal risk to the subjects;
- The research could not practicably be carried out without the requested waiver or alteration;
- If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;
- The waiver or alteration will not adversely affect the rights and welfare of the subjects; and
- Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

[45 CFR 46.116(f)(3)]

No

No waiver or alteration of informed consent is allowed.

Yes

Waiver: An IRB may waive the requirement to obtain informed consent for research provided the IRB satisfies this requirement. However, if an individual was asked to provide broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens in accordance with the requirements at 45 CFR 46.116(d), and refused to consent, an IRB cannot waive consent for the storage, maintenance, or secondary research use of the identifiable private information or identifiable biospecimens.

[45 CFR 46.116(f)(1)]

Or

Alteration: An IRB may approve a consent procedure that omits some, or alters some or all, of the elements of informed consent set forth in 45 CFR 46.116(b) and (c) provided the IRB satisfies this requirement. However, an IRB may not omit or alter any of the requirements described at 45 CFR 46.116(a). If a broad consent procedure is used, an IRB may not omit or alter any of the elements required under 45 CFR 46.116(d).

[45 CFR 46.116(f)(2)]

CAN DOCUMENTATION OF INFORMED CONSENT BE WAIVED UNDER 45 CFR 46.117(c)?

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