

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

Has HHS **prohibited** exemption of the human subjects research? (Most research involving prisoners, some research involving children.)

[45 CFR 46.104(b)]

No

Will the **only*** involvement of human subjects be in one or more of the following categories?

Yes

No exemptions to 45 CFR part 46 apply. Provisions of 45 CFR part 46, subpart A apply, and subparts B, C, and D also apply if subjects are members of populations covered in those subparts.

Research conducted in **established or commonly accepted** educational settings, involving **normal education practices**?

Yes

Exemption 45 CFR 46.104(d)(1) may apply.

Go to Chart 03

Or

Research only including interactions involving **educational tests, survey procedures, interview procedures, or observation of public behavior**?

Yes

Exemption 45 CFR 46.104(d)(2) may apply.

Go to Chart 04

Or

Research involving benign **behavioral interventions** and collection of information from **adults** with their agreement?

Yes

Exemption 45 CFR 46.104(d)(3) may apply.

Go to Chart 05

Or

Secondary research use of identifiable private information or identifiable biospecimens?

Yes

Exemption 45 CFR 46.104(d)(4) or (d)(8) may apply.

Go to Chart 06 & Chart 10

Or

Research studying, evaluating, or examining **public benefit** or **service programs**?

Yes

Exemption 45 CFR 46.104(d)(5) may apply.

Go to Chart 07

Or

Research involving **taste and food quality evaluation** of **consumer acceptance studies**?

Yes

Exemption 45 CFR 46.104(d)(6) may apply.

Go to Chart 08

Or

Storage or maintenance of identifiable private information or identifiable biospecimens for secondary research use?

Yes

Exemption 45 CFR 46.104(d)(7) may apply.

Go to Chart 09



***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



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.

Start
Here

Is the research conducted in established or commonly accepted educational settings?

Yes

No

Research is not exempt under 45 CFR 46.104(d)(1) exemption.

Go to the other exemption decision charts to see if any other exemptions apply.

No

Does the research specifically involve normal education practices not likely to adversely impact students' opportunity to learn required educational content or assessment of educators who provide instruction? This includes most research on regular and special education instructional strategies, instructional techniques, curricula, or classroom management methods.

Yes

Research may be exempt under 45 CFR 46.104(d)(1).

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)

For use after January 20, 2019



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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)]

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)]

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)]

Yes

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)]

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)

For use after January 20, 2019



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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

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

Yes

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.

No

No

Yes

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.

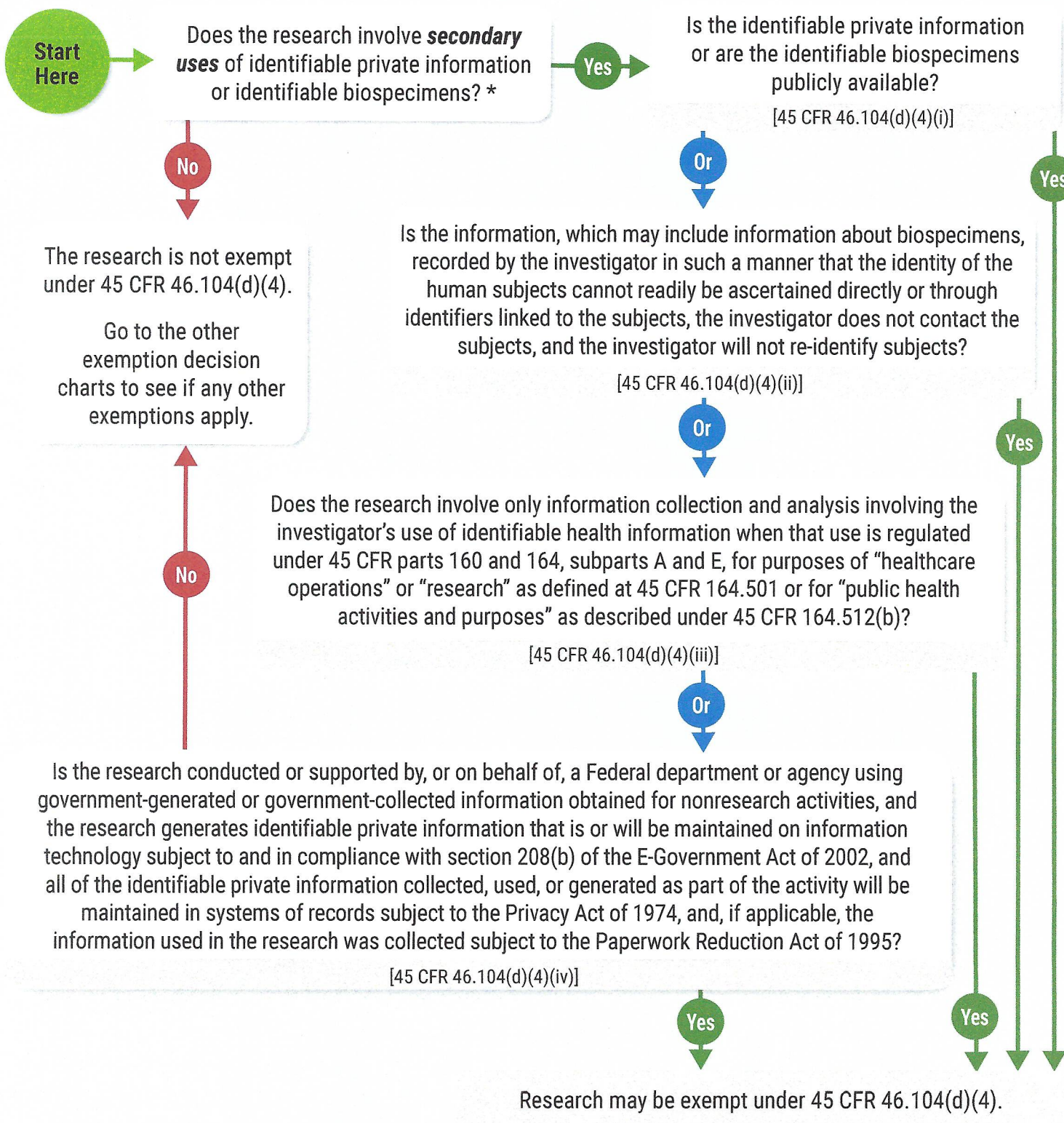
DOES EXEMPTION 45 CFR 46.104(d)(4) FOR SECONDARY RESEARCH THAT DOES NOT REQUIRE CONSENT APPLY?

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

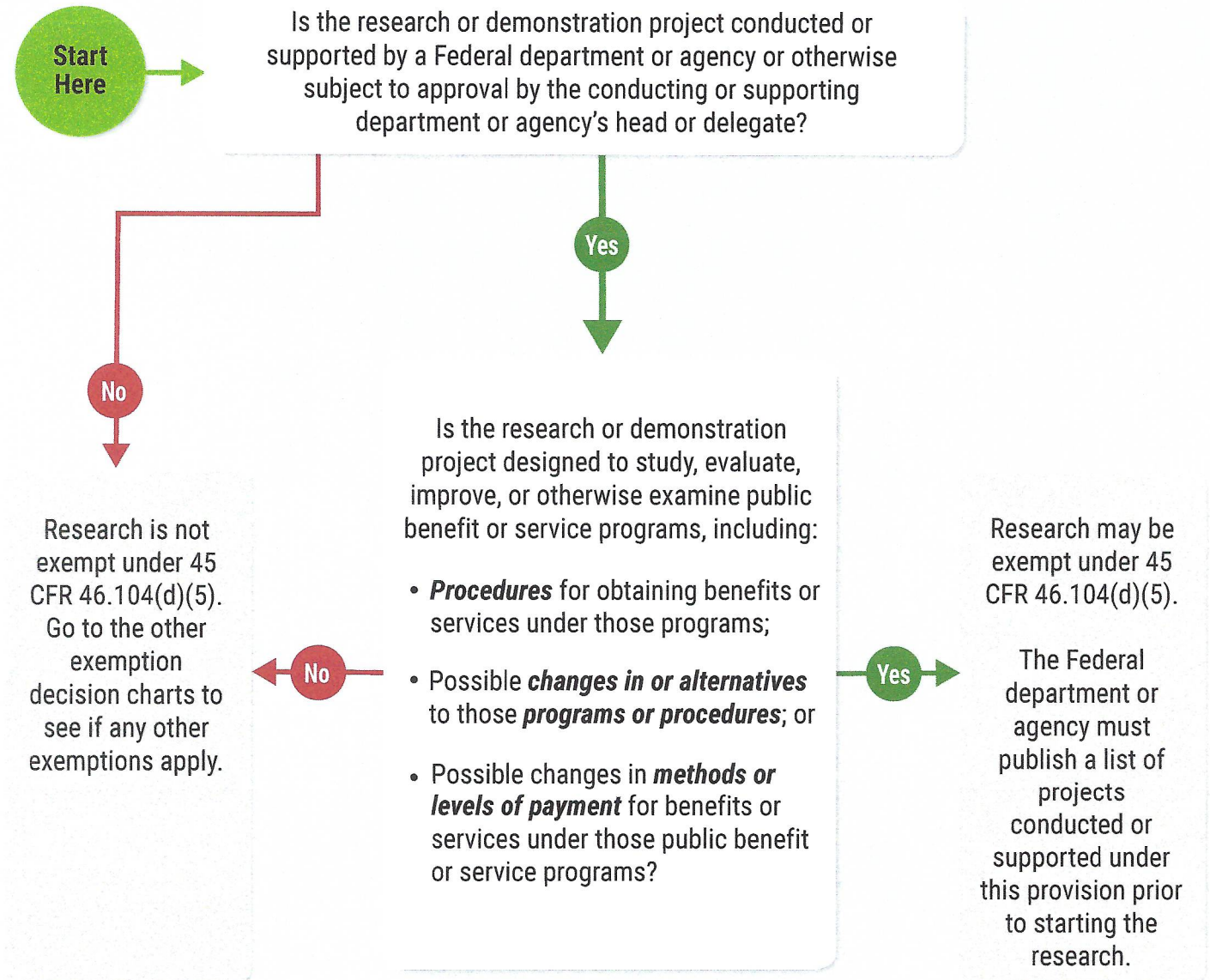
DOES EXEMPTION 45 CFR 46.104(d)(5) FOR PUBLIC BENEFIT OR SERVICE PROGRAMS APPLY?

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For use after January 20, 2019



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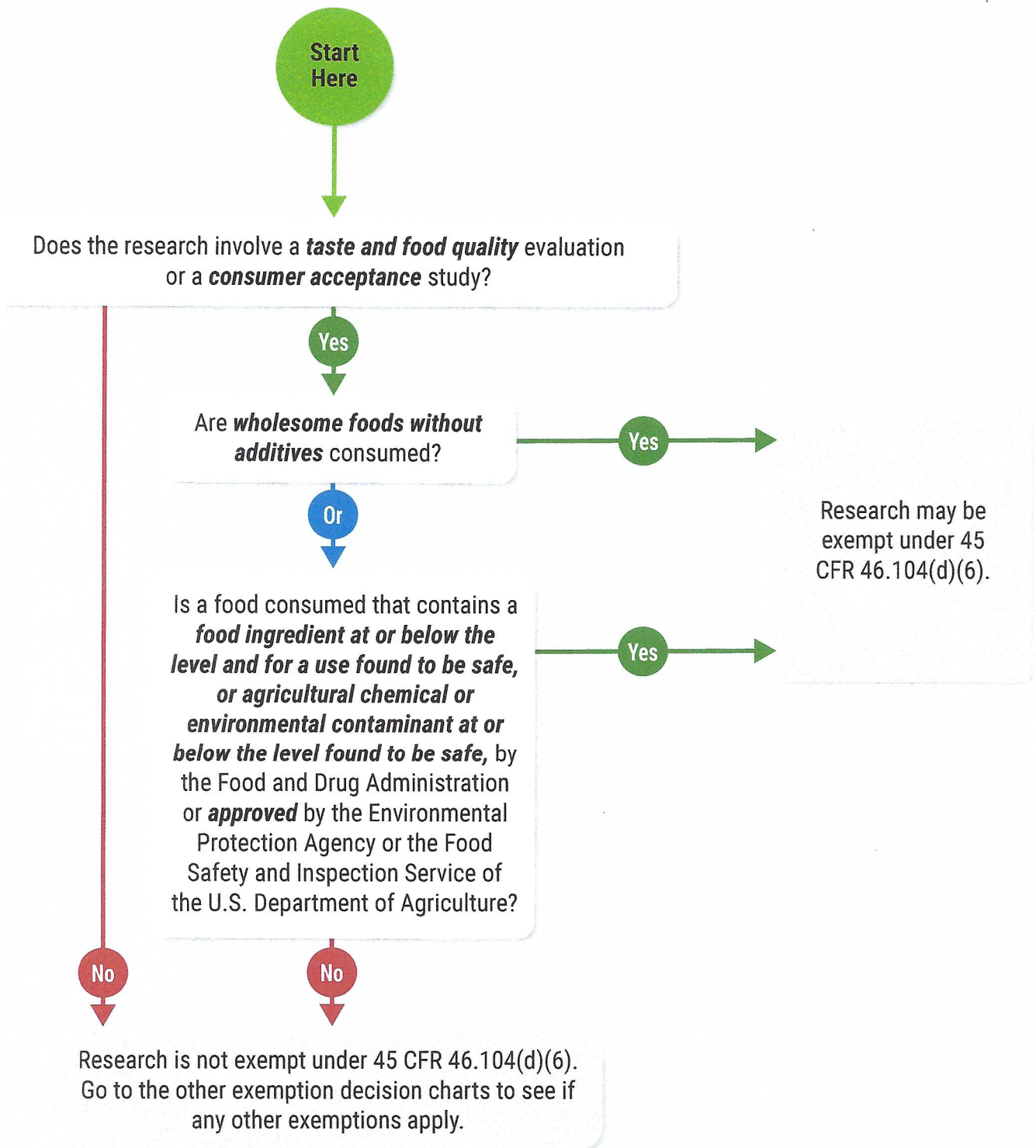
DOES EXEMPTION 45 CFR 46.104(d)(6) FOR FOOD, TASTE, AND ACCEPTANCE STUDIES APPLY?

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)(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)

For use after January 20, 2019



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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

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.

No

▶ 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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For use after January 20, 2019



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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.