Burrell College of Osteopathic Medicine Research Activities That Require IRB Review And Approval	SOP #: RSP.009.01
Effective Date	11/11/19
Last Revision/Review	07/09/2020

1. Purpose

To document the procedures and provide guidance for the Burrell College of Osteopathic Medicine Institutional Review Board to determine whether an activity requires IRB review and approval.

2. Related Policy/Authority

B8530 Human Research Protection Program Statement of Compliance

45 CFR 46: Subpart A

3. Faculty/Staff Responsibilities

Execution of SOP: Principal Investigator (PI)/Study Personnel, Assistant Dean for Research, IRB Chairperson, IRB Members, ORSP Staff, Institutional Official (I.O.) for Research.

4. Definitions/Abbreviations

4.1 **Research**- is defined in the BCOM Human Research Program Statement of Compliance, B8530. Activities which meet this definition constitute research for purposes of this SOP, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

4.2 **Human Subjects**- is defined in the BCOM Human Research Program Statement of Compliance, B8530.

4.3 **Intervention**- includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

4.4 **Interaction**-includes communication or interpersonal contact between investigator and subject.

4.5 **Private Information**- includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or

may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

4.6 **IRB**- means an institutional review board established in accord with and for the purposes expressed in this policy.

4.7 **IRB approval**- means the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements.

5. Procedural Steps

5.1 Investigator Responsibilities

5.1.1 It is the investigator's responsibility to make sure that IRB review and approval is obtained prior to initiation of any research involving human subjects.

5.1.2 It is the investigator's responsibility to make a preliminary assessment as to whether or not the information collected will be used to contribute to generalizable knowledge.

5.1.3 If the investigator is not sure whether his/her project qualifies as "human subjects and research", the investigator must contact the IRB Chair or Authorized Institutional Official (I.O.) for Research for advice. At BCOM, the I.O. is the Assistant Dean for Research.

5.1.4 The IRB Chair will make a final determination whether the project requires or does not require IRB review or approval. The IRB Chair may seek input from members of the IRB and will delegate this responsibility to the IRB Vice-Chair or other IRB member in the event of conflicts of interest.

5.1.5 The IRB Chair communicates with the investigator in writing. Copies of the correspondence are kept on file in the IRB files with the protocol.

5.2 IRB Responsibilities

5.2.1 **IRB Chair**

5.2.1.1 The IRB Chair will review the protocol upon receipt and make a determination as to the level of review. The IRB chair may consult the IRB Vice Chair, other members of the IRB or Institutional Official for advice if necessary. In the event of conflicts of interest by the IRB Chair, the IRB Chair shall recuse from this stage of the review process and the responsibilities will be handled by the IRB Vice-Chair or another member of the IRB who does not have a conflict with the proposal. The Decision Charts for IRB developed by the NIH Office of Human Research Protection serve as guidance for the decision with the understanding that the IRB Chair's decision may include protocol specific reasons for classification of the proposal for review and may not always follow the decision charts.

5.2.1.2 **Levels of Review**

5.2.1.3 **Exempt Review:** Research activities in which the only involvement of human subjects present no greater than minimal risk to subjects and fit into one or more categories defined below may be exempt from requirements of 45 CFR 46. The determination of Exempt status must be made by the IRB chairperson or designee or knowledgeable ORSP staff member

upon review of a request for determination of exempt status and shortened application from the investigator. If the research is found to be exempt, it need not receive full committee or expedited review. The research may not begin until the investigator has received notification by a formal determination letter that the research qualified for exemption. The following types of research may be eligible for exempt review:

A. **Exemption 1:** Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

B. **Exemption 2:** 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) if additional criteria of 45 CFR 46 are met.

C. **Exemption 3:** Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection if additional criteria of 45 CFR 46 are met.

D. **Exemption 4**: Secondary research for which consent is not required or Secondary research that uses identifiable private information or identifiable biospecimens, if additional criteria of 45 CFR 46 are addressed.

E. **Exemption 5:** Research and demonstration projects that are conducted or supported by a Federal department or agency, 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), and that are 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.

F. **Exemption 6**: Taste and food quality evaluation and consumer acceptance studies, if additional criteria of 45 CFR 46 are addressed.

G. **Exemption 7:** Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by 45 CFR 46.

H. **Exemption 8:** Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if additional criteria of 45 CFR 46 are met.

5.2.1.4 **Expedited Review:** Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure authorized by 45 CFR 46 and 21 CFR 56. The expedited review procedure consists of a review of research involving human subjects by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB in accordance with the requirements set forth in 45 CFR 46. Categories eligible for expedited review are:

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
   a. Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required.
   b. Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
   a. from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or

b. from other adults and children [2], considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

3. Prospective collection of biological specimens for research purposes by noninvasive means.
   Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;
   (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.
4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.
5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis) that is not exempt. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46)
6. Collection of data from voice, video, digital, or image recordings made for research purposes.

7. Research on individual or group characteristics or behavior that is not exempt (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46. This listing refers only to research that is not exempt.)
8. Continuing review of research previously approved by the convened IRB as follows:
    a. where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or
    b. where no subjects have been enrolled and no additional risks have been identified; or
    c. where the remaining research activities are limited to data analysis.
9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

5.2.1.5 **Full Committee Review:** Review of research must be conducted by the IRB at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas (i.e., a quorum), except where expedited or exempt review is appropriate as defined in 45 CFR 46. Approval of research is by a majority vote of this quorum. Should the quorum fail during a meeting (e.g., loss of a majority through recusal of members with conflicting interests or early departures, or absence of a nonscientist member), the IRB may not take further actions or votes unless the quorum can be restored.

5.2.2 **Institutional Review Board (IRB)**

5.2.2.1 The IRB, in their deliberations of protocols will utilize resources listed under Sections 5.3 of this document for guidance in deliberations and actions on

protocols. In interpreting regulations, the IRB will interpret mandatory items as those preceded by the terms "shall" and "must". Mandatory items must be followed according to federal regulations. Items preceded by "should" are viewed as suggestions which are typically discussed more in the context of best practices, institutional practices, and protocol specifics.

5.3 NIH Office of Human Research Protection Decision Charts for IRB

5.3.1 Human Subject Regulations Decision Charts

The Office for Human Research Protections (OHRP) provides the following graphic aids as a guide for institutional review boards (IRBs), investigators, and others who decide if an activity is research involving human subjects that must be reviewed by an IRB under the requirements of the U.S. Department of Health and Human Services (HHS) regulations at 45 CFR part 46. The charts address decisions on the following:

- whether an activity **is research** that must be reviewed by an IRB
- whether the research is eligible for an **exemption**
- whether the review may be performed by **expedited procedures**, and
- whether **informed consent** or its documentation may be waived.

5.3.2 Considerations for Use of Charts

The charts are intended to assist IRBs, institutions, and investigators in their decision-making process and should not be used as substitutes for consulting the regulations. OHRP cautions that the full text of applicable regulatory provisions should be considered in making final decisions.

These charts are necessarily generalizations and may not be specific enough for particular situations. Other guidance documents are available related to specific topics, at OHRP Policy Guidance by Topic. The charts do not address requirements that may be imposed by other organizations, such the Food and Drug as Administration, National Institutes of Health, other sponsors, or state or local governments.

The charts are provided in subsequent pages.

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.

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)?

CHART 01

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)

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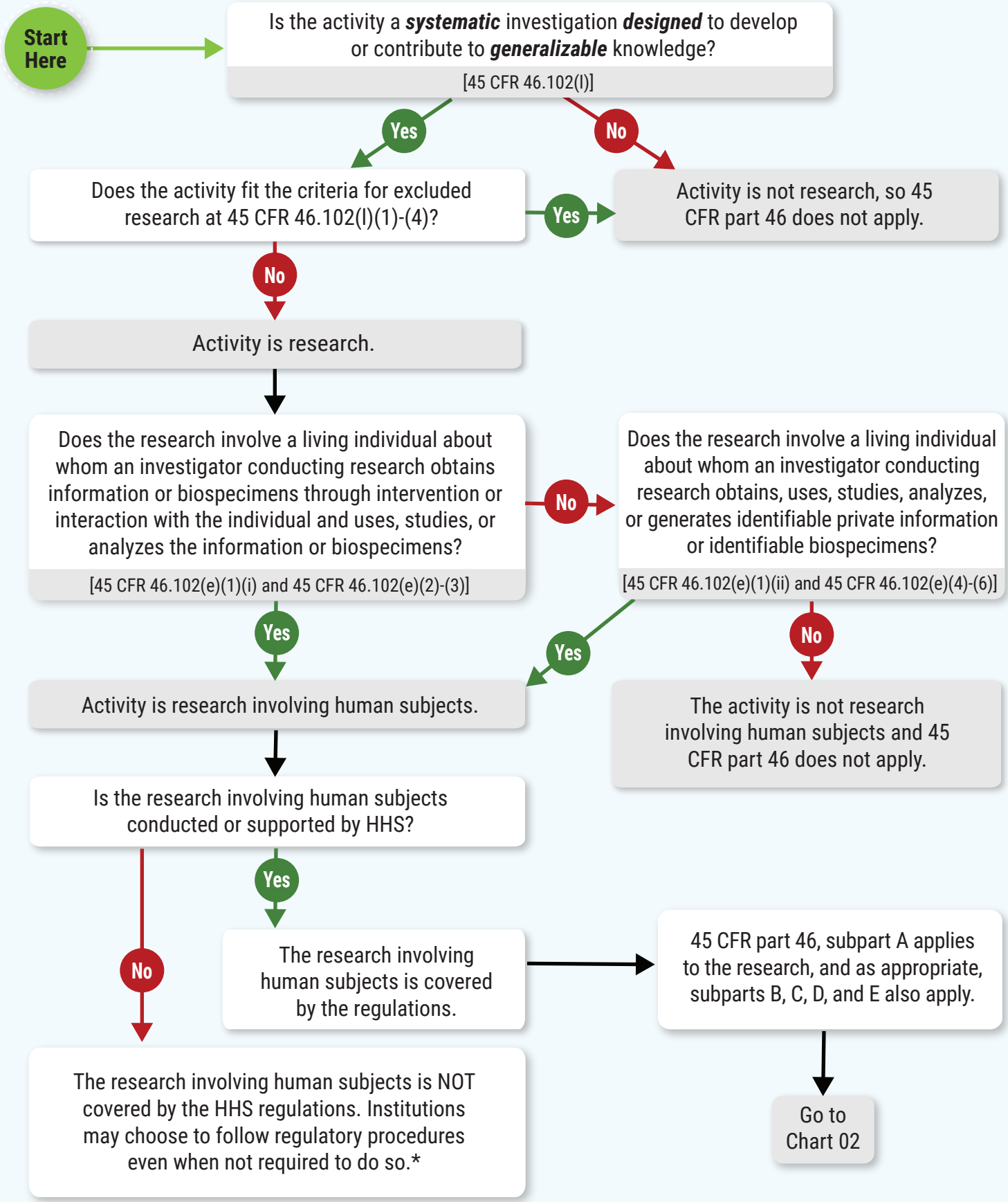

*For information on whether an institution needs to revise its FWA because of the 2018 Requirements, see, ***https://www.hhs.gov/ohrp/education-and-outreach/revised-common-rule/revised-common-rule-q-and-a/index.html***

CHART 02

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)

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

[45 CFR 46.104(b)]

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.

No

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

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 biospecmens?

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.

CHART 03

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)

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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.

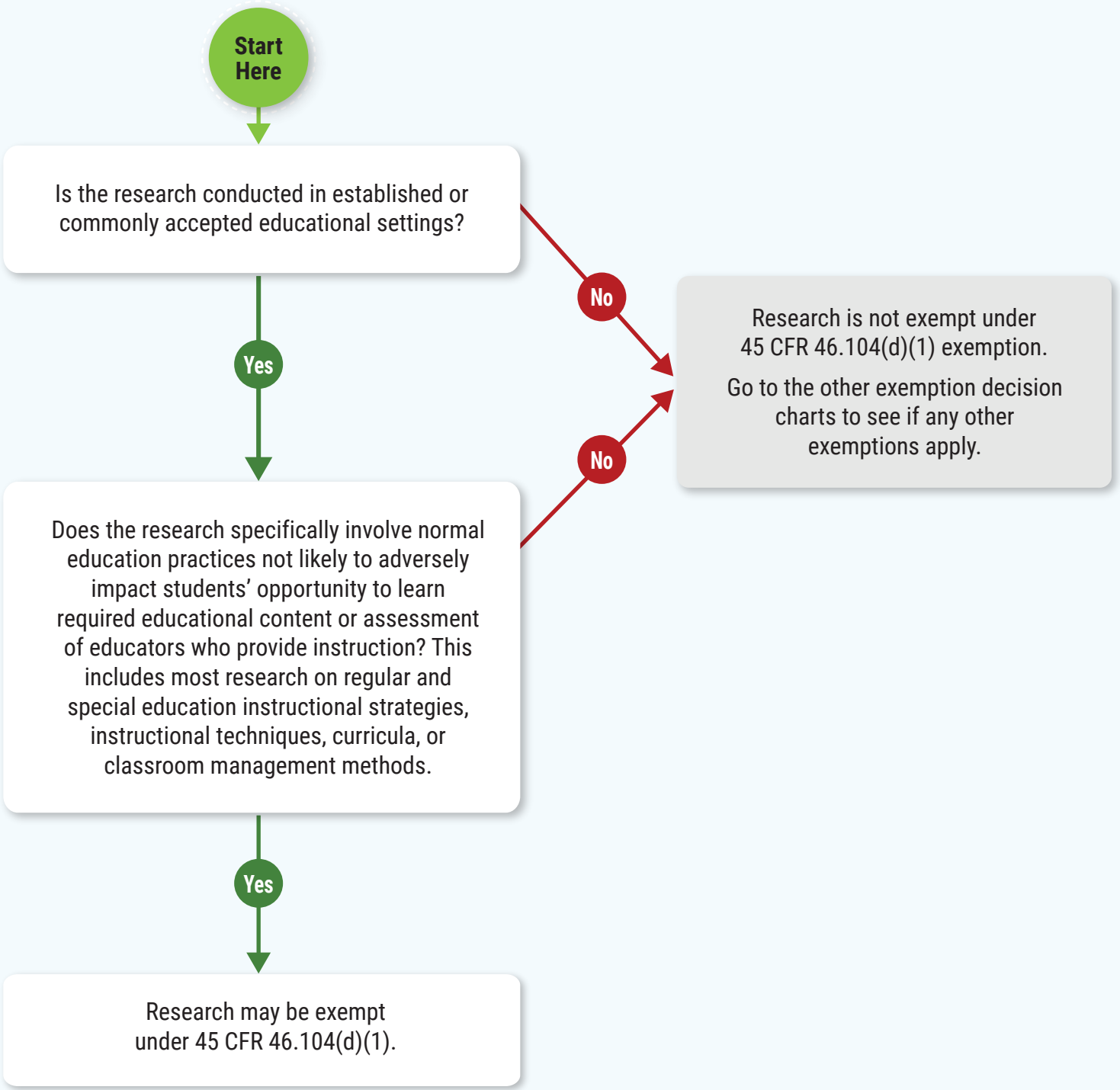

CHART 04

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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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)?

No → 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.

Yes

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 → 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 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 → 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.

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)]

CHART 05

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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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?

Yes

No

Yes

No

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.

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.

CHART 06

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)

OHRP Office for Human Research Protections

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

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

Yes

Is the identifiable private information or are the identifiable biospecimens publicly available?

[45 CFR 46.104(d)(4)(i)]

Yes

Or

Is the information, which may include information about biospecimens, 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, the investigator does not contact the subjects, and the investigator will not re-identify subjects?

[45 CFR 46.104(d)(4)(ii)]

Yes

Or

Does the research involve only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for purposes of "healthcare operations" or "research" as defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b)?

[45 CFR 46.104(d)(4)(iii)]

Yes

Or

Is the research conducted or supported by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, and the research generates identifiable private information that is or will be maintained on information technology subject to and in compliance with section 208(b) of the E-Government Act of 2002, and all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995?

[45 CFR 46.104(d)(4)(iv)]

Yes

Research may be exempt under 45 CFR 46.104(d)(4).

No

The research is not exempt under 45 CFR 46.104(d)(4).

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

No

No

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

CHART 07

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

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

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For use after January 20, 2019

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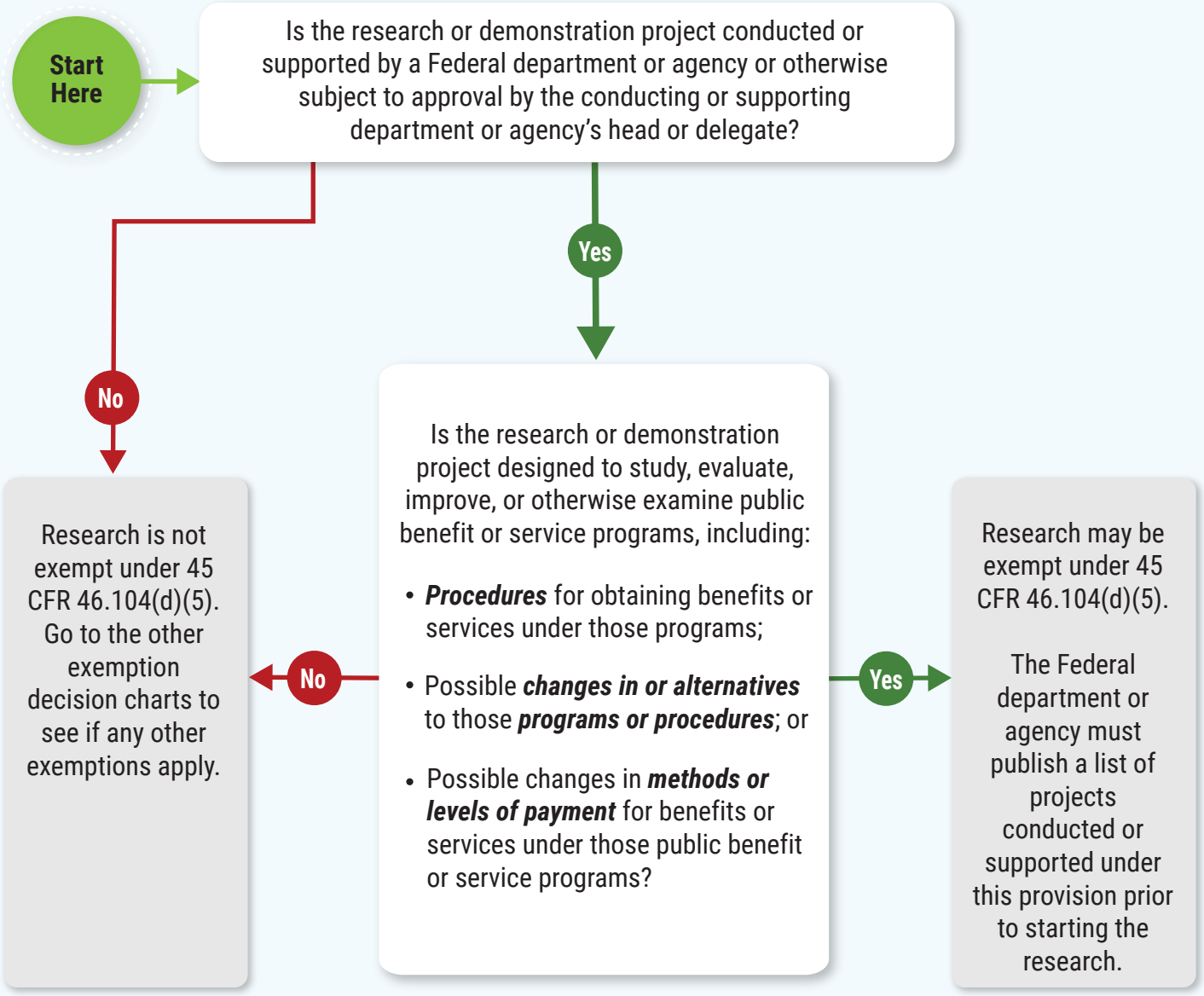

CHART 08

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)

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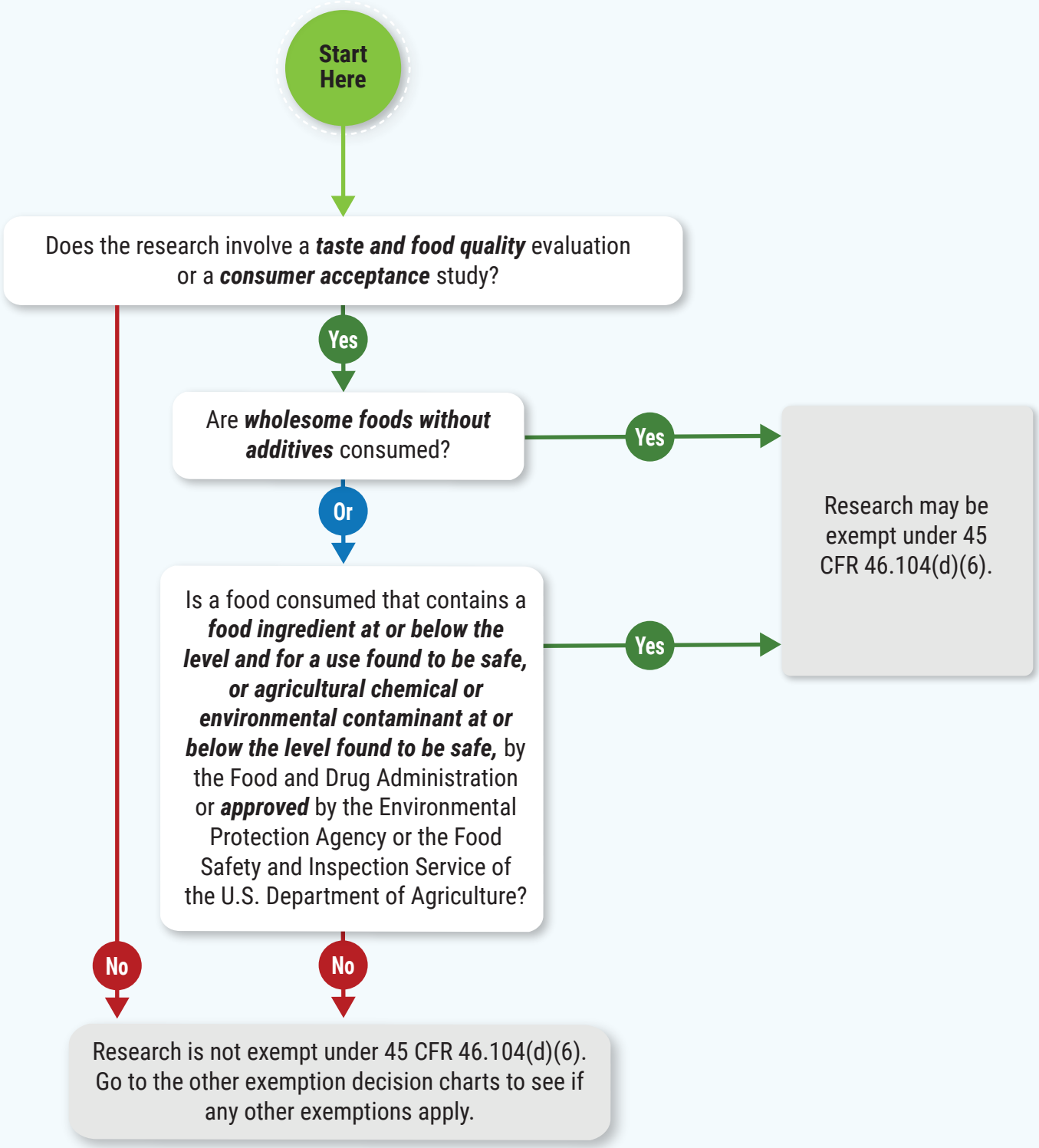

CHART 09

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

OHRP Office for Human Research Protections

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

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.

CHART 10

DOES EXEMPTION 45 CFR 46.104(d)(8) 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)

OHRP Office for Human Research Protections

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

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?

No

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

Yes

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.

No

No

No

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.

CHART 11

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

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

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For use after January 20, 2019

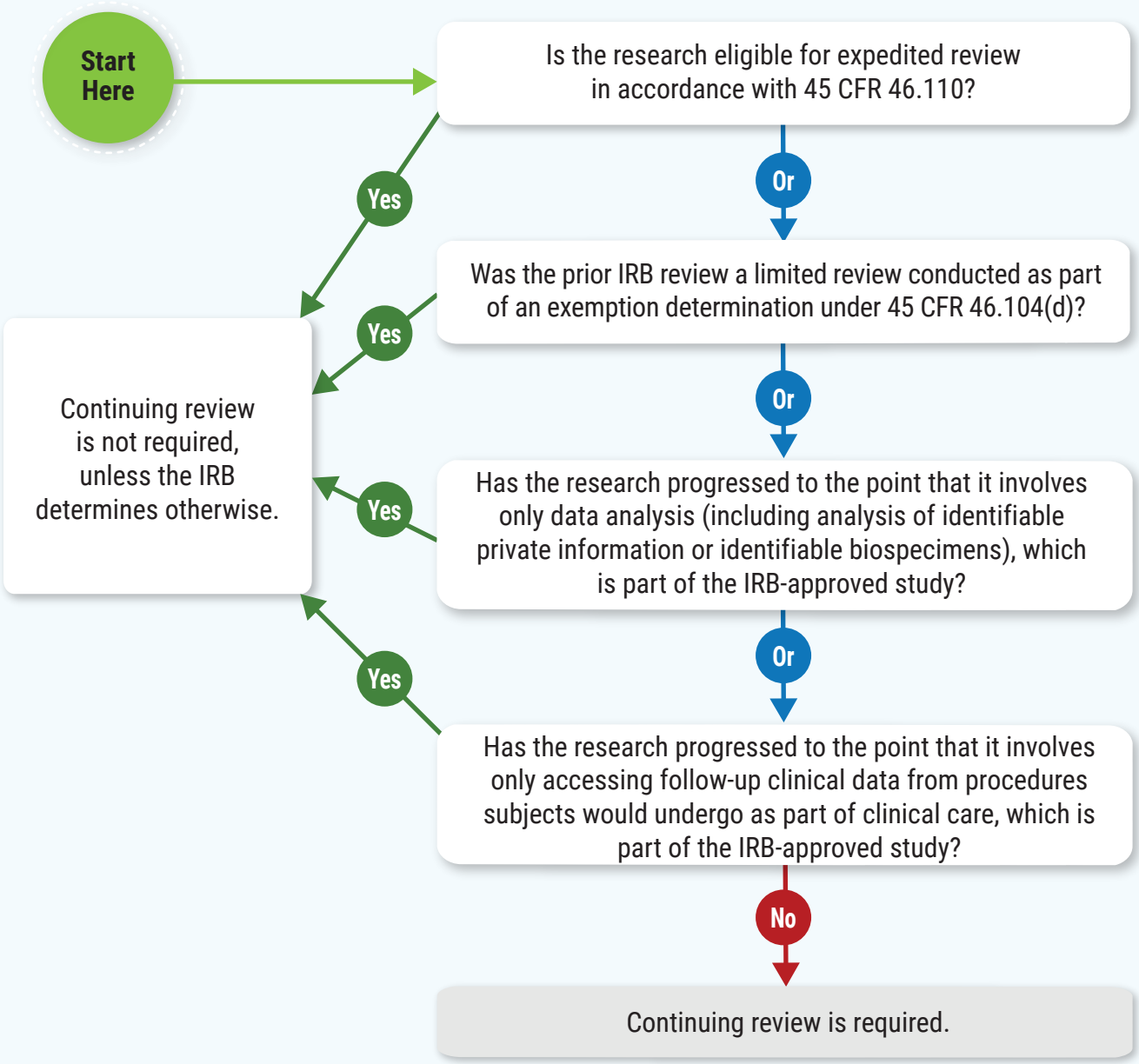

CHART 12

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))

OHRP Office for Human Research Protections

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

For use after January 20, 2019

Start Here

Has an IRB found and documented that the research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine any of the following:

- Public benefit or service programs;
- 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?

[45 CFR 46.116(e)(3)(i)]

No → No waiver or alteration of informed consent is allowed.

Yes

Has an IRB found and documented that the research could not practicably be carried out without the waiver or alteration?

[45 CFR 46.116(e)(3)(ii)]

No → No waiver or alteration of informed consent is allowed.

Yes

Waiver: An IRB may waive the requirement to obtain informed consent, provided the IRB satisfies the requirements for waiver at 45 CFR 46.116(e). 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(e)(1)]

Or

Alteration: An IRB may approve a consent procedure that omits some, or alters some or all, of the elements of informed consent found at 45 CFR 46.116(b) and (c) provided the IRB satisfies the requirements at 45 CFR 46.116(e). 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 at 45 CFR 46.116(d) as stipulated under 45 CFR 46.116(e)(2).

[45 CFR 46.116(e)(2),(3)]

CHART 13

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

OHRP Office for Human Research Protections

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

For use after January 20, 2019

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)]

CHART 14

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

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

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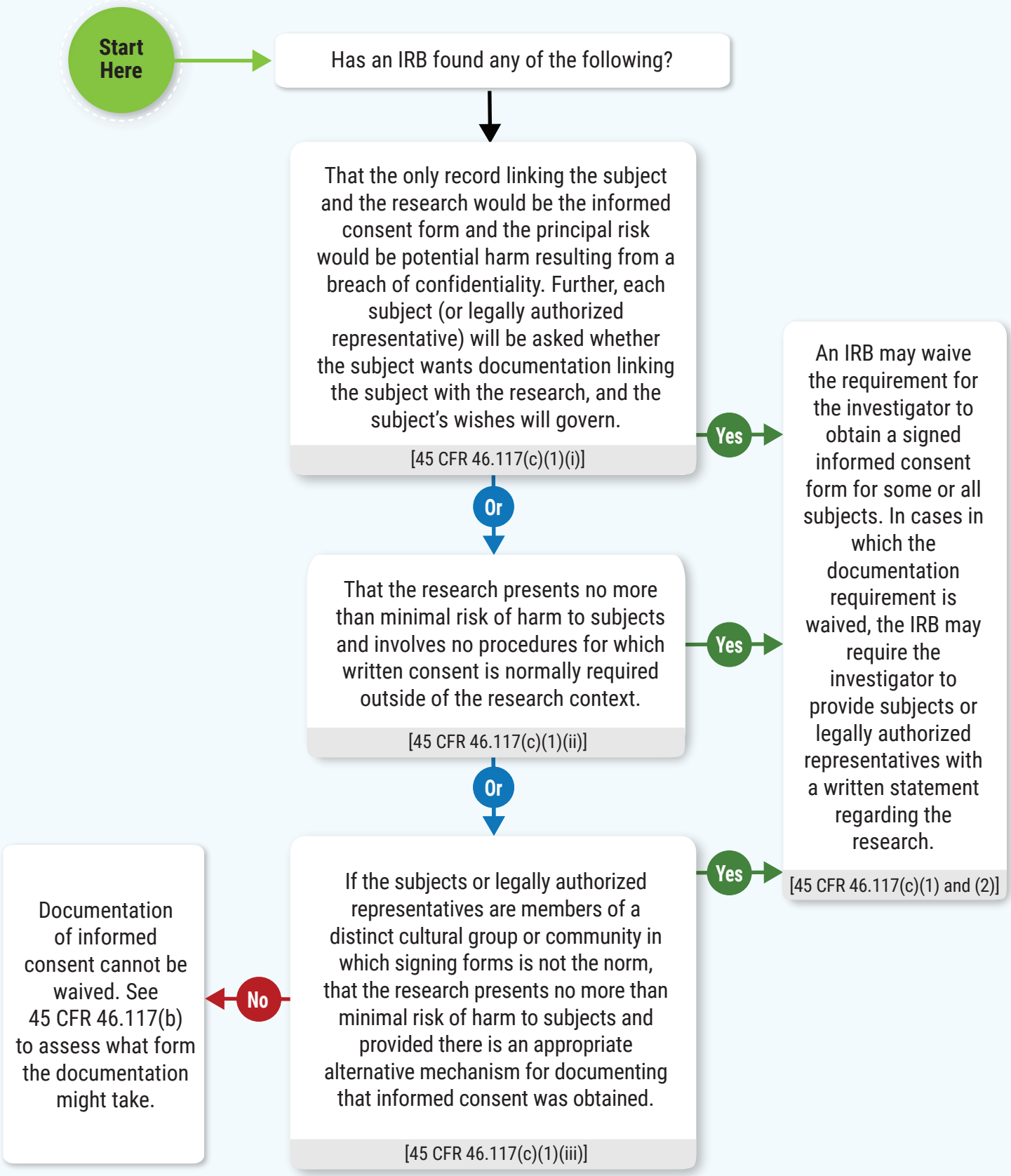
For use after January 20, 2019



6. Reports/Charts/Forms/Attachments/Cross References

Applicable Rules and Regulations:

- 21 CFR 56.102
- 21 CFR 50
- 45 CFR 46
- The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research
- Human Subject Regulations Decision Charts: Select *Chart 1: Is an Activity Research Involving Human Subjects?*
- Office for Human Research Protections (OHRP)

7. Maintenance

Assistant Dean for Research, IRB

The SOP will be reviewed as needed but not less than annually.

8. Signature

Signature on File	11/11/2019
Joseph Benoit, PHD	Date

9. Distribution List

Internal/External

10. Revision History

Revision Date	Subsection #	Summary of Changes	New/Cancellation/ Replacement Procedure? (if applicable)	Approval Date
1	5.3.2	NIH Revised Charts Inserted		07/09/2020