

# Research Determination Flow Charts

## *Before You Begin*

The following flow charts are intended to be used as a visual reference guide to better understand the federal definition of research involving human subjects, and the types of IRB review required for different types of research activities.

These charts are **NOT** to be used in place of the IRB Questionnaire used to determine human subjects research. The questionnaire is **REQUIRED** before you may fill out and submit an IRB application.

[The IRB Questionnaire can be found here.](#)

**Step 1**  
Research  
Determination

This activity is a systematic investigation designed to develop or contribute to generalizable knowledge.

**Yes**

**This activity is research.**  
Go to Step 2.

**No**

**This activity is not research.**  
You may proceed without IRB review.

**Step 2**  
Human Subjects  
Determination

Will the research be obtaining information about living individuals?

**Yes**

Does the research involve intervention or interaction with subjects?

**Yes**

**Research involves human subjects.**  
Go to Step 3.

**No**

Will the information be individually identifiable?

**Yes**

Is the information to be collected private?

**Yes**

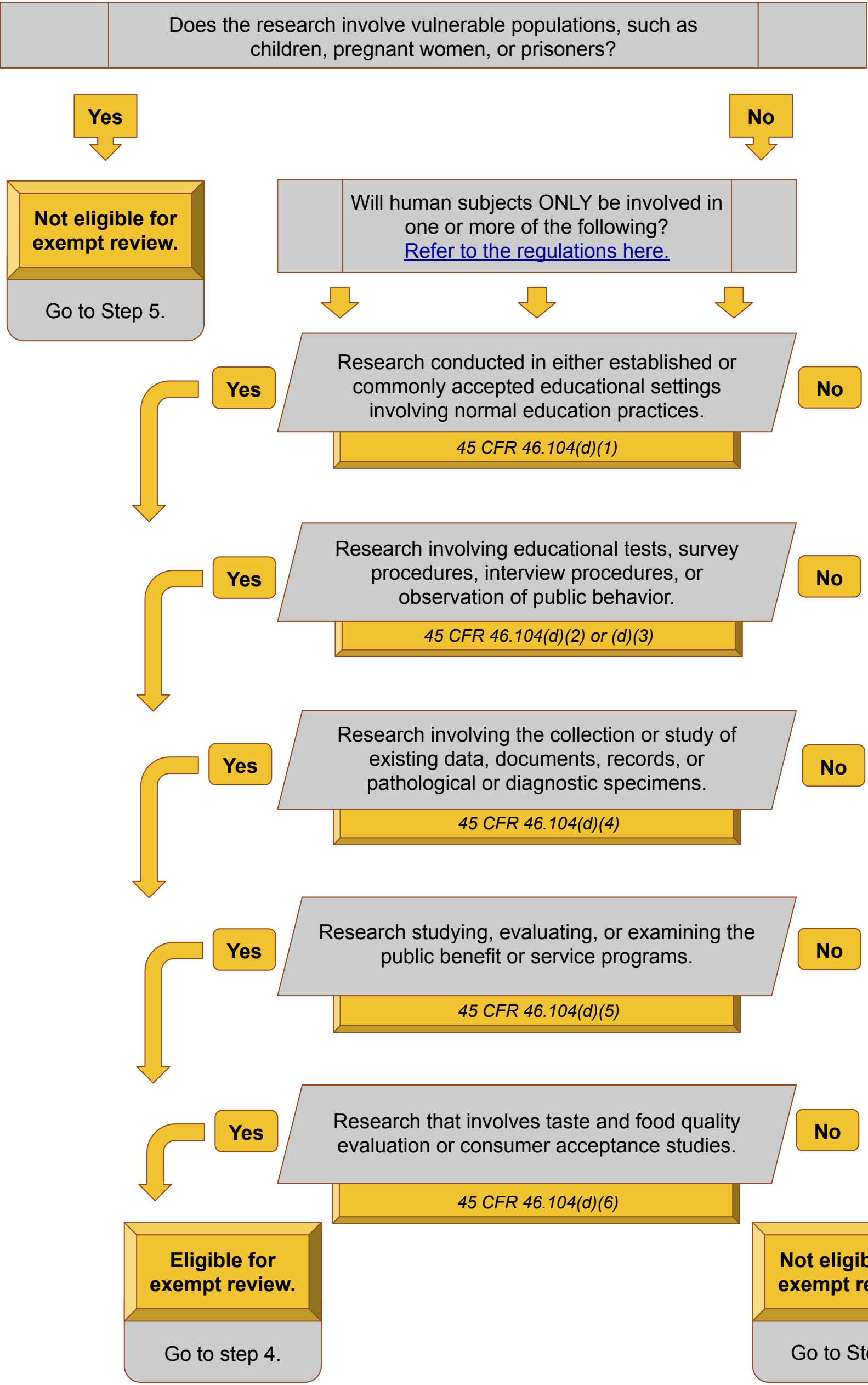
[45 CFR 46.102\(e\)\(4\)](#)

**No**

**Human subjects are not involved.**  
You may proceed without IRB review.

**No**

**No**



**Step 4**  
Eligibility for  
Limited Review

Does the research ONLY include interactions involving educational tests, survey procedures, interview procedures, or observation of public behavior?

OR

Does the research ONLY involve benign behavioral interventions alongside data collection from adult subjects through verbal or written responses, or audiovisual recording?

Yes

No

Does at least one of the following statements apply?



The information recorded in a way that the identity of the human subjects cannot be established directly or through identifiers linked to the subjects.

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

The information is obtained in a manner that allows the identity of subjects to be readily ascertained, whether directly or through linked identifiers.

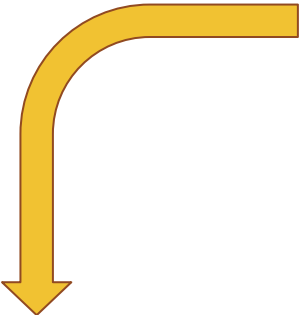
Yes

No

**Eligible for limited review.**  
Complete and submit forms.



**Not eligible for limited review.**  
Eligible for exempt review.



Does this research involve secondary research of identifiable private information or identifiable biospecimens?

No

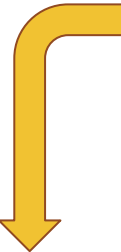
Yes



Has broad consent for this use been obtained?

No

Yes



Has informed consent or waiver of documentation been obtained?

No

Yes

Will individual results be returned to subjects as part of the study plan?

No

Yes



**Eligible for limited review.**  
Complete and submit forms.

**Step 5**  
Eligibility for  
Expedited Review

