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

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

No

Will the information be individually identifiable?

Yes

Is the information to be collected private?

Yes

45 CFR 46.102(e)(4)

No

No

No
Step 3
Eligibility for Exempt Review

Does the research involve vulnerable populations, such as children, pregnant women, or prisoners?

Yes: Not eligible for exempt review. Go to Step 5.

No: Will human subjects ONLY be involved in one or more of the following? Refer to the regulations here.

Yes: Research conducted in either established or commonly accepted educational settings involving normal education practices. Not eligible for exempt review.

No: Research involving educational tests, survey procedures, interview procedures, or observation of public behavior. Not eligible for exempt review.

Yes: Research involving the collection or study of existing data, documents, records, or pathological or diagnostic specimens. Not eligible for exempt review.

No: Research studying, evaluating, or examining the public benefit or service programs. Not eligible for exempt review.

Yes: Research that involves taste and food quality evaluation or consumer acceptance studies. Not eligible for exempt review.

No: Go to step 4. Eligible for exempt review.
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

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.

No

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

Yes

Has broad consent for this use been obtained?

No

Has informed consent or waiver of documentation been obtained?

No

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

Yes

Eligible for exempt review.

Complete and submit forms.

Not eligible for limited review.

Eligible for exempt review.

Eligible for limited review.

Complete and submit forms.
Step 5
Eligibility for Expedited Review

Does the research involve no more than minimal risk, and also involve only the procedures outlined here?

Yes

No

Is this research classified?

No

Yes

Not eligible for expedited review.

A full review is required.

Could identification of subjects put them at risk of criminal or civil liability, or be socially or economically damaging?

No

Yes

Are there measures to ensure risks are no more than minimal?

Yes

No

Eligible for expedited review.

Complete and submit forms.