## 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.



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

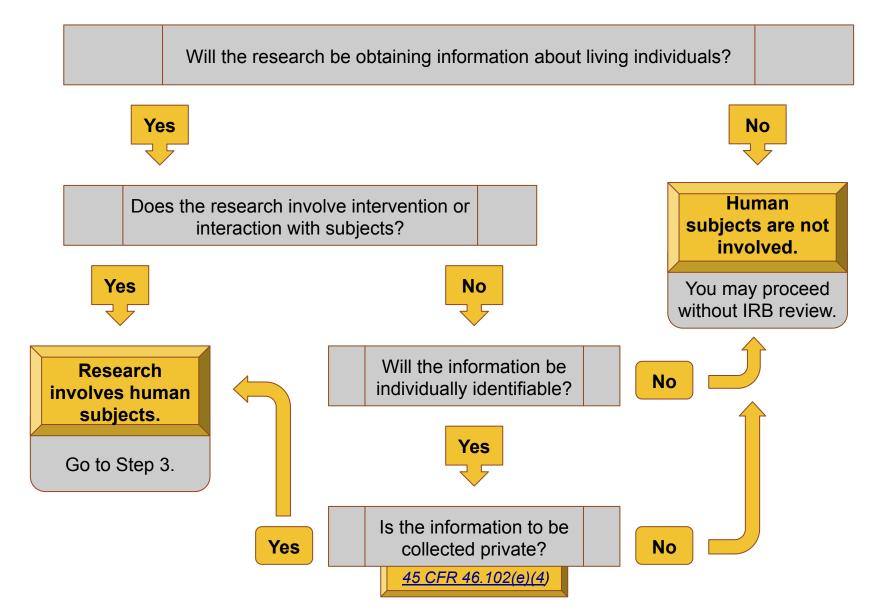
Yes

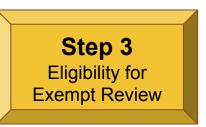
This activity is research.

This activity is not research.

You may proceed without IRB review.

Step 2
Human Subjects
Determination





Does the research involve vulnerable populations, such as children, pregnant women, or prisoners? No Yes Will human subjects ONLY be involved in Not eligible for one or more of the following? exempt review. Refer to the regulations here. Go to Step 5. Research conducted in either established or commonly accepted educational settings No Yes involving normal education practices. 45 CFR 46.104(d)(1) Research involving educational tests, survey procedures, interview procedures, or No Yes observation of public behavior. 45 CFR 46.104(d)(2) or (d)(3) Research involving the collection or study of existing data, documents, records, or Yes No pathological or diagnostic specimens. 45 CFR 46.104(d)(4) Research studying, evaluating, or examining the No Yes public benefit or service programs. 45 CFR 46.104(d)(5) Research that involves taste and food quality evaluation or consumer acceptance studies. 45 CFR 46.104(d)(6) **Eligible for** Not eligible for exempt review. exempt review. Go to Step 5. Go to step 4.



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 Does this research involve statements apply? secondary research of identifiable private information or identifiable biospecimens? The information recorded in a way that the Yes No identity of the human subjects cannot be established directly or through identifiers linked to the subjects. Has broad consent for this use been obtained? Any disclosure of the responses outside of research would NOT place subjects at risk of No Yes criminal or civil liability, or be damaging to the subjects' financial standing, employability, educational advancement, or reputation. Has informed consent or waiver of documentation been obtained? The information is obtained in a manner that allows the identity of subjects to be readily ascertained, whether directly or through linked No Yes identifiers. Will individual results be returned to subjects as part No of the study plan? Yes No Not eligible for Eligible for limited review. limited review. Complete and Eligible for exempt **Eligible for** submit forms. limited review. review. Complete and submit forms.



Does the research involve no more than minimal risk, and also involve only the procedures outlined <a href="here">here</a>? Yes Is this research classified? Not eligible for expedited review. A full review is No Yes 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.