

University of Pikeville Institutional Review Board (IRB)
Exempt Application

Primary Researcher:

Name: Email:

Mailing address: City:

State: Zip: Phone:

Names of Additional Researchers for this study:

Name: Email:

Mailing address: City:

State: Zip: Phone:

Name: Email:

Mailing address: City:

State: Zip: Phone:

Select the exemption category you believe applies to this project (see category descriptors at end of form).

Category 1

Start date of research: Completion date of research:

subjects, and an IRB conducts a limited IRB review to make the determination required

(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. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

1. (i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.
2. (ii) [Reserved]

(6) Taste and food quality evaluation and consumer acceptance studies:

1. (i) If wholesome foods without additives are consumed, or
2. (ii) If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

(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 [§46.111\(a\)\(8\)](#).

(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 the following criteria are met:

(i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with [§46.116\(a\)\(1\)](#) through [\(4\)](#), [\(a\)\(6\)](#), and [\(d\)](#);

(ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with [§46.117](#);

(iii) An IRB conducts a limited IRB review and makes the determination required by [§46.111\(a\)\(7\)](#) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph [\(d\)\(8\)\(i\)](#) of this section; and

(iv) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.