



IRB EXEMPTION REQUEST FORM
OHIO DEPARTMENT OF HEALTH (ODH)
Institutional Review Board (IRB)

1. PROJECT TITLE

2. PRINCIPAL INVESTIGATOR

Name (Last, First, MI): Degree(s):
Title:
E-mail: Phone:

3. SCREENING QUESTIONS (See the list of IRB Exemption Categories on page 2 for the list of categories and their descriptions). Data which was previously collected must already be de-identified and publically available for review in order to be eligible for exemption.

- a. Will the research expose participants to discomfort or distress beyond that normally encountered in daily life?
b. Could disclosure of participants' responses outside the research reasonably place participants at risk of criminal or civil liability...
c. Does any part of the research require deception or incomplete disclosure of information to participants?
d. Will prisoners (or their data and/or specimens) be participants in the research?
e. For research proposed under category 1, will the research be conducted outside of commonly accepted educational settings...
f. For research proposed under category 2, will the research involve surveys or interview procedures with children?
g. For research proposed under category 2, will the research involve observations of the public behavior of children...
h. For research proposed under category 4, will any of the data, documents, records, or biological specimens be collected or created after the date of this application for exemption?
i. For research proposed under category 4, will any of the information obtained from private sources of data, documents, records, or biological specimens be recorded by the investigator...
j. For research proposed under categories 1-5, is the research subject to FDA regulations?

If you checked YES to ANY of the questions above, your research is NOT EXEMPT. Do not complete this form. Submit an IRB Application for Protocol Review.

4. EXEMPT CATEGORY

Please check the categories of exemption for which you are applying. You may check more than one box. 1 2 3 4 5 6

5. DESCRIPTION

Please briefly describe your research project and explain how you will ensure that the data stays de-identified.

6. ASSURANCE: PRINCIPAL INVESTIGATOR (or Advisor)

I agree to follow all applicable federal regulations, guidance, and state and local laws related to the protection of human subjects in research, as well as professional practice standards and generally accepted good research practices for investigators.

I verify that the information provided in this Application for Exemption is accurate and complete. I will initiate this research only after having received notification of exemption determination.

Signature of Principal Investigator

Date

Printed name of Principal Investigator

**CATEGORIES OF RESEARCH ACTIVITIES EXEMPT FROM REVIEW
BY ODH INSTITUTIONAL REVIEW BOARD**

These exemptions **DO NOT APPLY** when **deception** of human subjects may be an element of the research; when the activity might expose the human subjects to **discomfort** or **harassment** beyond levels encountered in daily life; or individuals **involuntarily confined** or **detained** in penal institutions are subjects of the activity.

CATEGORY #1	Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as: a. research on regular and special education instructional strategies b. research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods
CATEGORY #2	Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless : a. information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; AND b. any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation (NOTE: The exemption under Category 2 DOES NOT APPLY to research involving survey or interview procedures or observation of public behavior when individuals under the age of 18 are subjects of the activity except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed.)
CATEGORY #3	Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under Category 2, IF : a. the human subjects are elected or appointed public officials or candidates for public office, OR b. federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
CATEGORY #4	Research, involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified directly or through identifiers linked to the subjects.
CATEGORY #5	Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: a. public benefit or service programs; b. procedures for obtaining benefits or services under those programs; c. possible changes in or alternatives to those programs or procedures; OR d. possible changes in methods or levels of payment for benefits or services under those programs.
CATEGORY #6	Taste and food quality evaluation and consumer acceptance studies, a. if wholesome foods without additives are consumed; OR b. 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.