



CONFLICT OF INTEREST (COI) DISCLOSURE:

Yes No Clear	Do you have a conflict of interest (personal, financial, academic or other interest) in reviewing this protocol that would prevent you from conducting a fair and objective review?
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If No, please continue with your review by completing all areas of the checklist.

If Yes, please contact your IRB Coordinator immediately. You will be provided with specific instructions should your conflict of interest be valid. Please complete this COI section only and save this checklist in the appropriate study within the ERICA system.

- *Example of personal COI – your spouse, an immediate family member, your advisor*
- *Example of academic COI – your student, my research partner/colleague*
- *Example of financial COI – income from stock in etc. the Sponsor or company whose business is substantially related to the subject matter of the research.*

Reviewer Description of Conflict of Interest:

Determining if Human Research is Exempt from IRB Review

Complete each section (A-C) as instructed.

SECTION A

If either of the following questions is answered "yes", this study **cannot** be exempt. Skip to the Determination section and mark "no".

If both of the following questions are either "no" or "N/A", continue to SECTION B.

Yes
 No Does the research involve prisoners as participants?
 Clear

Yes
 No For categories 1-5, is the research subject to FDA regulation?
 N/A N/A if exempt category 6
 Clear

SECTION B

Please indicate the category for which this research qualifies and answer the subsequent questions.

The IRB administrator assigned to review this proposal selected category:

Category 1: Category 2: Category 3:
Category 4: Category 5: Category 6:

Category 1:

All of the following must be answered "yes" in order to qualify for exempt category 1:

Yes Is the research conducted in established or commonly accepted educational settings?
 No
 Clear

Yes Does the research involve normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods?
 No
 Clear

Category 2:

All of the following must be answered "yes" in order to qualify for exempt category 2:

Yes Does the research involve the use of **one or more** of the following?
 No
 Clear

- Educational tests (cognitive, diagnostic, aptitude, achievement)
- Survey procedures
- Interview procedures
- Observation of public behavior

Yes Is **either** of the following true?
 No

- Information obtained is recorded in such a manner that participants **CANNOT** be identified, directly or through identifiers linked to the participants
- Any disclosure of the participants' responses outside the research could **NOT** reasonably

Clear

place them at risk of criminal or civil liability or be damaging to their financial standing, employability, or reputation

Only answer the following for research involving children. Leave blank if children are not involved. The following must be answered "yes" in order to qualify for exempt category 2:

Yes

When the research involves children as participants, are the procedures limited to:

No

- Educational tests (cognitive, diagnostic, aptitude, achievement)
- Observation of public behavior where the investigator(s) will **NOT** participate in the activities being observed

Clear

Category 3:

All of the following must be answered "yes" in order to qualify for exempt category 3:

Yes

Does the research involve the use of **one or more** of the following that is not exempt under category 2?

No

- Educational tests (cognitive, diagnostic, aptitude, achievement)
- Survey procedures
- Interview procedures
- Observation of public behavior

Clear

Yes

Is **either** of the following true?

No

- The participants are elected or appointed public officials or candidates for public office.
- Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter

Clear

Category 4:

All of the following must be answered "yes" in order to qualify for exempt category 4:

Yes

Does the research involve the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens? *The reviewed materials currently exist and are **NOT** prospectively collected.*

No

Clear

Yes

Is at least **one** of the following true?

No

- These sources are publicly available
- Information is recorded by the investigator in such a manner that the subjects cannot be identified directly or through identifiers linked to the subjects

Clear

Category 5:

All of the following must be answered "yes" in order to qualify for exempt category 5:

Yes

Is the project a research or demonstration project?

No

Clear

Yes

Is the project conducted by or subject to the approval of Department or Agency heads?

No

Clear

Yes

Is the project designed to study, evaluate, or otherwise examine:

No

- (i) Public benefit or service programs;
- (ii) procedures for obtaining benefits or services under those programs;
- (iii) possible changes in or alternatives to those programs or procedures; or
- (iv) possible changes in methods or levels of payment for benefits or services under those programs

Clear

Yes

Does the program under study deliver a public benefit (e.g., financial or medical benefits as

No provided under the Social Security Act) or service (e.g., social, supportive, or nutrition services as provided under the Older Americans Act)?
Clear

Yes Is the project conducted pursuant to specific federal statutory authority?
No
Clear

Yes There is no statutory requirement that an IRB review the project.
No
Clear

Yes The project does not involve significant physical invasions or intrusions upon the privacy of participants.
No
Clear

Category 6:

All of the following must be answered "yes" in order to qualify for exempt category 6:

Yes Does the research involve a taste and food quality evaluation or consumer acceptance studies?
No
Clear

Is at least **one** of the following true?

Yes
No
Clear
• Wholesome foods without additives will be consumed.
• A food will be consumed that contains a food ingredient at or below the level to be safe and is for a use found to be safe.
• A food will be consumed that contains an agricultural chemical or environmental contaminant and **one** of the following is true:
o The agricultural chemical or environmental contaminant is at or below the level found to be safe by the Food and Drug Administration
o The agricultural chemical or environmental contaminant is at or below the level approved by the Environmental Protection Agency
o The agricultural chemical or environmental contaminant is at or below the level approved by the Food Safety and Inspection Service of the U.S. Department of Agriculture

SECTION C

Instructions:

Mark the appropriate box.

- If you answer "yes", the ethical standard is satisfied.
- If you answer "no", the ethical standard is not satisfied. You may request modifications in the "Specific Concerns" section.
- According to the guidelines provided, if you mark "not applicable (N/A)", the standard is not required. However, based upon the IRB's discretion, the information may be required. You may request the information or modifications in the "Specific Concerns" section.

Yes Does the research hold out no more than minimal risk to participants?
No Clear

Is the selection of subjects equitable?

Yes
No Clear
• Appropriate inclusion and exclusion criteria for research participants are essential in order to ethically justify human subject research.
• Inclusion and exclusion criteria should be clearly stated and reasonable. Poorly specified inclusion/exclusion criteria may result in inadvertent exclusion of eligible research subjects and an imbalance of or inappropriate enrollment of research subjects.
• If for some extenuating reason, inclusion criteria are not equitable, the investigator must provide justification.

Yes
No If there is recording of identifiable information, are there adequate provisions to maintain the confidentiality of the data?

N/A *N/A if there is no recording of identifiable information.*

[Clear](#)

If there are interactions with participants, is there a consent process that will disclose such information as:

- Yes
 - No
 - N/A
1. That the activity involves research.
 2. A description of the procedures.
 3. That participating is voluntary.
 4. Name and contact information for the investigator.

[Clear](#)


N/A if there are no interactions with participants.


Yes
Are there adequate provisions to maintain the privacy interest of participants?

No [Clear](#)

Yes
No
Is the research conducted in an ethical manner which does not adversely affect the rights and welfare of the participants?

[Clear](#)

 Evaluating Ethical Standards

 Examples of Ethical Concerns

Comments:

Revisions:

DETERMINATION: Does the new study application meet the criteria for exemption?

- Yes.
- Yes, if the above stipulation is met.
- No.

[Clear](#)

