

## Checklist 1.E Does the research activity qualify for EXEMPT review?

**The key personnel have documented completion of an education program for the protection of human research participants that has been approved by the Campus IRB.**

True  False

NOTE: If FALSE, the application can't be approved according the Campus IRB policies. All research key personnel must received certification of human subject research training PRIOR to conducting research.

### How is project funded?

- NONE. The project is not funded
- EXTERNAL SPONSOR: (e.g. grant, contract)
  - Pending
  - Awarded
- INTERNAL SOURCE: (any MU center, entity or unit)
  - Pending
  - Awarded

### The funding proposal was reviewed.

True  False

## Does the research activity qualify for EXEMPT review?

RULE Instruction: The Campus IRB is allowed to exempt certain types of human subject research from the federal regulations by determining whether the proposed activities meet the exemption criteria. To qualify for exemption, the research must meet the requirements established by the Department of Health and Human Services.

The proposed activities must meet the DHHS or FDA definition of human subject research to be eligible for exemption consideration.

## THE CRITERIA FOR ALLOWING EXEMPTION FROM FEDERAL REGULATIONS

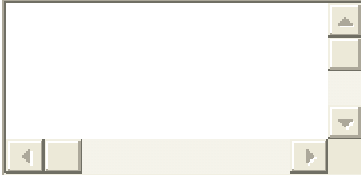
The following categories of research activities fall under the EXEMPT level of review. Please answer TRUE to all that apply to the proposal currently under review..

1. Research conducted in established or commonly accepted educational settings, involving 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.

- The research does not involve prisoners as participants.
- The research is not FDA regulated.

True  False

If TRUE, please justify:

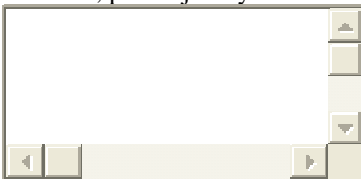


2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; AND (ii) 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.

- The research does not involve prisoners as participants.
- The research is not FDA regulated.
- If children are involved, their participation is limited to either educational tests or observation of public behavior where the investigator does not participate in the observed activities.
- If children are involved, the procedures do not involve survey procedures or interviews.

True  False

If TRUE, please justify:

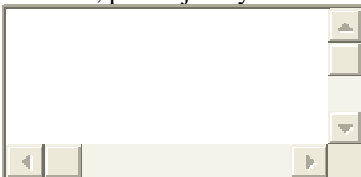


3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office; OR (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

- The research does not involve prisoners as participants.
- The research is not FDA regulated.

True  False

If TRUE, please justify:



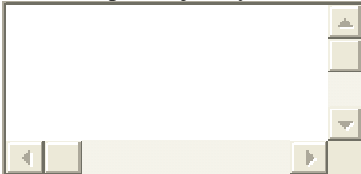
4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the

investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

- The research does not involve prisoners as participants.
- The research is not FDA regulated.

True  False

If TRUE, please justify:

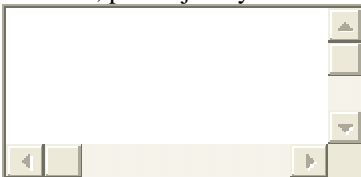


5. Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) 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.

- The research delivers a public benefit (e.g. financial or medical benefits as provided under the Social Security Act) or service (e.g., social, supportive, or nutrition services as provided under the Older Americans Act.)
- The research is conducted pursuant to specific federal statutory authority.
- There is no statutory requirement mandating IRB review of the research.
- The research does not involve significant physical invasions or intrusions upon the privacy of participants.
- The research does not involve prisoners as participants.
- The research is not FDA regulated.

True  False

If TRUE, please justify:



6. Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed OR (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.

- The research does not involve prisoners as participants.

True  False

If TRUE, please justify:

## **RULES**

- RULE Instruction: The proposed human subject research activities MUST qualify for at least one of the EXEMPT categories (indicated by a TRUE response) listed above to be exempted from federal regulations. If you did not answer TRUE to at least one of the categories above, the human subject research activities do not qualify for exemption, and must be reviewed at the expedited or full board level. Please continue on to complete the appropriate checklists.**

---

**RULE Instruction: If you selected one or more of the categories (1-6) above, the activities meet the criteria for EXEMPTION. Please confirm your determination by assuring the following items are true:**

### **7. ANALYSIS OF RISK AND BENEFITS**

- a. The research presents no more than minimal risk to participants.

*Minimal: The probability and magnitude of harm or discomfort "anticipated" in research are no greater in and of themselves than those ordinarily encountered in daily life OR during the performance of routine physical or psychological examinations or tests.*

*Moderate: Moderate risk is defined as what is considered a reasonable or average risk. The IRB may consider a project to have moderate risk if the risks that may result from participation in the research are reasonable under the given circumstances.*

*Substantial: Substantial risk is defined as what is considered extensive, significant, or large. The IRB may consider a project to have substantial or significant risk if the risks to which subjects are exposed to as a result from participation in the research are either major or considerable under the given circumstances.*

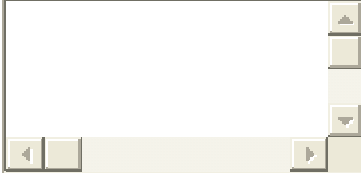
True  False

- b. The proposed risks to participants are reasonable in relation to the potential benefits to participants and to society.

True  False

**RULE:** If FALSE, please provide documentation for your determination. If the risks are greater than the benefit to the participant, the activities will FAIL to meet the criteria for exemption according to Campus IRB policies. The researcher will be required to submit an application for expedited or full board review.

If FALSE, please justify your determination:



## 8. RECRUITMENT TECHNIQUES

The selection of subjects is equitable.

True  False

The recruitment processes are free of undue influence or coercion.

True  False

Recruitment processes are not applicable to this proposal.

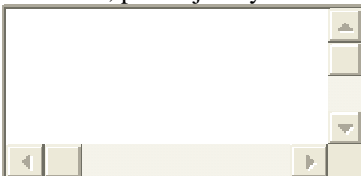
## 9. OBTAINING PARTICIPANTS' PERMISSION

Research that qualifies as Exempt is, by default, "exempt" from the regulatory requirements for Informed Consent. However, the Campus IRB compels investigators to obtain participant's consent whenever possible to comply with the guiding ethical principle of *Respect for Persons* outlined in the Belmont Report. Permission may be obtained orally or in writing. Investigators are not required to submit the Consent form for review; however, they must provide the IRB with a description of how they will obtain a subject's permission.

The description of the permission process is adequate.

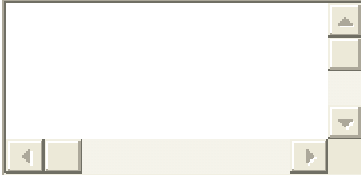
True  False

If FALSE, please justify:



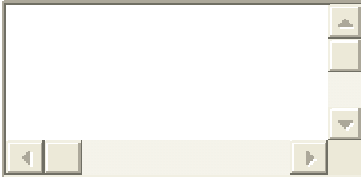
Permission processes are not required for this proposal.

Justification required:

An empty rectangular text box with a light beige background and a thin border. It has a scroll bar on the right side and a horizontal scroll bar at the bottom.

- Permission processes are not applicable to this proposal.

Justification required:

An empty rectangular text box with a light beige background and a thin border. It has a scroll bar on the right side and a horizontal scroll bar at the bottom.

#### 10. FINANCIAL CONFLICT OF INTEREST

Do any of the key personnel or research team members of this project have a financial interest with the sponsor of this research?

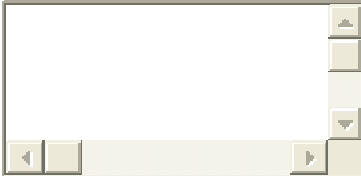
- Project not funded; not applicable  
 No  
 Yes. The Campus IRB may require disclosure of financial interests during the consent process.

If yes, has the financial interest been disclosed to the Conflict of Interest Committee?

- No  
 Yes.

If NO, please provide comments below. If NO, an updated Financial Disclosure form must be filed with the Conflict of Interest Committee simultaneously with the submission of this application. The IRB will take the Conflict of Interest Committee's decision into consideration when reviewing an application

If NO, please justify:

An empty rectangular text box with a light beige background and a thin border. It has a scroll bar on the right side and a horizontal scroll bar at the bottom.

---


**RULE Instruction: If you marked FALSE to one or more of the items above, the activity does not qualify for EXEMPT review. Please continue with checklist 1.F**

The activities qualify for EXEMPTION from the DHHS regulations governing human subject research

The activities DO NOT qualify for EXEMPTION from the DHHS regulations governing human subject research

---

Save

Move To Stage:   Move