

## 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.

### 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.
- The research can't involve significant physical invasions or intrusions upon the privacy of participants; or observation of behavior in settings where participants have a reasonable expectation of privacy
- The research can't involve deception of research participants
- The research can't involve techniques which expose participants to discomfort or harassment beyond levels encountered in daily life
- The research can't involve investigation of legal matters, illegal activities, and admissions of guilt involve illegal acts or violations of parole.

True  False

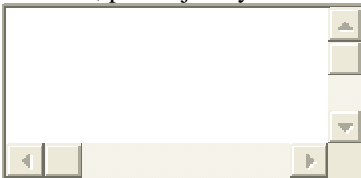
If TRUE, please justify:

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.

- If the research involves children, the activities must: (1) Be limited either to educational tests or to observation of public behavior where the investigator does not participate in the observed activities. (2) Not involve survey procedures, interview procedures or observation of public behavior where the investigators participate in the activities being observed.
- The research does not involve prisoners.
- The research is not FDA regulated.
- The research can't involve significant physical invasions or intrusions upon the privacy of participants; or observation of behavior in settings where participants have a reasonable expectation of privacy
- The research can't involve deception of research participants
- The research can't involve techniques which expose participants to discomfort or harassment beyond levels encountered in daily life
- The research can't involve investigation of legal matters, illegal activities, and admissions of guilt involve illegal acts or violations of parole.

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.
- The research can't involve significant physical invasions or intrusions upon the privacy of participants; or observation of behavior in settings where participants have a reasonable expectation of privacy
- The research can't involve deception of research participants
- The research can't involve techniques which expose participants to discomfort or harassment beyond levels encountered in daily life
- The research can't involve investigation of legal matters, illegal activities, and admissions of guilt involve illegal acts or violations of parole.

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.
- The research can't involve significant physical invasions or intrusions upon the privacy of participants; or observation of behavior in settings where participants have a reasonable expectation of privacy
- The research can't involve deception of research participants
- The research can't involve techniques which expose participants to discomfort or harassment beyond levels encountered in daily life
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True



False

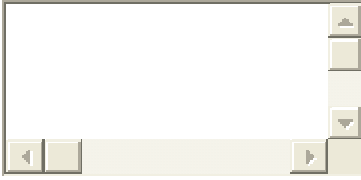
If TRUE, please justify:

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 provided under the Older Americans Act);
- The research is conducted pursuant to specific federal statutory authority;
- There is no statutory requirement that an IRB review the research.
- The research does not involve significant physical invasions or intrusions upon the privacy of participants.
- The research can't involve significant physical invasions or intrusions upon the privacy of participants; or observation of behavior in settings where participants have a reasonable expectation of privacy
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True  False

If TRUE, please justify:

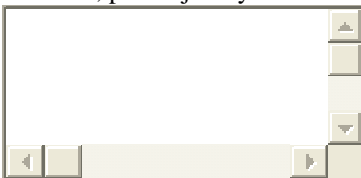


6. Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed OR (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below 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 can't involve significant physical invasions or intrusions upon the privacy of participants; or observation of behavior in settings where participants have a reasonable expectation of privacy
- The research can't involve deception of research participants
- The research can't involve techniques which expose participants to discomfort or harassment beyond levels encountered in daily life
- The research can't involve investigation of legal matters, illegal activities, and admissions of guilt involve illegal acts or violations of parole.

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.

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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.*

True  False

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**RULE Instruction:** Please indicate whether the project qualifies for Exempt Review

- 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
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