



***IRB #**

** An IRB number will be assigned to your protocol for tracking purposes when it is received in the IRB office.*

EXEMPTION SCREENING QUESTIONS

Research activities in which the *only* involvement of human subjects will be in one or more of the categories under 45CFR46.101 (b) qualify as exempt. Even if your study may qualify as exempt, you must complete and submit this application to the office of the IRB. The determination of exemption may only be made by the IRB, not the researcher. Exempt studies do not require continued IRB monitoring. However, any changes made to exempt research must be submitted on a Change in Protocol form and approved by the IRB. If you answer ‘yes’ to any of the questions below, your study will not qualify as exempt research and you must complete the full IRB application. If the question doesn’t apply, mark No.

- For research involving special populations, interventions or manipulations:*
- | | Y | N |
|--|--------------------------|--------------------------|
| A. Does your research involve prisoners? | <input type="checkbox"/> | <input type="checkbox"/> |
| B. Does your study involve deception of subjects? | <input type="checkbox"/> | <input type="checkbox"/> |
| C. Does your research involve survey or interview procedures with children as subjects? | <input type="checkbox"/> | <input type="checkbox"/> |
| D. Does your research involve observation of children in settings where investigator(s) will participate in the activities being observed? | <input type="checkbox"/> | <input type="checkbox"/> |

- For research using survey procedures, interview procedures or observational procedures (NOTE: exemption is not allowed in surveys or interviews with children as subjects):*
- | | Y | N |
|--|--------------------------|--------------------------|
| E. If the data are to be recorded by audiotape or videotape, and were the information to be revealed or disclosed, could this place subjects at risk (risks may be psychological, social, physical, economic, or legal)? | <input type="checkbox"/> | <input type="checkbox"/> |
| F. Are subjects identifiable (e.g. by name or through demographic data) and will collection of information include sensitive data (e.g., illegal activities or sensitive issues such as sexual orientation, sexual behavior, undesirable work behavior or other embarrassing information)? | <input type="checkbox"/> | <input type="checkbox"/> |
| G. If subjects are identifiable either by name or through demographic data, are there potential risks to subjects if the information is revealed or disclosed? | <input type="checkbox"/> | <input type="checkbox"/> |

- For research using existing or archived data,** documents, records or specimens:*
- | | Y | N |
|---|--------------------------|--------------------------|
| H. Will any data, documents, records or specimens be collected from subjects after permission is granted by the IRB to commence the research? | <input type="checkbox"/> | <input type="checkbox"/> |
| I. If the existing data, documents, records, or specimens are originally labeled with identifiers and are not publicly available, is the investigator recording the data in such a manner that subjects can be identified, directly or indirectly through identifying links (e.g., demographic information that might reasonably lead to the identification of individual subjects – name, phone number, medical record number, social security number or any code number that can be used to link the investigator’s data to the source record)? | <input type="checkbox"/> | <input type="checkbox"/> |

-
- If your study qualifies as exempt, proceed to the Exempt Research Application on page two.

EXEMPT RESEARCH APPLICATION

(cells will expand as needed)

Principal Investigator (PI)	(Last)	(Firs	(Initial)	(degree)
PI Status	<input type="checkbox"/> MBU Faculty/Staff <input type="checkbox"/> MBU Student			
PI Title (e.g., Assoc. Professor)				
Faculty Advisor (for students only)				
Division / Department			PI's Primary E-mail:	
PI's Address (street, city, state, zip)			PI's Phone #:	
			Alt Phone #:	
Co-Investigator(s) and Affiliation				
Protocol Title (must match the NIH/Sponsor title)				
Key Words	1	2.	3.	
Research Site(s)	<p>Indicate which of the following are expected sites of investigation :</p> <p>If any of the investigation is to be conducted at other institutions or locations off campus, please enter for each facility the:</p>			
Funding Source (include pending)				
Grant/Contract/Protocol#/Pending (Note: please provide a copy of the grant application or sponsor's protocol)				

Define any abbreviations and use simple language throughout the application.

- Designate the category(ies) in the space below that qualifies this proposal for exemption (see following categories), and justify this designation by responding to the questions below each category. If more than one exempt category is applicable, you must respond to the questions ("a" and "b") for each exempt category.

Exempt Category #:

CATEGORIES OF RESEARCH THAT QUALIFY FOR EXEMPTION (refer to the following categories to assist you in answering question #1)

45CFR46.101(b) Unless otherwise required by Department or Agency heads, **research activities in which the ONLY involvement of human subjects will be in one or more of the following categories are exempt from this policy:**

CATEGORY 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.

Information Required for Justification

- a. Explain how the research is part of the commonly accepted educational setting at the research site(s) you listed on page one **and** how the research involves normal educational practices.
- b. Describe the research in relation to (i) and/or (ii) above.

CATEGORY 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.

Information Required for Justification

- a. Describe the type of educational test or procedure.
- b. State how the information will be recorded and indicate any risk: Is information identifiable? If so, could disclosure of responses put subjects at risk? If information is identifiable **and** disclosure of responses could put subjects at risk, the study will not qualify as exempt.

NOTE: Exemption for research involving survey or interview procedures or observation of public behavior **does not** apply to children as subjects **except** for research involving observation 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 two, 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.

Information Required for Justification

- a. Describe the type of educational test or procedures to be used in the research activity.
- b. Discuss how the research qualifies for exemption based on item (i) or (ii) above.

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.

* Existing means that the materials are "on the shelf" at time of IRB approval; prospective collection is not permitted.

** Examples of publicly available information: driver's license and court records.

Information Required for Justification

- a. State: **type** of and **source(s)** from which the data/specimens will be collected, and **if they are publicly available**.
- b. Confirm that the materials are existing*, (e.g. provide dates) and discuss the method that will be used to record the data to assure that individual subjects **cannot be linked** to the research activity (i.e. no code numbers may be used to link the research data to the subject). **Research will not meet the criteria under this category unless it is clearly indicated that no one (including the PI) is able to link the data to any individual when the information is recorded as part of the research.** Submit a copy of the data collection sheet (e.g. a list or spreadsheet of the questions or data elements to be collected or studied).

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: (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.

Information Required for Justification

- a. Is this research subject to approval of federal governmental Department or Agency heads? Please explain.
- b. Discuss the purpose of the research. Discuss how the study qualifies for exemption based on item (i), (ii), (iii), or (iv) above.

CATEGORY 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.

Information Required for Justification

- a. Explain the purpose of the research.
- b. Discuss how the research qualifies for exemption based on item (i) or (ii) above.

2. Using lay language, briefly describe the **a.)** research background **b.)** objectives **c.)** description of how the research will be conducted and **d.)** the role of subjects.

a.) Background:
b.) Objectives:
c.) Description of Research Conduct:
d.) Role of Subjects:

3. State the minimum number of subjects, existing records, or specimens required.

- 4. **a.)** Are you collecting or recording data from anyone under the age of 18? Y N
- b.)** Are you collecting or recording data from anyone 90 years or older? Y N

NOTE: Collecting age information from anyone 90 years or older, is considered an identifier under [HIPAA regulations](#) when used in conjunction with protected health information (PHI), unless it is aggregated into a single category of age 90 or older

5. Type of Information to be collected or recorded: (see [IRB HIPAA web site](#) for more information)

- No health information.
- Health Information without [identifiers](#). Please complete the [De-Identification Certification form](#).
- Health information with [identifiers](#). This constitutes protected health information (PHI) and HIPAA applies. Please complete the full IRB application.

6. Describe the EXPECTED DURATION of the TOTAL STUDY (i.e. recruitment, data collection, data analysis, etc.), and the DURATION OF EACH SUBJECT'S participation. **NOTE: The IRB will assume the study is completed by the end date listed unless the investigator notifies the IRB that an extension is needed.**

--

7. Specify **a)** the risks to the subjects *and* the steps you will take to minimize each risk **b)** benefits to the subjects (*if there are no benefits to the subjects, please state so here and disclose this information to the subjects verbally or in a recruitment statement*) and **c)** the benefits to society.

a.) Risks to subject and steps taken to minimize risks:
b.) Benefits to subject:
c.) Benefits to society:

8. Will the identity of subjects and their responses be kept:

- Anonymous** (names and unique identifiers of subjects are never attached to the data). Describe the steps you will take to ensure anonymity.

--

or

- Confidential** (access to private data about a person is limited). Describe the steps you will take to protect confidentiality, including the identity of the subjects, their responses, and any data that you obtain from private records and/or capture on audiotape or videotape. Describe the disposition of the data and/or the tapes once the study has been completed.

--

9. **Data Security.** All information must be stored using at least two of the following safeguards and must be kept in

accordance with the MBU Security Policy. (If you are using both electronic data *and* hardcopy data, you will need two safeguards for each type)

Electronic Data: (mark at least two that apply)

<input type="checkbox"/>	secure network (e.g. firewall)
<input type="checkbox"/>	password access
<input type="checkbox"/>	data de-identified by PI or research team
<input type="checkbox"/>	coded, with master list kept as a hardcopy or on a secure network
<input type="checkbox"/>	not applicable
<input type="checkbox"/>	other. Please specify:

Hardcopy data: (mark at least two that apply)

<input type="checkbox"/>	locked suite
<input type="checkbox"/>	locked office
<input type="checkbox"/>	locked file cabinet
<input type="checkbox"/>	data de-identified by PI or research team
<input type="checkbox"/>	data coded by PI or research team with a master list secured and kept separately.
<input type="checkbox"/>	24 Hour personnel supervision
<input type="checkbox"/>	not applicable
<input type="checkbox"/>	other. Please specify:

10. **a.)** Explain how subject recruitment is to be carried out. Provide copies of letters, media ads, posters, etc. **b.)** If subject incentives are offered or payment to subjects is to be made, describe and justify. (Examples of incentives include gift certificates, extra credit for a class, etc.) **NOTE: Applicable to all exempt categories except category 4**

a.) Describe how subjects are recruited or state not applicable:
b.) Describe incentives or state not applicable:

11. Describe the composition of the proposed study population in terms of gender and racial/ethnic group, and provide a rationale for selection of such subjects.

--

12. Describe **a.)** how you have access to this study population (e.g. superintendent at the school, instructor of a class, etc.) *and/or* **b.)** describe your and any co-investigator's authorization to review existing data, documents, records or specimens (item b is only applicable to category 4) **NOTE: letters of agreement from cooperating research sites should be included as an appendix (if applicable)**

--

13. Discuss how subjects will be informed about this study (e.g., through a cover letter or statement from the investigator. Please provide a copy of such a letter or statement with this application). (See the Model Recruitment Statement on the IRB website for an example). **Applicable to all exempt categories except category 4. NOTE: A study cannot be considered exempt if a consent document is used**

--

14. Describe **a.)** the experience *and* **b.)** role of the investigator and co-investigators.

a.)
b.)

15. **Financial Conflict of Interest.** Indicate whether you, your spouse or dependent children, **or any investigator participating in the study** have, or anticipate having, any income from or financial interest in the **sponsor** of the protocol, the supporting organization, or a company that owns/licenses the technology being studied that may reasonably affect the outcome of the research. Financial Interest includes but is not limited to consulting, speaking or other fees; honoraria; gifts; licensing revenues; other research agreements; equity interests (including stock, stock options, warrants, partnership and other equitable ownership interests). **Check one of the following:**

1.) <input type="checkbox"/> No Financial Interest	2.) <input type="checkbox"/> Financial Interest Under \$10,000 In aggregate	3.) <input type="checkbox"/> Financial Interest Over \$10,000 in aggregate
--	---	--

If you have marked box #2 or #3:

- You must have a current, up-to-date Annual Conflict of Interest Disclosure Form on file with the Committee on Conflict of Interest (CCI) that describes the above financial relationship*
- If you do not have an Annual Conflict of Interest Form on file with the CCI (e.g. you are a student) and you have a conflict of interest as defined in the policy, you must submit a disclosure form describing the above financial relationship to the CCI.
- Date Annual Conflict of Interest Disclosure Form was submitted to the CCI: _____

You may not begin your study until your disclosure form has been reviewed and any required management plan has been approved by the CCI

* This information must be disclosed to the MBU IRB review by the MBU _____ prior to enrolling subjects in this study. If your current Financial Disclosure Statement does not contain this information, contact your research administration office to update your form. For questions regarding Conflict of Interest consult the:
University Conflict of Interest Policy

Submit this application with the following materials, if applicable:

- Formal research protocol (e.g., grant application, sponsor protocol)
Questionnaires, interview questions
 - Data collection sheets (e.g. a list or spreadsheet of the questions or data elements to be collected or studied)
Recruitment materials (flyers, advertisements)
 - Telephone scripts
Cover letters or recruitment statement to subjects
 - Letters of cooperation from other sites.
 - HIPAA related materials (e.g. De-Identification Certification Form)
Documentation that all investigators have completed IRB training for human subjects protection.
 - Documentation of external IRB approval from other sites where research is conducted
-

Your signature below (on page 9) indicates that you accept responsibility and have used the ethical guidelines set forth by the Belmont Report, Declaration of Helsinki, the Nuremberg Code, or the Ethical Principles of the American Psychological Association for the research described.

The signature of the Principal Investigator and Department Chairperson or advisor indicates that the Principal Investigator has the requisite credentials, training and any necessary privileges to carry out all procedures involved in the protocol. *It is expected that universal precautions will be used in handling all research specimens.*

