



INSTITUTIONAL REVIEW BOARD

<i>Office Use Only:</i>	
IRB Submission #: _____	Date Received: _____
Exemption Category(ies): _____	Date of Determination: _____

The PI is responsible for obtaining IRB approval prior to initiation of any future human subjects' research activities. Detailed information for each Exemption category is provided at the end of this form.

IRB Exempt Status Review

Exemption Categories 1, 2, 3, 4, 5, and 6

Title of Project:	
Principal Investigator:	Co-Investigator:
Department:	Department:
Email Address:	Email Address:
Phone:	Phone:

I. PRODUCT DESCRIPTION

1. If the research will be supported by funding (MSU or Extramural), indicate the Source of the funding:

Does the sponsor require IRB review of your project? Yes No

2. Describe the proposed project:

Exemption 2: Research that only includes interactions involving educational tests, survey procedures, interview procedures, or observation of public behavior. At **least one** of the following criteria must be met:

2.1 -The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

2.2 - Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation;

a) Does the research involve minor participants?
No Yes

b) If yes to a), does the research involve surveys or interviews? No Yes

c.) If yes, to a) and b), Exempt Category 2(i) or 2(ii) does not apply.

2.3 - The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a **limited IRB review** to make the determination required by § 46 .111(a)(7). This category may NOT be applied to research with children.

d.) Does the research involve an intervention? *Intervention* is defined as, "manipulations of the subject or the subject's environment that are performed for research purposes."

No Yes

If yes, Exempt Category 2 does not apply.

Exemption 3: Research involving *benign behavioral interventions** in conjunction with the collection of information from an adult subject.

Describe the benign behavioral intervention:

AT **least one** If the following criteria is met:

3.1 The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

3.2 Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

3.4 The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a **limited IRB review** to make the determination required by § 46.111(a)(7).

3.5 If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

- a.) Does the research involve deception? No Yes
- b) If so, will subjects prospectively agree to be unaware of or misled regarding the nature of the research? No Yes
If yes to a), but no to b), the research does not qualify under this Exemption 3.
- c) Does the research involve minors? No Yes
If the research will involve minors, the research does not qualify under Exemption 3.

Exemption 4: Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens.

1. **The activity will utilize only publicly available, anonymous existing data.**
No Yes
2. **If data is not publicly available, the research will utilize only existing de-identified data.**
No Yes

Describe Data:

3. **Name of providing organization or source of the data above.**

4. Does the provider or source require execution of a data use, privacy, or HIPAA agreement?

No Yes

5. Does the data provider or course require you obtain IRB review of this project?

No Yes

Exemption 5: Research and demonstration projects that are conducted or supported by a Federal department or agency.

NOTE: Exemption under Category 5 is only permitted upon Federal Agency approval AND after being published on a federal website.

Exemption 6: Taste and food quality evaluation and consumer acceptance studies:

6.1 If wholesome foods without additives are consumed,

or

6.2 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.

III. PARTICIPANTS, RECRUITMENT AND INFORMED CONSENT

1. Describe the proposed participants:
2. Recruitment: Describe recruitment procedures. Include how participants will be initially identified, approached or contacted regarding the research and in what setting.
3. Please provide a copy of informed consent or script for informed consent.
Informed Consent Requirements for Exempt Categories

Consent is not required for the following categories:

- Exemption 1
- Exemption 4

Written or oral consent is **required** and subject authorization is **implied** through participation in study for the following categories:

- Exempt Category 2, if 2.1 and 2.52 are answered no.

- Exempt Category 3, (except 3.4)
- Exempt Category 6

Signed, written consent is required for the following categories:

- Exempt Category 2, if 2.3 is answered No.
- Exempt Category 3, 3.4

Please contact IRB chair regarding Exempt Category 5 requirements.

IV. INSTRUMENTS

* Provide the questionnaire(s), survey instrument(s), list of interview or focus group questions.

PRINCIPAL INVESTIGATOR ASSURANCES:

I certify that the information provided on this form is accurate that this research will be conducted in accordance with the statements provided above. I understand that if I want to make changes to the research protocol after IRB approval, I must submit a revision to the IRB for review prior to implementing any changes.

I will fully comply and assume responsibility for the enforcement of compliance with all applicable federal regulations and University policies for the protection of the right of human subjects engaged in research. I understand the failure to do so may result in the suspension or termination of proposed research and possible reporting to federal agencies.

Principal Investigator Signature

Date

Co-Investigator Signature

Date

Attached

- Consent
- Data Collection Instrument

Exemption Categories

Exemption 1: Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

- If the research could adversely impact student achievement in any way, the study does NOT qualify under Exemption 1.
- If the research could adversely impact the assessment of educators who provide instruction, the study does NOT qualify under Exemption 1.
- If the research involves a comparison of a proven educational technique to a novel technique, the study does NOT qualify under Exemption 1.

Exemption 2: Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

- 2.1 The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
- 2.2 Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation;

If the research involves minor participants (under age 18), AND if the research involves surveys or interviews, the study does not qualify under Exemption 2.

- 2.3 The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a **limited IRB review** to make the determination required by §46 .111(a)(7).
- If the research involves an intervention* the study does NOT qualify under Exemption 2.
* intervention defined as “manipulations of the subject or the subject’s environment that are performed for research purposes”

Exemption 3: Research involving benign behavioral interventions* in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection.

* **Benign behavioral interventions** are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

At **least one** of the following criteria is met:

- 3.1 The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
- 3.2 Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
- 3.3 The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a **limited IRB review** to make the determination required by § 46.111(a)(7).

3.4 If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

- If the research involves deception AND the subjects prospectively DO NOT agree to be unaware of or misled regarding the nature of the research, the study does NOT qualify under Exemption 3.
- If the research involves minors, the study does NOT qualify under Exemption 3.

Exemption 4: Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens.

Exemption 5: Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

NOTE: Exemption under Category 5 is only permitted upon Federal Agency approval AND after being published on a federal website.

Exemption 6: Taste and food quality evaluation and consumer acceptance studies:

- 6.1 If wholesome foods without additives are consumed, OR
- 6.2 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.