

*Office Use Only:*

**IRB Submission #: Date Received**: **Exemption Category(ies): Date of Determination:**

INSTITUTIONAL REVIEW BOARD

**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.**

NOTE: Research involving prisoners, surveys or interviews of children, observation of children when the investigator will interact with them, and research procedures where information is recorded in such a way that the identity of individuals can be identified either directly or through identifiers linked to the individuals AND disclosure of participants’ responses could reasonably place them at risk of criminal or civil liability or be damaging to the individual's financial standing, employability or reputation are not eligible for Exempt Status. Please use the Expedited form for these studies.

IRB Exempt Status Review

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

|  |
| --- |
| Title of Project: Click or tap here to enter text. |
| Principal Investigator: Click or tap here to enter text. | Co-Investigator: Click or tap here to enter text. |
| Department: Click or tap here to enter text. | Department: Click or tap here to enter text. |
| Email Address: Click or tap here to enter text. | Email Address: Click or tap here to enter text. |
| Phone: Click or tap here to enter text. | Phone: Click or tap here to enter text. |

# PRODUCT DESCRIPTION

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

**Source of the funding:** Click or tap here to enter text.

1. **Does the sponsor require IRB review of your project?** [ ] **No** [ ] **Yes**
2. **Describe the proposed project:**

 Click or tap here to enter text.

1. **Describe what subjects will be asked to do, what information will be collected about them, and when or how often research procedures will be conducted.**

Click or tap here to enter text.

#  List the research site(s):

Click or tap here to enter text.

1. **Indicate the expected start date and end dates for the research procedures which will involve human subjects:**

**Anticipated start date:** Click or tap here to enter text.[ ]  **or after IRB approval**

**Anticipated end date:** Click or tap here to enter text.

1. **Will information/data be collected using methods that are repeated with multiple participants?** [ ] **No** [ ] **Yes**

# Is the knowledge gained by conducting the activity is intended to be generalized (i.e applicable to populations and settings outside from which it was collected)?

#  [ ] No [ ] Yes

# EXEMPTION CATEGORIES:

Descriptions of Exemption categories are located at <https://www.minotstateu.edu/IRB/Exemption-Categories.shtml>.

Check the category or categories which apply and respond to the questions within that exemption section:

[ ] **Exemption 1:** Research conducted in established or commonly accepted educational settings,

1. Describe the established or commonly accepted educational setting of the research:

Click or tap here to enter text.

1. Could the research adversely impact student achievement in anyway? [ ] No [ ]  Yes, The study does not qualify under Exemption 1.
2. Could the research adversely impact the assessment of educators who provide instruction?

[ ] No [ ]  Yes, The study does not qualify under Exemption 1.

1. Does the research involve a comparison of a proven educational technique to a novel technique?

[ ] No [ ]  Yes, The study does not qualify under Exemption 1.

[ ] **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;

* 1. Does the research involve minor participants?

[ ] No [ ] Yes

* 1. If yes to a), does the research involve surveys or interviews? [ ] No [ ] Yes

 c.) If yes, to a) and b), Exempt Category2(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.

1. 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\**](https://www.minotstateu.edu/irb/terms-and-definitions.docx)in conjunction with the collection of information from an adult subject.

**\* 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.

Describe the benign behavioral intervention:

 Click or tap here to enter text.

 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.

1. Does the research involve deception? [ ] No [ ]  Yes
2. 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.

1. 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**

1. **If data is not publicly available, the research will utilize only existing de-identified data.**

[ ] **No** [ ] **Yes**

Describe Data:

 Click or tap here to enter text.

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

 Click or tap here to enter text.

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

[ ] **No** [ ] **Yes**

1. **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.

1. **PARTICIPANTS, RECRUITMENT AND INFORMED CONSENT**
2. Describe the proposed participants:

Click or tap here to enter text.

1. Recruitment: Describe recruitment procedures. Include how participants will be initially identified, approached or contacted regarding the research and in what setting.
Click or tap here to enter text.
2. 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** (no signature required) through participation in study for the following categories:

* Exempt Category 2, 2.1, 2.2 if a is 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.

# 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 assumer 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

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