Exemption 1

Completion of this section is required based on the Exemption Category selected in question 1-1.1.

This exemption covers research conducted in established educational settings and involving normal educational practices, so long as the research is not likely to adversely affect students' opportunity to learn required content or the assessment of educators who provide instruction.

Hide

1* Is the research conducted in an established or commonly accepted educational setting?
In addition to schools and colleges, an educational setting could be any place where educational activities regularly take place, including an after-school program, work place, library, or a museum.

● Yes ○ No Clear

1.1* Identify the educational setting:

bjk

No to 1 or 2 activates:

This project does not qualify for Exemption 1. Click Continue to move to the next question in the Comprehensive IRB application.

2* Does the research involve normal educational practices ONLY?
Examples of normal educational practices include: Research on regular and special educational instruction strategies, research on the effectiveness of or the comparison among accepted instructional techniques, curricula, or classroom management methods. May include the use of technology, such as an online course or use of computer software. The research must focus on educational practices. Research that collects information about personal characteristics, beyond basic demographics, of students, families, or teachers, such as mental health, personal beliefs or opinions beyond those associated with the curriculum or learning, is not exempt under this category.

● Yes ○ No Clear

3* Is the research likely to adversely affect students' opportunity to learn required educational content?
The research should not take time or attention away from normal instruction in a way that might negatively impact student achievement (e.g. negative impact on student standardized test scores or time away from required curriculum).

○ Yes ● No Clear

Yes to 3, or 4 activates:

This project does not qualify for Exemption 1. Click Continue to move to the next question in the Comprehensive IRB application.

4* Is the research likely to adversely affect the assessment of educators who provide instruction?
Research designed to evaluate the practice of individual teachers or that takes time away from normal instruction (as described above) could adversely impact the assessment of educators.

○ Yes ● No Clear

REWORDED

5* Does the research require access to student education records protected by FERPA (Family Educational Rights and Privacy Act)?
Education records

- Are maintained by or for an educational institution, including classroom instructors
- Contain personally identifiable information about a student

Almost all U.S. K-12 schools, colleges and universities are subject to FERPA regulations.

● Yes ○ No Clear

Yes

- activates Q5.1 below
- requires IRB staff evaluation of application (i.e. no system-generated determination option)

For examples of the materials considered "education records," see U.S. Dept of Ed What is an education record?

The information may be recorded in any way, such as:

- Hard-copy and scans of written or printed student work products
- Electronic communication for academic purposes, including email and class-specific social media channels
- Audiovisual recordings and transcripts of in-person or virtual class meetings

See also U-MIC on FERPA.

Exit Save Continue

5.1* Describe the information or data elements from the student record that will be obtained by the investigator.

Include a detailed listing of the data elements/variables to be used. You may w to upload a data dictionary or spreadsheet

6* Will the research involve the access, collection, use, maintenance, or disclosure of protected health information (PHI)? [Require Section 25]

● Yes ○ No Clear

Yes
- activates Section 25
- requires IRB staff evaluation

**NOTE - Only Michigan Medicine faculty, staff, or students may access U-M PHI for reasearch purposes.

Protected Health Information (PHI) include one or more HIPAA identifiers.

Most data generated from clinical records regulated by the Health Insurance Portabil and Accountability Act (HIPAA). HIPAA generally covers both data provided direct a HIPAA "covered entity" and data provide bya central data broker and protected by contractual agreements.

7* Provide a brief summary of your research (subject population, study procedures, location of research) or upload protocol below. Include a description, if relevant for your project, to describe how the research contributes to the required curriculum.

brief

Enter "n/a" if a protocol including this information is uploaded in question 8.

8 Upload documents (e.g. protocol document, survey or interview questions, Data Use Agreements, or other documents applicable to your research).

Researchers are reminded that while the submission of an informed consent document is not reviewed as part of an exempt application, researchers still have an ethical obligation to ensure that participants are fully informed about the nature of a research project so that they can make an informed decision to participate.

+ Add

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Interviews/surveys/tests must be provided allow the IRB to verify the research focus i assessment of the educational practice.

For Exempt research, the IRB does not re & approve a specific consent process and documents. **Please Note** that if an Exemp determination is issued, **no** documents wil "finalized." As always, the study team has "ethical obligation to ensure that participan are fully informed about the nature of a research project so that they can make an informed decision to participate" (UM HRP OM Part 4, VI, A, paragraph 4). A brief pro and exempt consent template can be foun the IRB Health Science/Behavioral Scienc consent webpage.

9* Will subjects receive payment or other incentives for their participation in the study?

● Yes ○ No Clear

Yes activates 9.1.

9.1* What is the estimated maximum total payment to an individual subject?

$0.01-$25

N/A
N/A
$0.01-$25
$26-$100
$101-$200
$201-$300
$301-$400
$401-$500
$501-$599
$600-$9,999

Anything except N/A activates 9.2

This number is required for U-M IRS repor purposes. This number should only repres cash and cash-equivalent incentives. Ansv "N/A" if you are only offering non-cash-equivalent items such as course credit, tok gifts, pizza parties, etc.

This amount is used to calculate the Subje Payment Tier. Tier Information.

For more information, contact the Human Subjects Incentive Program Office.

9.2* In addition to collecting name and physical mailing address, which is required, indicate other information that will be collected, see help text for more details.

Select all that apply:

- [ ] Email Address
- [ ] Social Security Number (SSN)
- [ ] No additional information

10* Will the study potentially involve any interaction and intervention with research participants who are younger than age 18 years? Interaction is defined as communication occurring via any mode *(e.g., face-to-face, email, texting, social media, phone)* whether bidirectional or unidirectional *(e.g., study team members texting potential participants even if the potential participants do not respond)*.

(●) Yes ( ) No Clear