Editing: HUM00255711

Exemption 3

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

Exemption 3 is limited to research involving benign behavioral interventions. A behavioral intervention involves the performance of cognitive, intellectual, educational or behavioral tasks or the manipulation of the subject's physical, sensory, social or emotional environment. It does not include medical interventions such as medical tests, procedures or use of medical devices.

A benign behavioral intervention must be:

- Brief in duration
- Harmless
- Painless
- Not physically invasive
- Not offensive or embarrassing
- Not likely to pose a significant lasting adverse impact on subjects

Data collection methods are limited to verbal (oral) or written responses from the subject (such as surveys or interviews, test responses, data entry) or observation of the subject. Audiovisual recording is permissible. Data cannot be collected via physical procedures (e.g. blood pressure monitoring, EEG, activity trackers (Fitbit), blood draws).

Examples of behavioral interventions that may qualify for this exemption includes:

- Playing an online game
- Solving puzzles under various noise conditions
- Playing an economic game
- Being exposed to stimuli such as color, light or sound (at safe levels)
- Performing cognitive tasks
- Providing educational materials to participants with the intention of changing their behavior (e.g. smoking cessation, eating habits)

Hide Help

1* Based upon the information above, does your project meet the definition of a benign behavioral intervention?

(●) Yes ( ) No Clear

No to 1, 1.1, 2, 3.1, or 4 disqualifies from Exemption:

This project does not qualify for Exemption 3. Click Continue to move to the next question in the Comprehensive IRB application.

NEW

1.1* Is the intervention brief in duration?

The intervention (whether in-person, remote, or a combination) should take no longer than a total of a few hours, and should take place over a short period of time (usually a single day). It can be acceptable to continue brief data collection over a longer period with an individual participant (e.g. text-based survey).

(●) Yes ( ) No Clear

No disqualifies from Exemption.

Refer to U-M IRB Guidance "Exemption #3: Tips and Examples"

NEW

1.2* Does the intervention occur more than once?

( ) Yes (●) No Clear

Yes requires IRB staff evaluation of application (i.e. no system-generated determination)

Examples of repeated interventions:

- Reminders or prompts sent by text to support a behavior change.
- Multiple sessions playing an online game, separated by breaks.

NEW

1.3* Does the dataset for analysis include information about participants from other sources (research or non-research)?

Answer "no" if use of other sources is limited to identifying and contacting potential participants.

( ) Yes (●) No Clear

Yes:
* activates reminder before Q8
* requires IRB staff evaluation

Use of aggregate data (e.g. census records) in connection with this Exemption can be appropriate. However, linking a participant's information collected via the Exemption to other personally-identifiable data is not permitted.

2* Confirm that your project involves research with adults only:

(●) Yes ( ) No Clear

No disqualifies from Exemption.

Research with children is not permitted under this exemption. By regulatory definition (45 CFR 46.402(a)), "Children are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted." For further information, see U-M HRPP Operations Manual Part 7.

3* Does the research involve deception?

This means that subjects will be given false information, will be misled about some key aspect of the research, or will not be told the purpose of the research. Examples include: providing false feedback regarding test performance or using a confederate to influence participant's behavior in the research. Note: Use of experimental controls is not deception.

(●) Yes ( ) No Clear

Yes:
* activates Q3.1
* requires IRB staff evaluation

For example, the researcher intentionally does not reveal trhe whole truth to subjects, including elements of the informed consent process. Research involving deception typically requires waiver or alteration of informed consent, and a debriefing.

3.1* Will you tell subjects that they will be participating in a project that involves deception?

● Yes ○ No Clear

No disqualifies from Exemption.

4* In order to qualify for this exemption, the researchers must describe the intervention and data collection methods to potential subjects and seek their prospective agreement to participate. Confirm that you obtain prospective agreement to participate:

This exemption does not apply to projects where participants are not aware that they are participating in research, such as videotaping pedestrian behavior when a walk/don't walk sign is being manipulated for research purposes

● Yes ○ No Clear

No disqualifies from Exemption.

4.1* Describe how prospective agreement will be obtained. For projects where subjects will be informed about deception, include a description of that process.

test

For projects involving deception, participants must be told that they will be deceived or misled prior to the conduct of the research in order to qualify for this exemption.

5* Does the research collect information about the subject in such a manner that their identity can be readily ascertained by the study team, directly or through identifiers linked to the subjects?

This means that the information is collected with direct identifiers (name, address, email, phone number, social security number, student ID, medical record number) or indirect identifiers, such as a code that can link back to the subject or data elements that could be combined to readily re-identify an individual (dates, employment history, etc.).

● Yes ○ No Clear

Yes activates Q5.1.

For further clarification on "anonymous" data collection, see U-MIC presentation "Anonymous, Coded, and Deidentified Data..." or the "Key Definitions" heading at Data Security Guidelines.

REWORDED

5.1* Does the research involve requesting information that the participants may consider sensitive or private?

This includes information about experiences, behaviors, or attitudes that

- the participant may find stigmatizing or traumatic, and/or
- could pose legal risks to the participant

If a specific participant community is targeted, consider whether participants' peers are likely to stigmatize additional behaviors or attitudes.

○ Yes ● No Clear

Yes
* activates reminder below Q8
* requires Section 11 & "Limited IRB Review"
* requires IRB staff evaluation

Examples: requesting information about

- Personal biases, including implicit bias
- Financial insecurity
- Mental health issues or sensitive health conditions (HIV, STDs)
- Sexual attitudes, preferences, or practices
- Use of alcohol, drugs, or other addictive products
- Negativity towards employers, teachers, or family members

6* Will the research involve the access, collection, use, maintenance, or disclosure of protected health information (PHI) to identify eligible subjects? [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) includes one or more HIPAA identifiers.

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

Use of PHI under this exemption is limited to identifying potential subjects. It cannot be linked to other data collected under this investigation.

NEW

As part of the brief summary, or an uploaded protocol, below:
Provide details about the type(s) of additional data sources used. Indicate whether any identifiers are included, and how the data are combined with the information collected from participants.

Reminder activated by Yes to Q1.3

7* Provide a brief summary of your research (subject population, study procedures(including description of the benign intervention and data collection methods), location of research) or upload protocol below.

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

8 Upload documents (e.g. protocol document, survey/interview questions, or other documents relevant to your research).
The submission of an informed consent document is not required for studies that do not collect identifiable, sensitive data. 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

Name	Version
There are no items to display	

Interviews/surveys/tests must be provided to allow the IRB to evaluate the sensitivity of the research. **Please Note** that consent or other documents are **not** "finalized" for Exempt studies. However, the study team still has the 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.

IRB-HSBS guidance resources on Exempt studies include

- Tips and Examples
- Brief protocol with data management and security questionnaire
- Consent template

IRBMED guidance is available by searching for "Exempt" on Research A-Z.

Because your study will collect identifiable, sensitive information, the IRB must review your recruitment materials, consent materials, and data management and security plan. Please upload below.

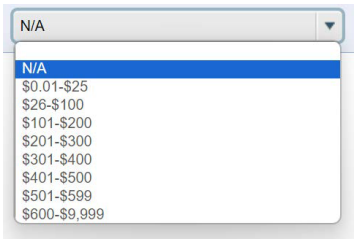
Reminder activated by Yes to Q5.1.

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

(●) Yes ( ) No Clear

Yes activates Q9.1

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



Anything except N/A activates 9.2.

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

This amount is used to calculate the Subject 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

If the study is compensating participants more than $400 in a calendar year, a SSN is required to be collected. Name and Physical Mailing Address is required for all payments. If seeking an exemption from collecting this information, contact HSIP (subject-incentives@umich.edu).