Editing: HUM00255710

Exemption 2

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

Exemption 2 applies to projects that include either:

1. Observation of Public Behavior; or
2. Interactions with human subjects that involves collection of information ONLY using the follow methods:
   - Surveys
   - Interviews (including cognitive interviews)
   - Focus Groups
   - Educational tests (cognitive, diagnostic, aptitude, achievement)
   - Observation of public behavior

Audio and/or video recording of these observations or interactions is permitted.

This exemption does not apply if the research involves:

- Interventions/manipulations that are distinct from the information collection methods
- Collection of biospecimens in conjunction with surveys/interviews/educational tests
- Linking information collected via this exemption to other personally-identifiable data

Hide Help

1* Confirm that your research involves the collection of information ONLY using one or more of the following:

- **Surveys (information collected through questionnaires, in person or online)**
- **Interviews**
- **Focus Groups**
- **Educational Tests (cognitive, diagnostic, aptitude, achievement)**
- **Observation of public behavior**

No to 1 or 1.2 disqualifies from Exemption:

(●) Yes ( ) No Clear

This project does not qualify for Exemption 2. Click Continue to move to the next question in the Comprehensive IRB application.

Collection of biospecimens, linking to other personally-identifiable information, and Intervention/manipulations that are distict form the information collection methods are not permitted under this exemption.

"Public" is defined as taking place in a location generally open to any member of the public and does not require special permission to enter, such as a public park or museum, or a website that does not require login. Research in a public school (or university) is not considered to be a public location.

1.1* Does the research involve children?

(●) Yes ( ) No Clear

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.

1.2* Is the interaction with children limited to educational tests, or observation of public behavior where the investigator does not participate in the activity being observed?

(●) Yes ( ) No Clear

No disqualifies from Exemption:

Research with children under this exemption is limited to

- educational tests

or

- observation of public behavior where the investigator does not participate in the activities being observed.

"Public" is defined as taking place in a location generally open to any member of the public and does not require special permission to enter, such as a public park or museum, or a website that does not require login. Research in a public school (or university) is not considered to be a public location.

Additional Help

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 Q4
• requires IRB staff evaluation (i.e. no system-generated determination)

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* 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

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.

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 2.1

REWORDED

2.1* 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 Q4
* 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

3* 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 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

4* Provide a brief summary of your research (subject population, study procedures, location of research) or upload protocol below.

test

Enter "n/a" if a protocol including this information is uploaded in question 5.

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 Q2.2

5* Upload documents (e.g. protocol document, survey/interview/test 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.

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2010.SOPsPart3p17.pdf(0.01)	•••	0.01

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

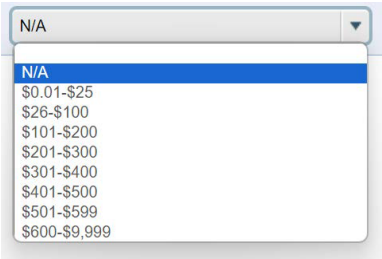
IRBMED guidance is available by searching for "Exempt" on Research A-Z.

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

(●) Yes ( ) No Clear

Yes activates Q6.1.

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



Anything except N/A activates Q6.2.

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.

6.2* 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).