**Exemption Category 2**

**Surveys, Interviews, Educational Tests, or Observation** [**45 CFR 46.104(d)(2)**](https://www.ecfr.gov/current/title-45/part-46/section-46.104#p-46.104(d)(2))

This exemption covers 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)

**Protocol Title** Click or tap here to enter text.

**Principal Investigator Name** Click or tap here to enter text.

**Faculty Sponsor Name (if applicable)**

1. **Please check only one of the following Exempt 2 criteria you are applying for:**

[ ]  (i) **The information obtained is recorded by the investigator in such a manner that the identity of the human participants cannot readily be ascertained, directly or through identifiers linked to the participants.**

[ ]  (ii) **The information obtained is recorded by the investigator in such a manner that the identity of the human participants can readily be ascertained, directly or through identifiers linked to the participant s.**

 (Any disclosure of the human participant s' responses outside the research would not reasonably place the participant s at risk of criminal or civil liability or be damaging to the participant s' financial standing, employability, educational advancement, or reputation.)

[ ]  (iii) **The information obtained is recorded by the investigator in such a manner that the identity of the human participants can readily be ascertained, directly or through identifiers linked to the participant s, and an IRB conducts a limited (expedited) IRB review to make the determination required by** [**§ 46.111(a)(7).**](https://www.ecfr.gov/current/title-45/section-46.111#p-46.111(a)(7))

 (Disclosure of the responses outside the research could reasonably place the participant s at risk therefore, criterion (2)(iii) requires a limited IRB review to determine that adequate provisions are in place to protect the privacy of participant s and the confidentiality of data. It may not be applied to research involving children under subpart D.)

1. **Indicate all the possible types of research methods used to collect data:**

[ ] **Surveys** (data collected through questionnaires, in person or online)

[ ] **Interviews**

[ ] **Focus Groups**

[ ] **Educational Tests** (cognitive, diagnostic, aptitude, achievement)

[ ] **Observation of public behavior** (e.g., a public place where there would not be an expectation of privacy such as a public street or park but not a public school, a business, or a hospital)

[ ]  **My protocol involves additional procedures (e.g., intervention, data linking, biospecimen collection**.) [The protocol does not qualify for Exemption 2; however, Exemption 3 may apply.]

[ ]  **My protocol involves ONLY one or more of the above data collection methods.**

(continue to 3a)

**3.a. Does the research involve children?**

[ ]  **Yes** (continue to 3b)

[ ]  **No** (continue to 4)

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

[ ]  **Yes** (continue to 3c)

[ ]  **No** [The protocol does not qualify for Exemption 2; however, Exemption 1 may apply.]

**3.c. Does the research with children include interventions in addition to the educational tests or observation of public behavior.**

[ ]  **Yes** [The protocol does not qualify for Exemption 2]

[ ]  **No** (continue to 4)

1. **Does the research involve populations that simply by participating in the study may result in an increased risk of harm from disclosure?** (e.g., undocumented individuals, people who have not yet identified publicly they are LGBTQIA)

[ ]  **Yes** [The protocol does not qualify for Exemption 2.]

[ ]  **No** (continue to 5)

**5. Does the research collect information about the participant in such a manner that their identity can be readily ascertained by the investigator, directly or through identifiers linked to the participant s?** This means the data are collected with direct identifiers (name, address, email, phone number, social security number, student ID, patient ID) or code that can link back to the participant or data elements that could be combined to readily identify an individual (dates, employment history, etc.).

**Select one:**

[ ]  The participants are directly identifiable.

[ ]  The participant is indirectly identifiable (using a code to link back to participant)

[ ]  The participant is not identifiable (e.g., de-identified).

**6. Will the research generate data that, if revealed outside the protocol, could reasonably place the participant s at risk of criminal or civil liability, or damage their financial standing, employability, educational advancement, or reputation?** This means that the research involves the collection of sensitive data, about the participant, such as information about illegal behaviors, mental health issues, sensitive health conditions, genetic information, or negative opinions/attitudes about employers or teachers. A disclosure of this information outside of the research (breach of confidentiality) could pose legal risks or risks of social stigmatization to the participant s.

**Select one:**

[ ]  The data is not sensitive.

[ ]  The data is sensitive.

**Please describe the sensitive data to be collected if applicable:** Click or tap here to enter text.

**7. Provide a summary of your research:**

**7.a. Include the study objectives & purpose:**

**7.b. Describe the participant population and process for recruitment:**

**7.c. Describe study procedures including:** the anticipated time commitment for each study procedure; if surveys/interviews/focus groups are conducted in person or virtually, including on what platforms they are hosted; if interviews/focus groups are recorded (audio and/or video), please include programs used for recording and transcription**.**

**7.d. Data storage and analysis including:** storage locations, physical and electronic security, who has access to the data, how long it will be stored, and data sharing.

*Please note:*

* *survey/interview/focus group questions need not be included here. Please upload a stand-alone*

*document on the Local Site Documents Page under Other Attachments.*

* [*Information Sheet*](https://uvmoffice.sharepoint.com/%3Aw%3A/s/OVPRFiles/EVadyij8Gb1EmitkQm3rUNkBi_r42KOLYkxpVa4q_R6XVg?e=3iKew8) *should be uploaded on the Local Site Documents page under Consent when requesting implied/verbal consent*
* *If you are applying for Exemption 2(iii) the Research Data Management and Security Plan form is required to be submitted and attached to the Click record. Please note that a DMSP is not required for Exempt 2(i) and 2(ii) studies.*