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**Exempt Category 2** applies to studies that collect data using one or more of the following research methods:

- Surveys
- Interviews (including cognitive interviews)
- Focus groups
- Educational tests (e.g., cognitive, diagnostic, aptitude, achievement)
- Observation of public behavior (i.e., behavior that occurs in a public place where there is no expectation of privacy and where no special permission is required to observe others such as a public street, or park).

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## Limitations

In order to qualify for Exemption #2, one of the following must be true:

- Data are collected anonymously.** This means that no one, not even members of the study team, has the ability to link data with individual subjects at any time, directly or indirectly through the use of coding.
- The **study does not collect sensitive information** about subjects that could place them at risk if inadvertently disclosed outside the research. Sensitive information refers—but is not limited—to illegal activities, genetic or medical information, sexual behaviors, negative attitudes/opinions about one’s employer or coworkers, etc. Risks include criminal liability, social stigmatization, etc.
- The study collects **sensitive and identifiable information** about the subjects. In this case, the IRB will conduct a “limited” IRB review to ensure adequate provisions are in place to protect the subject privacy and the confidentiality of the data. This means that the IRB must review and approve procedures for data management and security where sensitive information is collected with direct identifiers (e.g., name, address, email, phone number, social security (See Data Security section below)).

In addition, to qualify for Exemption #2:

- Prisoners cannot be the study population.
- Children are not involved (except for educational tests or public observations where the investigator does not interact with the children being observed)

## Examples

Examples of research studies that are exempt under category #2:

- An online survey about sexual behavior that does not collect email or IP address or any other identifying information about respondents. If data are truly anonymous, then almost any survey or interview project could qualify for Exemption #2 no matter how sensitive the questions.

- A focus group discussion for which participants are audio recorded and identified by name in transcripts, but for which breach of confidentiality would pose no risk. Audio and/or video recording of interactions or observations is permitted under Exemption #2.
- Observation of behavior in a public park or on the street.

Examples of research studies that are *not* exempt under category #2:

- Projects that involve interventions/manipulations that are distinct from the information collection methods
- Collection of biospecimens in conjunction with surveys/interviews/educational tests
- Linking information collected via Exemption #2 to other personally-identifiable data
- Projects that involve children (except for educational tests or public observations where the investigator does not interact with the children being observed)
- Observation of behavior in a public school, business, or hospital.

## Required Documentation

Only the URI Human Research Protection Program can make the determination that their research qualifies as Exempt.

Required documentation include:

1. Exempt Research Application
2. Survey and Interview tools
3. Recruitment materials (e.g., emails, flyers)
4. CITI training record(s) for Principal Investigator and Student Investigator
5. If non-URI entities will be used, written authorization from appropriate site authority
6. Informed Consent document (see URI templates for low risk research, child assent, and parental permission).
7. If research will be used for thesis or dissertation, include thesis/dissertation approval form and thesis/dissertation proposal

## Data Security

The IRB requires the researchers to describe methodology for data security to ensure adequate protection of the privacy of subjects and to maintain the confidentiality of the data.

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## Regulatory Language (45 CFR 46.104(d)(2) – Exempt Category 2

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) if at least one of the following criteria is met:

- i. 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;
- ii. 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
- iii. 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).