



Exemption 2 - 45 CFR 46.104(d)(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).

Exemption #2 applies to studies that collect data using one or more of the following research methods ONLY:

- 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.

In the revised common rule, the first two criteria for Exemption #2 remain the same:

1. 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.

-OR-

2. 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 third criterion for Exemption #2 allows research that collects sensitive identifiable data, but requires “Limited IRB Review” to ensure that adequate protections are in place to protect subject privacy and the confidentiality of 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 number, student ID, patient ID) or indirect identifiers such as a code that can link back to a subject, or data elements that could be combined to readily re-identify a subject (e.g., dates, employment history, etc.). Additional guidance from OHRP on the criteria for limited IRB review and approval is forthcoming.

Examples of studies that meet the criteria for Exemption #2 include:

- 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 studies that do *not* meet the criteria for Exemption #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.

A system-generated exempt determination is permitted for category #2 if the information to be collected is not identifiable or not sensitive.

Although an exemption determination eliminates the need for continuing IRB review and approval, investigators still have an obligation to understand and abide by generally accepted principles of responsible and ethical conduct of research. Examples of these principles can be found in the Belmont Report (such as the obligation to obtain informed consent) as well as in guidance from professional societies and scientific organizations.

Exemption category	Study example	Exempt? Y/N	Explanation
#2	Online survey of sexual behaviors; responses cannot be linked to respondents at any time, directly or indirectly.	Yes	Data are collected anonymously .
#2	Focus group about consumer products; participants' name, address, and phone number are collected.	Yes	Data are not sensitive .
#2	Survey about illegal activities; a code is used to link back to individual respondents.	Yes*	Data are sensitive (risk of criminal liability) and identifiable . * <i>Limited IRB Review is required.</i>
#2	Behavioral observation at a public park.	Yes	Behavior occurs where no special permission is required to observe.
#2	Observation of attorneys and clients at a law practice.	No	Behavior occurs where there is a reasonable expectation of privacy .
#2	Focus group conducted with children.	No	Use of exemption #2 with minors is limited to observation without interaction.
#2	Participants complete a questionnaire before and after a counseling intervention.	No	The study involves an intervention that is distinct from the data collection method.
#2	Study involves saliva collection and blood draw.	No	Collection of biospecimens is not allowed under exemption category #2.

Exemption category	Study example	Exempt? Y/N	Explanation
#2	Survey that links responses to respondents' financial information.	No	Linking of data with other personally-identifiable information is not allowed under exemption #2. Informed consent is necessary when survey/interview data is linked to other sources.
#2	A longitudinal survey with previously recruited participants that will link current survey responses to survey responses provided ten years ago.	No	Linking of current data with data provided in the past is not permissible. Informed consent is necessary when survey/interview data is linked to other sources.