



TIP SHEET: EXEMPT CATEGORY 2

In the revised Common Rule (Final Rule), the category for minimal risk interview/survey research has been expanded to include studies that involve risk to participants if there are adequate protections in place for protecting privacy and maintaining confidentiality.

Exempt category 2

Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior (including visual or auditory recording) uninfluenced by the investigator if at least one of the following criteria is met:

- (a) The information obtained is recorded without direct or indirect identifiers;
 - (b) Disclosure outside of the research would not reasonably place the subjects at risk of harm (e.g., legal, financial, reputational, employability); or
 - (c) The information obtained is recorded with either direct or indirect identifiers and there are adequate protections in place for protecting privacy and maintaining confidentiality. (*Requires limited IRB review.*)
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My study involves children. Is it eligible for exemption under category 2?

It depends on the nature of the proposed research. The exemption under category 2 does not apply when individuals under the age of 18 are subjects of the activity, except for research involving educational tests or observations of public behavior when the investigator(s) do not participate in the activities being observed.

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What is limited IRB review?

The third criterion under exempt category 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 when sensitive information is collected with either direct identifiers or indirect identifiers, such as a code that can link back to the participant, or data elements that could be combined to readily re-identify a subject.

Exempt category	Study example	Exempt?	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’ names, addresses, and phone numbers are collected.	Yes	Data are not sensitive .
2	Survey about illegal activities; a code is used to link survey data 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 .

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Exempt category	Study example	Exempt?	Explanation
2	Focus group conducted with children.	No	Use of exempt category 2 with minors is limited to educational tests or 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 permitted under exempt category 2.
2	Survey that links responses to respondents' financial information.	No	Linking data with other personally identifiable information is not permitted under exempt category 2.
2	A longitudinal survey with previously recruited participants that will link current survey responses to survey responses provided ten years ago.	No	Linking current data with data provided in the past is not permitted under exempt category 2.

This tip sheet has been adapted from materials developed by the University of Michigan Health Sciences & Behavioral Sciences IRB.