**Exempt Category 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).

**Examples of Exempt Category 2 Research**

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

If you have further questions about Exemption Category 2, please contact the UTK HRPP at (865) 974-7697 or email us at utkirb@utk.edu