

Definition and Criteria

Exemption #3 is intended for research studies that involve “benign behavioral interventions” (to which participants must prospectively agree) combined with the collection of information from adult subjects through verbal or written responses including data entry, or through audiovisual recording.

For the-M 2018 Flexibility Initiative:

Exemption #3 will be applied to **non-federally-sponsored research only**. It replaces the current U-M Exemption 2a.

A **behavioral intervention** involves the performance of a cognitive, intellectual, educational, or behavioral task; or the manipulation of the subject’s physical, sensory, social, or emotional environment. Because medical interventions are not behavioral interventions, studies that include medical tests, medical procedures, and/or the use of medical devices are not eligible for exemption under category #3.

Benign behavioral interventions must be:

- Brief in duration
- Harmless
- Not physically invasive
- Not likely to pose a significant lasting adverse impact on subjects
- Not offensive or embarrassing

Examples of benign behavioral interventions:

- Performing cognitive tasks
- Providing educational materials to participants with the intention of changing their behavior (e.g. smoking cessation, eating habits)
- Playing an online game
- Playing economic games
- Being exposed to stimuli such as color, light or sound at safe levels
- Solving puzzles under various noise conditions

The **methods of data collection** allowed under exemption category #3 are limited to verbal or written responses from subjects (e.g., surveys or interviews, test responses, or data entry), observation, and audiovisual recording. Data cannot be collected via physical procedures such as blood pressure monitoring, EEG, activity trackers (e.g., Fitbit), eye trackers, and blood draws.



Other key points:

- The same conditions and qualifiers for Exemption #2 (see below) apply to Exemption #3, except that Exemption #3 is limited to research with *adults*.
 - 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-
- 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.
- Projects that involve the collection of sensitive *and* identifiable data require “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.).
- In order to qualify for Exemption #3, the investigator must describe the intervention and data collection procedures to potential subjects and seek their prospective agreement to participate. Exemption #3 does *not* apply to projects where subjects are not aware that they are participating in research (such as videotaping pedestrian behavior when a walk/don’t walk sign is being manipulated for study purposes).
- Exemption #3 does *not* permit the use of concealment or deception unless subjects are told prior to their participation that they will be unaware or misled about the nature or purposes of the research and they agree to participate. Debriefing is still encouraged.
- Self-exemption is permitted for category #3 when the information collected is not identifiable or not sensitive, and when the study does not involve concealment/deception.
- 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.

- The IRB must determine whether an Exempt #3 determination is appropriate for projects that involve concealment/deception with notice. Studies that utilize concealment/deception without notice are not eligible for Exemption #3 and require a standard IRB application.

Regulatory Citations:

2018 Revised Common Rule – 45 CFR Section 104(d)(2)

Examples

Exemption category	Study example	Exempt? Y/N	Explanation
#3	Subjects play a violent videogame and complete a written test. The investigator describes the study procedures and intervention, and subjects (who play video games regularly) prospectively agree to participate.	Yes	Benign behavioral intervention (subjects are unlikely to be offended); collection of non-sensitive information via written responses; prospective agreement .
#3	Subjects prospectively agree to memorize and recall a list of words while being distracted; responses are audio recorded. Subjects are told they will be unaware or misled regarding the nature or purpose of the study. The investigator conceals details of the distraction.	Yes*	Benign behavioral intervention (subjects are unlikely to be embarrassed); prospective agreement ; collection of non-sensitive information via audio recording; concealment with notice . *IRB must make exempt determination.
#3	Subjects are given educational materials with the intention of changing their behavior (e.g., smoking cessation), and then they report sensitive health history via an anonymous survey. The investigator describes the study procedures and intervention, and subjects prospectively agree to participate.	Yes	Benign behavioral intervention (not likely to pose a significant lasting adverse impact); prospective agreement ; survey collects sensitive data anonymously .
#3	Teams of adult volunteers prospectively agree to engage in brief cooperative activities and then verbally report their progress.	Yes	Benign behavioral intervention (brief); prospective agreement ; collection of non-sensitive information through verbal responses.



Exemption category	Study example	Exempt? Y/N	Explanation
#3	Subjects prospectively agree to play an economic game and complete a written survey about negative attitudes toward their employer. The survey includes dates and employment history that could be used to re-identify respondents.	Yes*	Benign behavioral intervention (harmless); prospective agreement ; collection of sensitive (potential employability risk) identifiable information via written responses. * <i>Limited IRB Review is required.</i>
#3	Subjects prospectively agree to give an impromptu speech and complete a math task aloud while being rushed. Deception is involved in the form of frowning judges. Subjects are not told they will be unaware or misled regarding the nature or purpose of the study.	No*	The behavioral intervention is not benign (subjects could be embarrassed; without debriefing, the intervention could pose a significant lasting adverse impact). The use of deception without notice is not allowed. * <i>Comprehensive IRB review is required.</i>
#3	Investigators videotape pedestrian behavior when a “Walk/Don’t Walk” sign is manipulated for research purposes.	No	Exemption #3 does not apply to studies where subjects are not aware that they are participating in research.
#3	Benign behavioral intervention followed by verbal responses from children.	No	Exemption #3 is limited to research with adults .
#3	Study involves medical tests, procedures, and/or devices.	No	Medical interventions are not behavioral interventions.
#3	Study collects data via activity trackers (e.g., Fitbit) and eye trackers.	No	Data cannot be collected via physical procedures.
#3	Internet survey with embedded intervention (health scenarios) links responses to respondents’ criminal records.	No	Linking of data with other personally-identifiable information is not allowed under exemption #3.