**Exempt Category 3  
Benign Behavioral Intervention**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| * 1. Does the proposed research involve ONLY the participation of adults? [[1]](#endnote-1) | | | | |
| Yes | | Continue to question 2. | | |
| No | | This research does not qualify for exemption under this category. | | |
| * 1. Does the research involve the use of benign behavioral [[2]](#endnote-2) [interventions](#Intervention)? | | | | |
| Yes | | If “yes,” answer the following: | | |
|  | | 1. **Is the intervention brief in duration? [[3]](#endnote-3)** | | |
|  | | Yes | | Explain: |
|  | |  | |  |
|  | | No | | This research does not qualify for exemption under this category. |
|  | | 1. **Is/are the benign behavioral intervention(s) harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and neither offensive nor embarrassing? ii** | | |
|  | | Yes | | Explain: |
|  | |  | |  |
|  | | No | | This research does not qualify for exemption under this category. |
| No | | This research does not qualify for exemption under this category. | | |
| * 1. Does the benign behavioral intervention include collection of information only through verbal (oral) or written responses (including data entry) or audiovisual recording?[[4]](#endnote-4) | | | | |
| Yes | | Continue to question 4. | | |
| No | | This research does not qualify for exemption under this category. | | |
| * 1. Will participants prospectively agree to the intervention and information collection? | | | | |
| Yes | | Explain: | | |
|  | |  | | |
| No | | This research does not qualify for exemption under this category. | | |
| * 1. Select the following condition(s) that apply to this research: | | | | |
|  | The information obtained is recorded in such a manner that the identity of the human subjects cannot readily be ascertained either directly or through identifiers linked to the subjects; | | | |
|  | Explain: | | | |
|  |  | | | |
|  | 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; | | | |
|  | Explain: | | | |
|  |  | | | |
|  | Information obtained is recorded in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects but adequate provisions have been made to ensure that the data collected are appropriately monitored and secured to ensure the privacy of the subjects. | | | |
|  | Describe provisions to protect privacy of **participants**: | | | |
|  |  | | | |
|  | Describe provisions to maintain confidentiality of **participant data**: | | | |
|  |  | | | |
|  | None of the above statements applies. | | | |
| * 1. Does the research involve deception or misleading the subjects about the nature or purpose of the research? [[5]](#endnote-5) | | | | |
| Yes | | | Explain: | |
|  | | |  | |
|  | | | **If “yes,” does the research include prospective agreement by the participant in which the participant is informed that he or she will be unaware of or misled regarding the nature or purposes of the research?** | |
|  | | | Yes | Explain: |
|  | | |  |  |
|  | | | No | This research does not qualify for exemption under this category. |
| No | | |  | |
| * If you answered ‘yes’ to Questions 1-5 and answered ‘yes’ to Question 6(a)(i) or ‘no’ to 6(b), your project may qualify for exemption:   + Complete any additional category worksheets applicable to your research;   + Proceed with completing Parts III-VI of the Exempt Application Form;   + Submit the items noted in the Submission Checklist at the end of the form to Research Compliance Services (RCS). RCS will review and verify the exempt determination;   + If RCS determines the study does not qualify for exemption, you will need to prepare and submit a protocol using the Initial Review Application. * If you answered ‘no’ to Questions 1-5 or ‘no’ to Question 6(a)(ii), this research is not exempt under this category. Return to the screening form to identify alternative categories for exemption. If you conclude that no categories are applicable to your research, your study is not eligible for exemption. Proceed with preparing an Initial Review Application. | | | | |

1. Although the regulation does not require competency checks, it is assumed that the participants will have adequate decision-making capacity to agree to participate in the proposed research. Research requiring decision-making on behalf of the participant by a legally authorized representative does not qualify for this exemption. [↑](#endnote-ref-1)
2. Benign behavioral interventions are harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and neither offensive nor embarrassing. Medical interventions (including medical tests, procedures and devices) may not be used.

   The term behavioral intervention is used to define research procedures that are employed in the study of psychological states and processes, cognition, ideas and attitudes, or behavior. It does not include physical (bodily) tasks or physical manipulations unless these are minor activities that are incidental to the behavioral intervention and do not increase risk. Behavioral interventions typically rely only on communication or interpersonal contact with the subject, the performance of a cognitive, intellectual, educational or behavioral task, or manipulation of the subject’s physical, sensory, social, or emotional environment.

   This exemption is limited to interventions that are not expected to cause physical or emotional harm, persistent discomfort, be experienced by the subject as embarrassing, or be offensive. Ordinary, mild, transient forms of discomfort, such as the stress associated with completing a timed cognitive task, anxiety about performance, and boredom, are consistent with the intent of the exemption. Similarly, while research cannot meaningfully eliminate all risk of embarrassment or offense, the research should include only interventions that the researcher has no reason to think subjects will find offensive or embarrassing considering the characteristics of the subject population, the research context, and how they might impact the subject’s experience of the research intervention. [↑](#endnote-ref-2)
3. Brief in duration refers to the intervention itself. Data collection activities could proceed over a longer period of time without precluding the applicability of this exemption. If the intervention and the data collection are intertwined or difficult to separate, the entirety of the activity should be brief in duration. To meet the requirement of brief in duration, the benign behavioral intervention should last a few minutes to a few hours. While it does not have to occur in a single session, the entire time for the intervention should occur on a single day and not exceed a few hours in its entirety. [↑](#endnote-ref-3)
4. For exemption under this category, only certain data collection methods can be used. Even very low risk physical procedures such as the application of sensors to the body (e.g. blood pressure monitoring, electroencephalogram, wearable activity trackers), minimally invasive procedures (e.g. blood drawing), and the collection of bodily fluids via introduction of a tool or sensor into the body (e.g. buccal swab) are not allowed. Data entry by a device (e.g., a Fitbit) would not meet the requirements of this exemption. [↑](#endnote-ref-4)
5. For exemption under this category, no deception may be used or if deception is used, the participants must be told that they will be kept unaware of or misled regarding the nature or purpose of the research. For example, participants may be informed that they will not be told the purpose of the research until after the study session is completed as long as they are informed of what will occur during the session. [↑](#endnote-ref-5)