2018 Exempt Category 3
Benign Behavioral Interventions
[Exempt Research: 45CFR46.104 (d) (3)]

START
Meets the definition of research.*

Does your research involve Benign Behavioral Interventions** through verbal or written responses (including data entry or audiovisual recording) from adult subjects?

YES

Will the subjects agree to the intervention in advance?

YES

Will subjects be informed before participating that they will be unaware of or misled regarding the research purpose?

YES

Criteria 1
Information obtained will be recorded by the investigator in such a manner that the identity of the human subjects cannot be readily ascertained, directly or through identifiers linked to the subjects.

NO

Or

YES

Criteria 2
Disclosure of the human subject’s responses outside the research would not place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, educational advancement, or reputation.

NO

Would your subjects be at risk if their responses were disclosed?

YES

May qualify as Exempt Category 3 if a limited IRB review approves the plan for the privacy and confidentiality of the data.

NO

Qualifies for Exempt Category 3
if Criteria 1 OR 2 is met
Submit application for
Exempt Research Designation

Does not qualify for Exempt Category 3
Submit a Non-Exempt Application

*"Research" means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

**"Benign behavioral interventions" are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing.