2018 Exempt Category 3: Benign Behavioral Interventions Use after 21 Jan 2019

START
Meets the definition of research

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.

Identifiers: 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.

104.(d)(2)(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.

The subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

Physiologic monitoring is not included in this exemption.

Only benign behavioral interventions with data collection?

Does not meet exempt 3 category requirements

Deception authorized by subjects?

Deception involved?

Risk of criminal or civil liability?

Subject identifiers readily ascertainable?

May qualify as Exempt Category 3 if a limited IRB review approves the plan for the privacy and confidentially of the data. .111(a)(7)

Qualifies for Exempt Cat 3

Are prisoners the targeted population?

Children involved?

YES

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