IRB SOP 502
Exempt Research

Purpose

Research activities in which the only involvement of human subjects will be in one or more specific categories (45 CFR 46.101(b)) may be exempt from IRB review. The determination by the IRB of exemption must be based on regulatory, institutional and ethical criteria, and be appropriately documented. In addition, the IRB, must determine whether research that qualifies for an exemption requires consideration under the HIPAA regulations for the use and/or disclosure of protected health information

Scope

This Standard Operating Procedure applies to all Investigators submitting exempt research for IRB review, and the IRB Office/designee when reviewing exempt request.

Definitions

Exempt Review Categories: The following six exemption categories are outlined by federal regulations as follows:

Category 1: Research conducted in established or commonly accepted educational settings that specifically involves normal educational practices that are not likely to adversely impact

a) The information obtained is recorded by the investigator in such a manner that the identity of the human participant's cannot readily be ascertained, directly or through identifiers linked to the participants;

b) Any disclosure of the human participants' responses outside the research would not reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, educational advancement, or reputation;

- or -

c) 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)

NOTE: Projects involving oral histories are not considered research unless the projects (a) utilize a "systematic investigation" with analysis of data to answer a scientific question and (b) are designed to develop or contribute to generalizable knowledge.

Category 3 Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agre(e)3 (ha)4(io)-2 (n)6 (j)4 (e)3 (c)8

under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

If the research involves deceiving the subjects regarding the nature or purpose of the research, this exemption is not, applicable unless 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.

Category 4 Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria are met:

a) The identifiable private information or identifiable biospecimens are publicly available; or

b) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human participants cannot readily be ascertained directly or through identifiers linked to the participants, the investigator does not contact the participants, and the investigator will not re-identify participants; or

c) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CF

Category 7 and 8 The USA IRB does not utilize these categories for review/approval of exempt research.

Policy

Research initially submitted as exempt before January 21, 2019, shall comply with the Common Rule pre-2018 requirements. Exempt research submitted and approved after January 21, 2019 will comply with the Common Rule 2018 requirements.

Research activities in which the only involvement of human subjects are in one or more of the categories listed 45 CFR 46.101(b) may be exempted from IRB review. Studies that qualify for exemption are only required to adhere to certain federal regulations and must also follow state laws and University policies applicable to research. Studies that qualify for exemption must adhere to principles of sound research design and ethics.

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4.4 If there are interactions with participants, conducting a consent process that will disclose such information as:
- 4.4.1 That the activity involves research
- 4.4.2 A description of the procedures
- 4.4.3 That participating is voluntary
- 4.4.4