



UNIVERSITY OF
SOUTH ALABAMA

IRB SOP 503
Exempt Research – Limited IRB Review

Purpose

The purpose of this policy is to describe the criteria and process of review for all proposed Exempt research requiring limited review, as described in the revised Common Rule implemented January 21, 2019. The provision for limited IRB review allows certain research categories as exempt, even when the identifiable information might be sensitive or potentially harmful if disclosed. In order to qualify for exemption, the study must meet the standards of the limited IRB review.

Definitions

Exempt Category 2: Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording: 2(iii)- 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.

Exempt 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 agrees to the intervention and information collection: 3(iii)- If the research involves deceiving the subjects regarding the nature or purposes 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.

Limited Review: is a type of IRB review that is required for granting exempt status in some circumstances for Exempt categories 2(iii) and 3(iii).

Policy

It is the policy of the USA IRB that all proposed exempt research requiring limited review be reviewed by the IRB Office and designated reviewer. An IRB member will be assigned the review and presented at the **Behavioral and Educational IRB Committee**. This review will document that the research meets all limited review requirements specific to the Exempt category in accordance with Health and Human Services regulations at 45 CFR §46.104. The limited review process will be completed for exempt research qualifying under categories 2(iii) and 3(iii). See *SOP 502: Exempt Research* for complete category descriptions.

Procedures

1.0 Limited Review Process

- 1.1 The PI must complete and submit the appropriate IRB application form via IRBNet.
- 1.2 The IRB Office will determine whether the project meets the limited review criteria. (Exempt categories 2(iii) and 3(iii))
- 1.3 The process of review for exempt research will follow the steps listed in the *SOP 502: Exempt Research Review*.
- 1.4 When limited review is permissible, the following process must also be followed:
 - 1.4.1 If the research requires limited review under Category 2(iii), 3(iii) per 45 §CFR 46.104, limited review will be completed by a designated IRB member and presented at the **Behavioral and Educational IRB Committee**. The review will determine that:
 - When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
 - The IRB will review the following information for projects collecting sensitive and identifiable under Exempt category 2 or 3:
 - Justification of needing identifiers in order to conduct the research
 - The extent to which identifiable private information is or has been de-identified and the risk that such de-identified information can be re-identified
 - Proposed use of the information
 - The extent to which the information will be shared or transferred to a third party or otherwise disclosed/released (who has access)

- Type (e.g. electronic and/or hard copy)
- Where stored
- Timeframe of storage
- Description of privacy provisions (security controls)

The IRB will review the above information/procedures for data management and security where identifiers or sensitive information is collected or indirect identifiers such as a code that can link back to a subject, or data elements that could readily re-identify a subject to ensure that data are securely managed and stored before an exemption is determined.

2.0 Annual Check-In

If the project has been granted exemption status, continuing review is not required. However, USA IRB has implemented an automated email notification via IRBNet requesting an annual check-in to report on status of the project and remind the study team of their responsibilities. IRBNet management system designates the annual check-in as “next report due”

At its discretion, the IRB may require annual renewal for continuation of the research project that meets the criteria under Exempt category 2(iii) or 3(iii).

Regulated Documents

45 §CFR 46.104

University Documents

[SOP 502: Exempt Research](#)

Supplemental Exempt Form: Data Management and Security Provisions for Exempt 2(iii) and 3(iii) (Located in IRBNet Forms and Templates)

History

Effective Date: January 21, 2019

Revisions:

Responsible Party:

Office of Research Compliance and Assurance