**LIMITED IRB REVIEW**

Effective 1.21.19

**This guidance applies only to research that is federally funded or supported.**

The revised federal regulations governing human subjects research, effective January 21, 2019, require a new type of review called "limited IRB review" for certain exempt and expedited protocols.

The new provision for limited IRB review allows certain research to be 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.

If the information is both identifiable and sensitive or potentially harmful, the safeguards offered by the limited IRB review may allow an exemption determination to be made.

***Limited IRB review is required in the following circumstances:***

1. Exempt category 2 (educational tests, surveys, interview or observations of public behavior) – When the information is recorded by the investigator in an identifiable manner and disclosure of the subject's responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement or reputation.
2. Exempt category 3 (benign behavioral interventions) – When the information is recorded by the investigator in an identifiable manner and disclosure of the subject's responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement or reputation.

***Reviews Related to Privacy and Confidentiality***

The purpose of limited IRB review is to assure adequate protections for the privacy of subjects and adequate plans to maintain the confidentiality of the data. In order to assure these protections, the limited IRB review may consider the following topics:

- The nature of the identifiers associated with the data
- The justification for needing identifiable materials to conduct the research
- The feasibility of conducting the research with fewer identifiers (to lower the risk of a breach)
- Characteristics of the study population
- The proposed use of the information
- The overall sensitivity of the data being collected
- Persons or groups who will have access to study data
- The process used to share the data
- The likely retention period for identifiable data
- The security controls in place

    - Physical safeguards for paper records
    - Technical safeguards for electronic records
    - Secure sharing or transfer of data outside the institution, if applicable
- The potential risk for harm that would occur if the security of the data was compromised.

Additional information about adequate protections will be outlined in guidance issued by the Secretary of HHS.

***Individuals Performing the Limited IRB Review***

Limited IRB review must be performed by the IRB Chair or by an experienced IRB member. The review can occur on an expedited basis and does not require consideration by a convened board. The reviewer may require modifications to the proposal prior to approval. Disapprovals must be made by the convened board. If the limited IRB review does not result in approval under the exempt categories, then the IRB can evaluate whether or not approval is appropriate under the expedited categories.

Expedited research must meet all the approval criteria under 45 CFR 46.111, including either informed consent or waiver of consent.