

LIMITED IRB REVIEW

In accordance with the revised Common Rule, effective January 19, 2018, the IRB will implement/require a new type of review – **LIMITED IRB REVIEW** – for certain categories of exempt and expedited protocols.

This new provision allows certain types of research categorized as Exempt, even when the identifiable information may be sensitive or harmful if disclosed. In order for the study to qualify for Exempt, the project must meet the standards of limited IRB review.

If the information is identifiable and sensitive or potentially harmful, the safeguards provided by limited IRB review may allow for a determination of exemption to be made. **This new regulation agrees with our current practice.**

Limited IRB review is required for the following exempt categories:

Exempt category 2: When the information is recorded in an identifiable manner and disclosure of study participant's response(s) would reasonably place them at risk of criminal or civil liability or may be damaging to persons financial standing, employment, education advancement or reputation.

Exempt category 3: When the information is recorded by PI in an identifiable manner and disclosure of the subject's responses would reasonably place them at risk of criminal or civil liability of may be damaging to persons financial standing, employment, education advancement or reputation.

NOTE: *Review in accordance to the above categories under categories 2 and 3, assures adequate protections for privacy and adequate plans to maintain confidentiality of data.*

Exempt category 7 and 8 - when a PI plans to store, maintain, or use identifiable private information or identifiable specimens collected for non-research purpose and the information/specimens have been obtain with broad consent.

NOTE: *Review of research under categories 7 and 8, limited review confirms the following:*

- Elements of **Broad Consent** meets federal requirements
- Consent process is appropriate
- Consent is documented

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- Privacy and confidentiality is protected and maintained