**LIMITED IRB REVIEW**

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.

What is limited IRB review? Limited IRB is increased oversight by the IRB for low-risk research (e.g. certain exempt categories) to ensure that either:

• The identifiable private information or biospecimens collected have the appropriate data security and privacy protections in place to reduce the chance of inappropriate disclosure; or

• Broad consent was obtained for the use of stored identifiable data or biospecimens.

The new provision for limited IRB review allows certain research to be 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 investigator records the information 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 investigator records the information 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.

3. Exempt categories 7 and 8 (broad consent)

When investigators plan to store, maintain or use identifiable private information or identifiable

Biospecimens collected for non-research purposes and the information/specimens are obtained with a broad consent process.\*[[1]](#endnote-1)

The IRB will determine that the research to be conducted is within the scope of the broad consent; and the investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

**Purpose of Limited IRB Review**

When reviewing the exempt categories 2 and 3, the limited IRB review assures adequate protections for the privacy of subjects and adequate plans to maintain the confidentiality of the data.

When reviewing for research involving broad consent under categories 7 and 8, the limited IRB review initially confirms that the elements of broad consent meet federal requirements that the consent process will be appropriate, that consent is documented as required and that privacy and confidentiality are protected. When research involving the data or specimens is proposed, the limited IRB review confirms that the proposed secondary use is within the scope of the broad consent.

The IRB will conduct limited IRB review during the initial review of the submitted project. In addition, Investigators are required to submit changes to the IRB when the context or conditions of the original limited IRB review change (e.g. if the location for the storage and protection of the data change).

Reviews Related to Privacy and Confidentiality

What are the data security standards?

* The nature of the identifiers associated with the data
* 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;
* The justification for needing identifiers in order to conduct the research
* 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 were compromised

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In addition, the IRB will assess whether the data collected as part of the proposed study require increased protections based on the following criteria:

• The use of the information;

• The extent to which the information will be shared or transferred to a third party or otherwise disclosed or released;

• The likely retention period or life of the information;

• The security controls that are in place to protect the confidentiality and integrity of the information; and

• The potential risk of harm to individuals should the information be lost, stolen, compromised, or otherwise used in a way contrary to the contours of the research under the exemption.

Individuals Performing the Limited IRB Review

Limited IRB review is 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 are 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.

Continuing review of research is not required for research that had limited IRB review.

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

1. \*Roosevelt University will implement research involving broad consent when compliance with technical and regulatory requirements can be confirmed. Additional guidance will be developed at that time. [↑](#endnote-ref-1)