

# Limited IRB Review

Effective January 21, 2019, the revised Common Rule requires a new type of review called “**Limited IRB Review**” for certain exempt protocols. All studies submitted to the GW IRB on or after January 21, 2019 will be reviewed under the revised Common Rule regulations.

The new provision for limited IRB review allows specific research to be reviewed as exempt, even if the identifiable information is sensitive or potentially harmful if disclosed.

To meet the exempt categories described below, the study must also meet the standards of the limited IRB review.

## When is limited IRB review conducted?

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 for exempt categories 2 and 3.

- **Exempt Category 2: Educational tests, surveys, interview or observations of public behavior**
- **Exempt Category 3: Benign behavioral interventions**

### What does information recorded in an identifiable manner mean?

*The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can be readily ascertained, directly or indirectly through identifiers linked to the subjects.*

- **Exempt Categories 7 and 8**

**Note:** A limited IRB review is conducted for certain provisions under exempt categories 7 and 8 (exempt research involving *broad consent*). However, GW is not utilizing a broad consent at this time and will not be making any determinations for exempt categories 7.

## What is the purpose of the limited IRB review?

When reviewing exempt categories 2 and 3, the limited review **ensures appropriate protections** for the **privacy of subjects** and **adequate plans to maintain confidentiality of data** are in place.

**When reviewing exempt category 8, the limited review ensures appropriate consent was obtained for the use of identifiable information or specimens.**

## **What is considered during limited IRB review under exempt categories 2 and 3?**

During limited IRB review, the reviewer may consider the following topics:

- The type of identifiers linked to the data
- The justification for needing identifiers, or certain identifiers, to conduct the research
- The characteristics of the study population
- The overall sensitivity of the collected data
- Individuals who will have access to the study data
- The process used to share the data
- The process used to protect and secure the data (physical, electronic)
- The duration of retention for identifiable data and justification for this
- The potential risk for harm that would occur if the security of the data and privacy of subjects was compromised

Additional information about adequate protections will be outlined in guidance issued by the Secretary of the U.S. Department of Health and Human Services (HHS).

## **What is considered during limited IRB review under exempt category 8?**

During limited IRB review, the reviewer will consider the following topics:

- If informed consent or broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with §46.116(a)(1) through (4), (a)(6), and (d) at the time the data were generated/collected
- If only data from participants who signed the Informed Consent/Broad Consent at the time of collection/generation will be used OR if documentation for consent was waived by an IRB at the time of collection/generation
- The research team must agree not to return individual results to participants except as required by law

## **Who performs the limited IRB review?**

Limited IRB review must be performed by the **IRB Chair** or by **an experienced IRB member (IRB Designee)**.

The limited IRB review is similar to the expedited review process and does not require review by a convened board. The reviewer may have stipulations to the proposal prior to approval. As with expedited review, disapprovals cannot be made during limited IRB review and must be made by the convened board. If the reviewer of a limited IRB review does not approve the research under the exempt categories, then the reviewer can evaluate whether approval is appropriate under the expedited categories. If the study status is changed from exempt to expedited, the study must

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

## Questions?

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Reference: KUMC. (n.d.) Limited IRB Review. Retrieved from:  
<http://www.kumc.edu/Documents/hrpp/Topical%20Guidance/KUMC%20Guidance%20on%20Limited%20IRB%20Review.pdf>