

New Process for Exempt Review: Limited IRB Review

The Final Rule introduces a new concept of **limited IRB review** as a condition of exemption for four of the exempt categories.

When is Limited IRB review required?

- For Categories 2 and 3, it is sometimes an option.
- For Categories 7 and 8, it is always required.



What does exempt mean?

“Exempt” does not always mean exempt from all of the requirements of the Common Rule (HHS 2017). Some of the new exempt categories require limited IRB review as a condition of being exempt from other regulatory requirements.



Who may be a limited IRB reviewer?

An IRB may use the expedited review procedure to review research for which limited IRB review is a condition of exemption.

“Under an expedited review procedure, the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB” (HHS 2017).

The Final Rule allows for the exemption of research collecting identifiable information with the potential to cause harm if disclosed, provided that the IRB has determined that “there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data” (46.117(a)(7)). This new requirement is called a limited IRB review.

Limited IRB review requires the IRB to determine that there are adequate provisions for protecting privacy and confidentiality. This requirement is not defined or explained; however, the preamble to the Final Rule presented considerations.



IRB Considerations for Privacy and Confidentiality Safeguards (Final Rule Preamble)

- Extent to which identifiable private information is or has been de-identified and the risk that such de-identified information can be re-identified
- Use of the information
- Extent to which the information will be shared or transferred to a third party or otherwise disclosed or released
- Likely retention period or life of the information
- Security controls that are in place to protect the confidentiality and integrity of the information
- 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

