

Complete Healthcare Compliance Manual

Resource: Sample Limited IRB Review Guidance Summary

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Limited IRB Review

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.

How is limited IRB review conducted?

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

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