



Institutional Review Board

Guideline: Applying Equivalent Protections to Human Subjects Research

The following reflects SHSU IRB's new guideline that outlines how the IRB will be applying equivalent protections to human subjects research **without voluntarily applying the Common Rule to all studies**, focusing on **burden-reducing procedures** that are permissible.

Purpose

This guideline provides a framework for Institutional Review Boards (IRBs) to apply equivalent protections to human subjects research that **does not fall under federal regulations** (e.g., unfunded or privately funded studies), while leveraging **burden-reducing flexibilities** allowed under current policy.

Scope

Applies to:

- Human subjects research **not federally funded**
 - Research **not otherwise subject to 45 CFR 46**
 - Studies where the IRB chooses **not to apply the Common Rule in full**
-

Key Principles

- Maintain **ethical standards** consistent with the Belmont Report
 - Ensure **risk minimization, informed consent, and privacy protections**
 - Apply **flexibilities** to reduce administrative burden while safeguarding participants
-

Burden-Reducing Procedures Allowed Under Equivalent Protections

1. Exemptions Without Documentation

- IRBs may allow **exempt research** without requiring formal documentation of exemption determinations.
- No need for full board or expedited review for exemption categories.

2. Waiver of Signed Consent

- For minimal risk studies, IRBs may waive the requirement for **signed informed consent** if:
 - The only record linking the subject to the research is the consent form
 - The principal risk is breach of confidentiality

3. Broad Consent Not Required

- IRBs are not required to implement **broad consent** provisions for secondary use of identifiable data or biospecimens.

4. Limited IRB Review Optional

- For exempt research involving identifiable data/specimens, **limited IRB review** is not mandatory under equivalent protections.

5. Continuing Review Not Required

- IRBs may waive **continuing review** for:
 - Minimal risk studies
 - Studies in data analysis or follow-up stages
 - Research reviewed under expedited procedures

6. Flexibility in Consent Documentation

- IRBs may approve **verbal consent** or **electronic consent** methods without requiring a written form, especially for low-risk studies.



Institutional Review Board

7. Expedited Review for Minimal Risk

- IRBs may use **expedited review procedures** for initial and continuing review of minimal risk research.

8. Tailored Review Procedures

- IRBs may develop **custom review procedures** for specific categories of research (e.g., student projects, quality improvement) that meet ethical standards but do not require full regulatory compliance.

Conclusion

This approach allows IRBs to uphold ethical standards while reducing unnecessary regulatory burden for studies not subject to federal oversight. It supports efficient review and oversight tailored to the nature and risk of the research.

Source: *Developing and Applying Equivalent Protections*, <https://www.aahrpp.org/resources/for-accreditation/tipsheets/developing-and-applying-equivalent-protections>, Accessed October 30, 2025.