

## Options for Conducting Secondary Research Using Information or Biospecimens Under the Final Rule

Not Human Subjects Research

Use non-identifiable information or biospecimens.

Exemption 4

Use information protected by HIPAA, or record information in a manner no longer identifiable, as long as the information or biospecimens were not originally obtained under provisions for broad consent.

Exemption 8

Use information or biospecimens collected under the new provisions for broad consent with a limited IRB review.

Waiver of Consent

Use identifiable information or biospecimens, and request a waiver of consent from the IRB. Justification for why secondary research cannot be carried out using non-identifiable information or biospecimens is required. Not applicable for information or specimens originally obtained under provisions for broad consent.

Consent For Secondary Use

Get specific or broad consent from subjects for the secondary use of their identifiable private information or biospecimens for research purposes.

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