

## Final Rule Key Concepts and Requirements for Secondary Research

Concept/Requirement	Explanations
<b>"Data" is now referred to as "Information or Biospecimens"</b>	No substantive change from pre-2018 rule, but emphasizes that research involving identifiable biospecimens is covered under the Final Rule
<b>Expansion of Exemption Criteria</b>	Allows for broader use of exemption category 4, and new exemptions 7 and 8 for research where information or specimens were originally obtained using broad consent
<b>NEW</b> <b>Consent Requirements</b>	Notifies subjects of potential secondary use of information or biospecimens
<b>NEW</b> <b>Broad Consent Requirements</b>	Provides option for consent for secondary research use of identifiable private information or biospecimens
<b>Changes in the IRB Waiver Criteria</b>	Limits when IRBs can waive consent for research involving identifiable information or biospecimens