

# Disclaimer –Laura Odwazny

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# Revised Common Rule – when effective, new informed consent requirements relevant to data sharing

- Study-specific informed consent must include either statement:
  - Identifiers might be removed from IPI or identifiable biospecimens and stripped information or biospecimens could be used for future research studies or given to another investigator for future research studies without additional informed consent;  
OR
  - Subject’s information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies (.116(b)(9))

# Revised Common Rule – when effective, new informed consent requirements relevant to data sharing (2)

- Broad consent for storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens must include:
  - Description of IPI or identifiable biospecimens that might be used in research, **whether sharing of IPI or identifiable biospecimens might occur**, and types of institutions or researchers that might conduct research with the IPI or identifiable biospecimens (.116(d)(3));
- Plus, new exemption for secondary research use conditioned on broad consent requires that IRB determine that the research to be conducted is within the scope of the broad consent (.104(d)(8)(iii))