

# Changes to Categories of Exempt Research

- Deleted – research involving public officials
- Revised – two existing exempt categories,
- New – three categories
  
- **What will stay the same?**  
The IRB will make the exempt determination
- **What will change?**  
More studies may qualify as exempt

# Revised Exempt Research Categories

- (2) Identifiable data can be recorded provided there is *limited IRB review*
- (4) Secondary research using identifiable data/biospecimens collected as part of clinical care or an IRB-approved study
  - Now applies both to retrospective *and* prospective data (but only *existing* specimens)
  - Investigators can have a master list/ identifiers
    - HIPAA applies

# New Exempt Research Categories

- (3) Benign behavioral interventions with adults – brief, harmless, painless, not invasive, not offensive and not embarrassing
- (7) Storage & maintenance of identifiable information for secondary research with *limited IRB review*
- (8) Research involving use of identifiable information/specimens with use of broad consent with *limited IRB review*

**Table 1. Exemptions.**

Pre-2018 __.101(b)	Final Rule __.104 (d)	Exemption description	New Final Rule allowance and conditions
(1)	(1)	Normal educational practices in commonly accepted settings	
(2)	(2)	Educational tests, surveys, interviews, observation of public behavior	Identifiable data can be recorded if there is limited IRB review*
(3) Deleted in final rule		Educational tests, survey and interview procedures, or observation of public behavior in public officials	
	(3) NEW in final rule	Benign behavioral interventions	Identifiable data can be recorded if there is Limited IRB review*
(4)	(4)	Secondary research uses of identifiable private information or biospecimens	Identifiable data can be collected and analyzed if regulated under HIPAA
5)	(5)	Research and demonstration projects by federal department or agency	Publication of project on a list prior to research
(6)	(6) (7) NEW in final rule	Taste and food quality Storage or maintenance of identifiable private information or identifiable biospecimens for secondary research	Broad consent Limited IRB review**
	(8) NEW in final rule	Research involving use of identifiable private information or identifiable biospecimens stored pursuant to a broad consent	Limited IRB review*

# New Requirement for Some Exempt Research: Limited IRB Review

- Additional requirement for certain categories of exempt research
- IRB must ensure there are adequate provisions to protect the privacy of subjects and maintain the confidentiality of data
- When broad consent applies, review ensures
  - appropriate consent/waivers were obtained
  - privacy and confidentiality are protected,
  - storage of the data is adequate (Note: the IRB must be informed of changes in data storage)