

# Overview of Changes to Exempt Determination Process

## What's new in the Final Rule?

- Exempt research has its own section at 46.104
- Two new processes introduced: Limited IRB review and broad consent
- New categories added; old categories revised and expanded
- Final Rule has 8 exempt categories
- Updates to Subpart applicability and exempt research

## How is research determined to be exempt?

The Final Rule does not specify or restrict who can determine if research is exempt. The institution usually has a policy on who has the authority to determine if research is exempt, but the Final Rule, like the pre-2018 rule, does not specify. Due to the potential for conflict of interest, however, the Office for Human Research Protections (OHRP) continues to recommend that investigators not be given the authority to make an independent determination that their own human subjects research is exempt.

## Updates to Exemption Categories

- Category 1 – Revised
- Category 2 – Revised
- Category 3 – Replaced\*
- Category 4 – Revised
- Category 5 – Revised
- Category 6 – Unchanged
- Category 7 – New
- Category 8 – New

\* (Pre-2018 Rule Category Eliminated; New Category Added for Final Rule)

Limited IRB review as a condition of exemption must be conducted by an IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB.

## Subpart B

• Final Rule consistent with the pre-2018 rule

• Each of the exemptions can be applied to research subject to Subpart B

## Subpart C

- Final Rule changes the pre-2018 rule to allow the exemptions to apply to Subpart C for research involving a broader subject population if the research only incidentally includes prisoners.
- Permits the exempt secondary research of information or biospecimens from subjects who are prisoners, if that research is not seeking to examine prisoners as a subpopulation.
- Final Rule also allows subjects to continue in exempt research if they become prisoners during a study.

## Subpart D

- Final Rule allows research with children to be exempt for categories 1, 4, 5, 6, 7, and 8.
- Final Rule does not permit the exemption of research with children that includes identifiable information and is reviewed under a limited IRB review.
- Consistent with pre-2018 rule, observation of the public behavior of children under Category 2 is allowed only if the researcher does not participate in the activities being observed.
- Consistent with pre-2018, surveying and interview procedures with children may not be exempt.