Final Rule Material:
Changes to Exempt Categories

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CITI Program Final Rule Materials

- This presentation can be used to introduce those involved in the research enterprise to the federal Common Rule changes, which are a result of the U.S. Department of Health and Human Services (HHS) Final Rule published in 2017.
- This presentation will review changes to the exempt categories of research.
- All CITI Program Final Rule materials are available on the "Resources" tab of the CITI Program website, www.citiprogram.org/en/resources.

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Introduction

- For consistency and clarity, this presentation uses citations to 45 CFR 46, Subpart A, version of the Common Rule.
- The regulations themselves should be read and understood before implementing changes.
  - *Note - the Final Rule's preamble is a good source for further explanation.*

Note: These resources are based on the Final Rule issued by the U.S. Department of Health and Human Services (HHS) at 45 CFR 46, Subpart A - "Federal Policy for the Protection of Human Subjects" (the Common Rule) on 19 January 2017. These resources have been updated to reflect the 19 June 2018 Final Rule. The general compliance date is now 21 January 2019.

Final Rule Updates to Exempt Research

- All but one category was revised.
- New categories were added.
- Two new processes were introduced with the new categories.
  - *Limited IRB review*
  - *Broad consent*

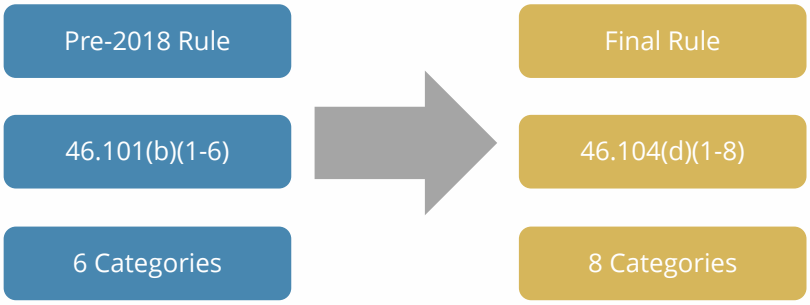
What Does Exempt Mean?

- **Exempt** means not subject to the requirements of the Common Rule.
- However, it is important to note that "exempt" does not always mean exempt from all of the requirements of the Common Rule, as certain exempt categories now have specified requirements as a condition of exemption (HHS 2017).

For Example	The new Exempt Category 7 includes specific regulatory requirements of broad consent and limited IRB review as a condition of being exempt from other regulatory requirements.

New Regulatory Section for Exempt Research

- The pre-2018 rule had six exempt categories in section 46.101(b).
- The revised Common Rule gives exempt categories an entire section in 46.104, and now includes eight categories in 46.104(d)(1-8).



Section 46.104, Exempt Research

New

Section 46.104 was previously "Reserved" in the pre-2018 rule.

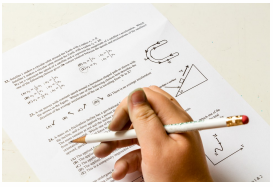
- Section 46.104 has been designated as "Exempt Research."
  - *Section 46.104(a) states that research activities must comply with the requirements of this section and as specified in each category in order to be exempt from the Common Rule.*
  - *Section 46.104(b) reviews the use of exemption categories for research subject to the requirements of Subparts B, C, and D.*
  - *Section 46.104(c) is reserved.*
  - *Section 46.104(d) lists the eight categories of exempt research.*

Category 1: Research in Established or Commonly Accepted Educational Settings

- This category has been amended from the pre-2018 rule to include a condition that the research is not likely to have adverse impacts on:
  - Students learning required educational content, or
  - Assessment of educators who provide instruction
- The exemption may only be used for studies about normal educational practices.

Category 2: Educational Tests, Surveys, Interviews, Observations of Public Behavior

- The new regulation allows for exemption as long as one of the three criteria is met:
  1. Information obtained is not identifiable
  2. Disclosure outside of the research would not put subjects at risk of harm
  3. Information obtained can be identifiable but the IRB has done a limited IRB review in keeping with 46.111(a)(7) which relates to there being adequate provisions for protecting privacy and maintaining confidentiality



Limited IRB review is only sometimes an option with this category.

Category 2, continued

- The Final Rule revised this category to include visual or auditory recording as research methods.
  - *Surveys also cannot be combined or paired with collection of biospecimens or interventions, as those additional activities would disqualify the research from this category.*
- When the research is subject to Subpart D and includes children, Category 2 still does not allow:
  - *Surveys*
  - *Interviews*
  - *Investigator participating in the activities being observed (public behavior observation without intervention is permitted)*

Category 3: Benign Behavioral Interventions in Conjunction with the Collection of Information From Adult Subjects

- This is a new category (the pre-2018 Category 3 was eliminated).
- This exemption is only for benign behavioral research with adults, and is not applicable to children.

An example provided is having subjects solve puzzles under various noise conditions.

Benign behavioral interventions are defined as "brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing" (HHS 2017).

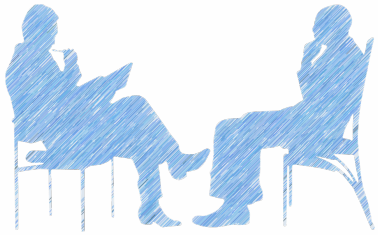
Category 3, continued

- Exemption is permitted if the data are recorded in such a way that the identity of the subjects cannot be readily ascertained either directly or indirectly or if the subjects' identities can be ascertained, a disclosure of the responses outside the research setting would not reasonably place the subjects at risk of harm.
- Alternatively, if the subjects' identities can readily be ascertained and if a disclosure of subjects' responses has potential to harm subjects, the exemption is permitted if the IRB conducts a limited review and determines that there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

Limited IRB review is only sometimes an option with this category.

Category 3 and Deception

- Research using deception is not eligible for exemption in this category unless the subjects prospectively agree that they will be unaware of or misled regarding the nature and purpose of the research.
  - *Deception is allowed if certain criteria are met.*



Category 4: Secondary Research for Which Consent is Not Required

- The Final Rule revised this category.
- Covers secondary research uses of identifiable private information or identifiable biospecimens.
- Category 4 does not require informed consent if certain criteria are met.
- It is important to note that data do not need to be existing ("on the shelf") at the time of the research study, as was previously required by the pre-2018 rule. The data can be collected prospectively and still be used for exempt research under Category 4 in the Final Rule.

Category 5: Research and Demonstration Projects that Are Conducted or Supported by a Federal Department or Agency

- The Final Rule revised this category to allow research supported by a federal agency (not just conducted) to:
  - *Qualify for this exemption.*
  - *Provide examples of the types of public benefit and service programs covered by the exemption.*
  - *Clarify the federal components for which the exempt research is subject to approval (for example, delegated subordinate agencies).*

Category 6: Taste and Food Quality Evaluation and Consumer Acceptance Studies

- This is the only unchanged category.

Category 7: Storage or Maintenance for Secondary Use for Which Broad Consent is Required

Limited IRB review is always required for this category.

- This is a new category.
- This category is for the storage of identifiable biospecimens and identifiable private information, prior to secondary analysis.
- The storage and maintenance may be exempt if the IRB conducts a limited IRB review to determine that there are adequate provisions to protect the privacy of subjects and maintain the confidentiality of data, and if broad consent is obtained.

Category 8: Secondary Research for Which Broad Consent is Required

Limited IRB review is always required for this category.

Category 8 also requires that the investigator does not include returning individual research results to subjects as part of the study plan; however, the exemption does not prevent investigators from returning results if required by law.

- This is a new category.
- Category 8 allows the secondary analysis of existing private identifiable data and identifiable biospecimens provided broad consent was secured and the documentation of consent was either secured or waived.
- IRBs must determine that there are adequate provisions to protect the privacy of subjects and maintain the confidentiality of data as noted in 46.111(a)(7), and that the use is within the scope of the broad consent.

Exempt Research and Subpart B Applicability

- Final Rule consistent with the pre-2018 rule.
- Each of the exemptions can be applied to research that is subject to Subpart B.

Exempt Research and Subpart C Applicability

- The 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.
- The Final Rule 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.
- The Final Rule also allows subjects to continue in exempt research if they become prisoners during a study.

Exempt research now allowed to incidentally include prisoners (research not seeking to examine prisoners as subpopulation).

Exempt Research and Subpart D Applicability

- The 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 investigator does not participate in the activities being observed.
- Consistent with pre-2018 rule, surveying and interview procedures with children may not be exempt.

Final Rule allows research with children to be exempt for categories 1, 4, 5, 6, 7, and 8.

Reference

- U.S. Department of Health and Human Services (HHS). 2017. "Federal Policy for the Protection of Human Subjects." *Federal Register* 82(12):7149-274.
- U.S. Department of Health and Human Services (HHS). 2018. "Federal Policy for the Protection of Human Subjects: Six Month Delay of the General Compliance Date of Revisions While Allowing the Use of Three Burden-Reducing Provisions During the Delay Period." Federal Register 83(118):28497-520.