Overview of the Common Rule Changes Affecting Minimal Risk Research

View this presentation to learn about Final Rule Impact on Minimal Risk Research.

Quick overview for Exemption updates:

- All but one category was revised
- New categories were added
- Two new processes were introduced with the new categories.
  - Limited IRB review: performed in some categories to determine that there are adequate provisions to protect the privacy of subjects and maintain the confidentiality of data.
  - Broad consent: used under new categories 7 & 8

Definitions:

- **Research**: has been expanded to list activities that are specifically deemed **not to be research**:
  - Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism)
  - Public health surveillance activities (e.g., required or authorized by a public health authority)
  - Collection and analysis of information, biospecimens, or records by or for a criminal justice agency (for activities authorized by law or court order solely for criminal justice or criminal investigative purposes)
  - Authorized operational activities (e.g. homeland security, defense, or other national security missions)
- **Human Subject:** For clarification, now references "information and biospecimens" (replacing "data") and adds "obtaining, using, studying, analyzing, or generating identifiable private information or identifiable biospecimens" as trigger events. Further, it clarifies that investigators may "obtain" (possess) information and biospecimens without triggering the human subject definition until they use, study, or analyze the information or biospecimens.
- **Identifiable private information/biospecimen:** Clarified to be described as a data/biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information/biospecimen.

Main changes to the minimal risk categories:

- **Collection of identifiable data now permitted in all categories, but must undergo a limited IRB review.**
- **Previous category 3 is now defined as not being considered research:** Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if:
  - (i) the human subjects are elected or appointed public officials or candidates for public office; or
  - (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
- **NEW category 3 (replacing the above):** Research involving benign interventions in conjunction with the collection of data from an **adult** subject through verbal or written responses (including data entry) or video recording if the subject prospectively agrees to the intervention and data collection. These procedures must be:
  - brief in duration
  - harmless
  - painless
  - not physically invasive
  - not likely to have a significant adverse lasting impact on the subjects
  - investigator has no reason to think the subjects will find the interventions offensive or embarrassing.
  - **Examples include:** which a subject is asked to read materials, review pictures or videos, play online games, solve puzzles, or perform cognitive tasks.
- **Previous Category 4**: Research involving the collection or study of ***existing*** data, documents, records, pathological specimens, or diagnostic specimens if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
  - **NEW Category 4**: ***Prospective*** collection is now permitted.
- **NEW categories 7 & 8:**

- **Category 7 (tissue banking)**: Allows storage and maintenance of identifiable private information and biospecimens for potential secondary research for which consent (or broad consent) is required.
- **Category 8 :** Allows use of identifiable private information and biospecimens for potential secondary research; for which broad consent is required, and all of the following are met:
    1. Broad consent previously obtained (specific to storage and maintenance for secondary uses)
    2. Documentation of informed consent or received waiver of documentation
    3. Study plan does not indicate plan to return individual results to participants; unless legal requirements are in place which require