New Rule Summary of Changes

• Effective January 19, 2018 (but that still could change)
• Consent forms will now require a concise summary of study activities, risks, and benefits presented to research participants in advance of the body of the consent document.
• Updates to the Exempt Categories:
  o (1) Research, conducted in established or commonly accepted educational settings
    ▪ NEW: A new ineligibility criterion will be added to this interaction/intervention exemption for research that involves possible "adverse effects" on student learning of the required education content and/or on the assessment of educators.
  o (2) Research that only includes interactions involving educational tests, survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) of adults.
    ▪ NEW: The scope will be expanded to include the collection of sensitive and identifiable data. However, the following is not allowed:
      • Interventions
      • The collection of biospecimens
  o NEW CATEGORY: (3) Research involving benign behavioral interventions with adult subjects if the subjects prospectively agrees to the intervention and information collection.
    ▪ Benign behavioral interventions are 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.
    ▪ The research may not involve deception.
  o (4) Secondary research uses of identifiable private information or identifiable biospecimens
    ▪ NEW: Prospective data review
  o (5) Research and demonstration projects that are conducted or supported by a Federal department or agency
    ▪ NEW: A new eligibility criterion for this interaction/intervention exemption will be that the project must be published on a federal website.
  o (6) Taste and food quality evaluation and consumer acceptance studies
    ▪ NO CHANGES
  o New Exempt research will be given a 3 year approval period
• Limited IRB Review
  o Exempt 2 (surveys/interviews) and Exempt 3 (benign behavioral interventions) where disclosure of the subjects’ responses outside the research reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, educational advancement, or reputation requires a “limited IRB review” of the confidentiality measures
• Continuing review requirements: Will no longer be requiring subject counts for minimal risk research