Exemption Category Changes

Exemption 1 - EDUCATIONAL EXEMPTION

What’s New: A new ineligibility criterion has been added for research that involves possible "adverse effects" on student learning of the required education content and/or on the assessment of educators.

Exemption 2 - SURVEYS, INTERVIEWS, EDUCATIONAL TESTS, AND OBSERVATION OF PUBLIC BEHAVIOR

What’s New: The scope will be expanded to include the collection of sensitive and identifiable data, excluding research involving:

i. Interventions
ii. The collection of biospecimens
iii. Linking to additional personally-identifiable data
iv. Research with children (except for educational tests or some public observation)

Exemption 3 (New) - BENIGN BEHAVIORAL INTERVENTION (link to FAQs)

What’s New: This new exemption permits data collection via an interaction (e.g., survey, interview, audio/visual recording) from adult subjects with prospective agreement, excluding research involving:

i. Research with children
ii. Deception, unless prior agreement obtained
iii. Physiological data collection methods (e.g., EEG; wearable devices; FitBitTM; blood pressure monitors)
iv. Linking to additional personally-identifiable data

Exemption 4 - SECONDARY RESEARCH (IDENTIFIABLE PRIVATE INFORMATION/BIOSPECIMENS)

What’s New: The scope of this exemption will be expanded to allow:

i. Prospective data review
ii. Maintenance of identifiers, if all study data is protected health information (PHI)*
iii. Research that is conducted by, or on behalf of, a Federal department/agency or using government-generated or government-collected information obtained for non-research activities

*Research must comply with HIPAA Privacy Protections. For most projects regulated under the Common Rule, you generally may only use or disclose PHI in connection with research after the potential subject has given written authorization.