

## Final Rule new list of Exempt categories

All research activities in a study protocol must meet one or more of the Exempt category criteria from the list to be determined 'Exempt'.

If one of the research activities in a study protocol meet the criteria for an Expedited activity or is determined to be more than minimal risk (Full Board), then the study is put in the category of highest risk.

### (§ 11.104(d)(1))

Research conducted in established or commonly accepted educational settings that specifically involves normal educational practices, so long as the research is not likely to adversely affect students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of, or the comparison among, instructional techniques, curricula, or classroom management methods.

### (§11.104(d)(2))

Research That Includes Only Interactions Involving Educational Tests (Cognitive, Diagnostic, Aptitude, Achievement), Survey Procedures, Interview Procedures, or Observation of Public Behavior (Including Visual or Auditory Recording), If at Least **One** of Three Criteria Is Met:

- (i) The information obtained is recorded by the investigator in such a manner that the identity of the human subject cannot readily be ascertained, directly or through identifiers linked to the subjects;
- (ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; **or**
- (iii) The information obtained is recorded by the investigator in such a manner that the identity of human subjects can readily be ascertained, directly or through identifiers linked to the subjects, **and an IRB conducts a limited IRB review** to make the determination required by § 11.111(a)(7) (which relate to there being adequate provisions for protecting privacy and maintaining confidentiality).

### (§11.104(d)(3)(i))

Research Involving Benign Behavioral Interventions in Conjunction With the Collection of Information From an Adult Subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least **one** of the following is met:

- (A) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects;
- (B) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; **or**

(C ) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subject, **and an IRB conducts a limited IRB review** to make the determination required by § 11.111(a)(7).

(ii)the term “benign interventions,” the word “behavioral” has been inserted to modify the type of intervention which may be included. The intent of this change is to exclude the use of medical interventions (including medical tests, procedures and devices)

For the purpose of this provision, the exemption describes benign behavioral interventions as being 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.

(iii)**Deception:** If the research involves deceiving the subjects about the nature or purposes of the research, this exemption would not be applicable unless the subject authorizes the deception. For the purpose of this provision, authorized deception would be prospective agreement by the subject to participate in research where the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

**(§ 11.104(d)(4))**

Secondary Research uses of identifiable private information or identifiable bio-specimens when consent is not required, if at least **one** of the following criteria is met:

- (i) The identifiable private information or identifiable bio-specimens are publicly available;
- (ii) The information is recorded by the investigator in such a way that the identity of subjects cannot readily be ascertained, and the investigator does not contact subjects or try to re-identify subjects;
- (iii) The secondary research activity is regulated under HIPAA; or
- (iv)The secondary research activity is conducted by or on behalf of a federal entity and involves the use of federally generated non-research information provided that the original collection was subject to specific federal privacy protections and continues to be protected.

**(§ 11.104(d)(5))**

Research and Demonstration Projects Conducted or Supported by a Federal Department or Agency

**(§ 11.104(d)(6))**

Taste and Food Quality Evaluation and Consumer Acceptance Studies

- (i) If wholesome foods without additives are consumed, or
- (ii) If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture

#### **II.104(d)(7),**

Exemption for the **Storage or Maintenance** for Secondary Use of Identifiable Private Information or Identifiable Bio-specimens for Which Broad Consent is Required:  
Storage or maintenance of identifiable private information or identifiable bio-specimens for potential secondary research use if an **IRB conducts a limited IRB review** and makes the determinations required by §II.111(a)(8).

#### **§II.104(d)(8)**

Exemption for Research Involving the **Use** of Identifiable Private Information or Identifiable Bio-specimens for Which Broad Consent is Required:

Research involving the use of identifiable private information or identifiable bio-specimens for secondary research use, if the following criteria are met:

- (i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable bio-specimens was obtained in accordance with §II.116(a)(1) through (4), (a)(6), and (d);
- (ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with §II.117;
- (iii) **An IRB conducts a limited IRB review** and makes the determination required by §II.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; **and**
- (iv) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.