

Exemption Criteria (45 CFR 46.101)

Revised Human Subjects Regulations (Common Rule) Wednesday, June 20th 2018

The regulations that human subjects researchers must adhere to (referred to as the Common Rule Regulations) were established in 1991. In 2011, federal agencies began the long-awaited process to revise these regulations and, on January 18, 2017, the **final revisions to the Common Rule** (Final Rule) were posted in the federal register. The effective and implementation dates have recently changed. As posted in the federal register on June 18, 2018, the revised final Common Rule is both effective and to be implemented on January 21, 2019 with the option of implementing 3 burden-reducing provisions before January 21, 2019.

To qualify for exemption, all of the project activity must qualify in one or more categories listed in the federal definition column. To qualify for a category, a project must meet the criteria in the conditions column. **Contact the**

Federal Definition

Category 1

Research conducted in established or commonly accepted education settings; and the research specifically involves normal educational practices that are not likely to adversely impact required educational content or the assessment of educators who provide instructions. §45CFR46.104(d)(1)

Category 2

Research [not involving children as participants] that only includes 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 the following is met: (i) 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; or (ii) Any disclosure of the
lace the subjects at risk of criminal or
reputation; or (iii) None of the above are true, but all of the following are true: There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data. §45CFR46.104(d)(2)

Category 3

Benign Behavioral Interventions (BBI) (brief in duration; harmless; painless; not physically invasive, not likely to have a significant adverse lasting impact on the subjects): Research involving BBI in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audio visual recording if the subject prospectively agrees to the intervention and information collection AND at least one of the following criteria 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

standing, employability, educational advancement, or reputation; or (C) None of the above are true, but all of the following are true: There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data. AND one of the following is true: The research does not involve deceiving subjects regarding the nature or purposes of the research; or (iii) The research involves deception, but subjects authorize the use of deception through a prospective agreement to participate in research in circumstances in which they are informed that they are unaware of or misled regarding the nature or purposes of the research.
§45CFR46.104(d)(3)

Category 4

Secondary Use of Identifiable Private Information or Identifiable Biospecimens: The research involves secondary uses of identifiable private information or identifiable biospecimens if at least one of the following is true: (ii) Information, which may include information about biospecimens, 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 subject [AND] the investigator does not contact the subjects, AND the investigator will not re-identify subjects; or (iii) The research involves only information collection and analysis involving the

lth care

Federal dept or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C.. 552a, and if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq. §45CFR46.104(d)(4)

Category 5

Federal Research or Demonstration Project: The research involves a research or demonstration project conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs; AND The Federal department or agency conducting or supporting the research has published that the research falls under this provision. §45CFR46.104(d)(5)

Category 6

Taste and Food Quality: The research involves taste and food quality evaluation and consumer acceptance studies, if one of the following are true: (i) Wholesome foods without additives are consumed; or (ii) 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. §45CFR46.104(d)(6)

Category 7

(TU