Exemption Categories

The Code of Federal Regulations identifies several different categories of minimal risk research as being exempt from the Common Rule, 45 CFR, Part 46.

Pursuant to Northeastern University (NU) policy, investigators do not make their own determination as to whether a research study qualifies for an exemption. The Office for Human Subject Research Protection (HSRP) provides oversight and communicates exempt determinations to the investigator(s). Exempt applications must receive the exempt determination before any research commences.

Category #1: Research conducted in established or commonly accepted educational settings that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes:

(i) most research on regular and special education instructional strategies,
(ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods

Category #2: Research 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 criteria 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 indirectly through identifiers linked to the subjects; OR
(ii) Any disclosure of 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 the human subjects can readily be ascertained, directly or indirectly through identifiers linked to the subject, and an IRB conducts a limited IRB review to make the determination requested by §46.111(a)(7).

Category 3: 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 criteria 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 indirectly, through identifiers linked to the subjects; OR

(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 the Human Subjects can readily be ascertained, directly or indirectly through identifiers linked to the subjects, AND an IRB conducts limited IRB review to make the determination requested by §46.111(a)(7).

Category 4: Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

(i) The identifiable private information or identifiable biospecimens are publicly available; OR

(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 subjects, 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 investigator's use of identifiable health information is regulated by HIPAA "health care operations" or "research" or "public health activities and purposes"

(iv) The research is conducted by, or on behalf of, a federal department or agency using government-generated or government-collected information obtained for non-research activities.

Category 5: Research and demonstration projects which are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of 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:

(i) public benefit or service programs, including procedures for obtaining benefits or services under those programs,

(ii) possible changes in or alternatives to those programs or procedures, or

(iii) possible changes in methods or levels of payment for benefits or services under those programs.

Category 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 Dept. of Agriculture.

Although the HHS IRB regulations list eight exemption categories, NU has opted to implement six of those categories at this time