

UNIVERSITY OF MAINE AT FORT KENT

HUMAN SUBJECT RESEARCH

FEDERAL EXEMPTION CATEGORIES UNDER 45 CRF 46.101 (In Part)

Institution judges whether exemptions will be honored.

Research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from these regulations unless research is covered by other sub parts of this part:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:
 - A. Research on regular and special education instructional strategies, or
 - B. Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), if information taken from these sources is recorded in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
3. Research involving or interview procedures except where all of the following conditions exist:
 - A. Responses are recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects,
 - B. The subject's responses, if they become known outside the research, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's own behavior, such as illegal conduct, drug use, sexual behavior, or use of alcohol.

All research involving survey or interview procedures is exempt, without exception, when the respondents are elected or appointed public officials or candidates for public office.

4. Research involving the observation (including observation by participants) of public behavior, except where all of the following conditions exist:
 - A. Observations are recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects,
 - B. The observations recorded about the individual, if they become known outside the research, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability, and
 - C. The research deals with sensitive aspects of the subject's own behavior such as illegal conduct, drug use, sexual behavior, or use of alcohol.

5. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

6. Unless specifically required by statute and except to the extent specified in (A), research and demonstration projects which are conducted by or subject to the approval of the Department of Health and Human Services, and which are designed to study, evaluate or otherwise examine:
 - A. Programs under the Social Security Act, or other public benefit or service programs;
 - B. Procedures for obtaining benefits or services under those programs;
 - C. Possible changes in or alternatives to those programs or procedures; or
 - D. Possible changes in methods or levels of payment for benefits or services under those programs.