

# Exempt Categories of Research

## Category 1

Research conducted in established or commonly accepted educational settings, involving normal educational practices such as: 1) research on regular and special education instructional strategies or 2) research on the effectiveness of or the comparison among instructional techniques, curricula or classroom management methods.

## Category 2

Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior unless:

- a. The information taken from these sources is recorded in such a manner that subjects can be identified, directly or through identifiers linked to the subjects; and
- b. Any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

## Category 3

Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior IF the human subjects are elected or appointed public officials or candidates for public office.

## Category 4

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.

## Category 5

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: 1) public benefit or service programs; 2) procedures for obtaining benefits or services under those programs; 3) possible changes in or alternatives to those programs or procedures; or 4) possible changes in methods or levels of payment for benefits or services under those programs.

## Category 6

Taste and good quality evaluations and consumer acceptance studies, if wholesome foods without additives are consumed or 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 FDA or approved by the EPA/USDA.

### *Applicability*

- A. *Research that (1) involves no more than minimal risk (Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests) and (2) only involves human subjects (or materials of human origin) in one or more of the following categories.*
- B. *Category 2 cannot be used for research involving children, except for use of educational tests (cognitive, diagnostic, aptitude, achievement) or research involving observations of public behavior when the investigator(s) do not participate in the activities being observed. Children are defined in the HHS regulations as "persons who have not yet attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted."*
- C. *Categories 1 – 6 cannot be used for classified research or research involving prisoners.*
- D. *Categories 1 – 5 cannot be used for research to which FDA regulations and policies apply.*