EXEMPTION CATEGORIES from 45 CFR 46.101(b)

E*xcept for research exempted or waived under §46.101(b)* or (i), no human subjects may be involved in any project supported by these awards until the project has been reviewed and approved by the IRB, as provided in this policy, and certification submitted by the institution, to the department or agency.

The exemptions at 45 CFR part 46.101(b) do not apply to research targeting prisoners, fetuses, pregnant women, or human in vitro fertilization, subparts B. and C.

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

Note: Commonly accepted educational settings can be broadly interpreted to include places such as nature camps, museums and zoos.

Note: Normal educational practices include online activities.

"Such as" indicates an example and not a requirement.

2) Research involving the use of **educational tests** (cognitive, diagnostic, aptitude, achievement), **survey procedures, interview procedures or observation of public behavior**, unless:
   i) Information obtained is recorded in such manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
   ii) 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.

This exemption cannot be used for children IF use of subpart D is a requirement unless it only involves observations of public behavior when the investigators do not participate in the activities being observed.

Agencies and institutions that have not accepted the subpart D, special regulations for children, may allow use of this exemption for children.

3) Research involving the use of **educational tests** (cognitive, diagnostic, aptitude, achievement), survey procedures or observation of public behavior that is not exempt under paragraph (b)(2) of this section if:
   i) The human subjects are elected or appointed public officials or candidates for public office; or
   ii) federal statutes(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

4) Research, involving the collection or study of ***existing***[1] **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.

Note: Existing is interpreted by OHRP as "on the shelf" at the time the request is made to the IRB. It is possible to interpret "existing" more broadly if DHHS funding is not involved.

Note: coded records may be found to have no human subjects and, thus, not even need an exemption.

5) Research and demonstration projects which are **conducted by or subject to the approval of department or agency heads**, and which are designed to study, evaluate, or otherwise examine:

i) Public benefit or service programs;

ii) procedures for obtaining benefits or services under those program;

iii) possible changes in or alternatives t those programs or procedures; or

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

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 hat contains a food ingredient at or below the level found to be safe, by the food and Drug Administrator or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

This is the ONLY exemption also allowed by FDA under 21 CFR 56.