Exemption Applications

Two copies of the IRC Exemption form (Form 4-13), signed by the applicant, should be submitted to IRC. The procedures must fit easily into an exemption category.

An exemption simply means that the application fit the criteria under the appropriate regulation. Informed consent, consideration of subject rights, privacy and other issues are not reviewed and may be appropriate.

EXEMPTION CATEGORIES

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 involving prisoners, fetuses, pregnant women, or human in vitro fertilization, subparts B. and C.

COMMON RULE 45 CFR 46

For all federally funded studies

46.101(b) Unless otherwise required by department or agency heads, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from this policy:

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.
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.

   The exemption at 45 CFR part 46.101(b)(2) for research involving survey or interview procedures or observation of public behavior, does not apply to research with children, subpart D, except for research involving observations of public behavior when the investigators do not participate in the activities being observed.
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.

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.

[1] Existing is defined as already collected and "on the shelf" when the application is submitted.

FOOD AND DRUG ADMINISTRATION

§ 56.104 Exemptions from IRB requirements: The following categories of clinical investigations are exempt from the requirements of this part for IRB review:

a) Any investigation which commenced before July 27, 1981, and was subject to requirements for IRB review under FDA regulation before that date, provided that the investigate remains subject to review of an IRB which meets the FDA requirements in effect before July 27, 1981.

b) Any investigation commenced before July 27, 1981 and was not otherwise subject to requirements for IRB review under Food and Drug Administration before that date.

c) **Emergency use of a test article, provided that such emergency use is reported to the IRB within 5 working days. Any subsequent use of the test article at t the institution is subject to IRB review.**

d) Taste and food quality evaluations and consumer acceptance studies, if

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.