

 JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH	Human Research Protection Program Policies & Procedures	
	Identification	Page 1 of 2
Title: Review of New Applications	Date Effective 11/05/04	Supercedes P&P dated 6/16/04

Exempt Review

An exempt classification is only given to minimal risk research in one of the categories listed below. If the research falls into one of these categories, but is determined to be more than minimal risk, it may not be classified as exempt.

- (1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular or special educational instructional strategies, or (ii) research on the effectiveness of, or the comparison among, instructional techniques, curricula, or classroom management methods. (45 CFR 46.101(b)(1)).
- (2) Research involving (a) educational tests, (b) survey or interview procedures or (c) observation of public behavior, unless: (i) information obtained is recorded in such a 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 subject's financial standing, employability, or reputation. (45 CFR 46.101(b)(2)).
NOTE: When observation of public behavior includes children it can qualify as exempt research only if the investigator does not participate in the activities being observed. When research involving educational tests, or survey or interview procedures, includes children it cannot qualify as exempt research.
- (3) Research involving the use of education tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under category (2) above, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter. (45 CFR 46.101(b)(3)).
- (4a) Research involving the study of existing data, documents, records, pathological specimens, or diagnostic specimens, if the sources are publicly available. *Note: This item concerns publicly available data that contain identifiers or can be linked to specific individuals. "Existing" means that the data, documents, records or specimens were collected prior to submission of the research application.*

- (4b) Research involving the study of existing data, documents, records, pathological specimens, or diagnostic specimens, if the information, although initially containing identifiers, is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. (45 CFR 46.101(b)(4))
Note: This item concerns research on existing data, whether publicly available or not,, that has been recorded by the investigator in a manner that does not allow individual subjects to be identified or linkage to individual subjects to be reestablished. If these data, documents, records or specimens can be linked to specific individuals by any person, the research does not qualify as exempt research. Research on existing data, whether publicly available or not, that do not contain identifiers and cannot be linked to personal identifiers is not human research and does not require review by CHR.
- (5) Research and demonstration projects that 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 alternative to those programs or procedures; or (iv) possible changes in methods or levels of payments for benefits or services under those programs. (45 CFR 46.101(b)(5)).
According to the OHRP, this category applies only to Social Security benefit programs, procedures for obtaining benefits under those program, or possible changes in these programs.
- (6) Taste and food quality evaluation and consumer studies, if (i) wholesome food without additives are consumed, or (ii) 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 U.S. Department of Agriculture. (45 CFR 46.101(b)(6)).

CHR does not conduct annual reviews of exempt research projects, but may, at its discretion, request periodic status reports. The investigator must notify CHR of any changes in the research plan that might affect the Committee's initial determination of exempt status. If, for example, analysis of an existing anonymized data set was initially classified as exempt, but the investigator now wishes to include analysis of an identifiable dataset, CHR must be notified and the change cannot be initiated without its prior approval.

Investigators conducting exempt research are bound to adhere to the ethical obligations outlined in the Belmont Report and 45 CFR 46. Informed consent must be obtained from all subjects regardless of the federal requirement, unless waived by CHR. Consent documents must be submitted with the CHR application for Certification of Exempt Status Research.