

IRB Policy #:	230
Policy Title:	<i>Exempt Research</i>
Date Approved:	
Date Reviewed:	

Purpose: To describe the exempt research category.

Policy:

Federal human subjects protection regulations define the following six categories of human subjects research as exempt (45 CFR 46.101(b)). All six categories apply to children, category 2 with a caveat. *Children* are defined as persons who have not attained the legal age for consent to procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.

Category 1: Research conducted in established or commonly accepted educational settings, involving normal education 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. *This category applies to children and allows exemption for research studies that involve evaluation of normal educational practices conducted in commonly accepted educational settings. Children, as well as adults, may be subjects of such studies. Commonly accepted settings are not limited to schools. A car may be a commonly accepted setting for a driver education program. A clinic may be a commonly accepted setting for a medical student or resident education program. A repair facility may be a commonly accepted setting for a technician education program. PIs must provide evidence that the educational practices to be studied are frequently used educational practices carried out in a place where such practices are commonly accepted for this exempt category to apply.*

Category 2: Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior unless: (a) information obtained is recorded in such a manner that human subjects can be identified directly or indirectly 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. *This category is applicable to children; however, for research involving survey or interview procedures or observations of public behavior, the exemption does not apply except for research involving observation of public behavior when the investigator(s) do not participate in*

the activities being observed.

Category 3: Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview 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 statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

Category 4: Research involving the collection or study of existing data, documents, records, pathological specimen, 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 department or agency heads, and which are designed to study, evaluate, or otherwise examine: (a) public benefit or service programs; (b) possible changes in or alternatives to those programs or procedures; or (c) possible changes in methods or levels of compensation or inducement for benefits or services under those programs.

Category 6: Taste and food quality evaluation and consumer acceptance studies, (a) if wholesome foods without additives are consumed or (b) 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 Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the US Department of Agriculture.

If the investigator makes any substantive changes to the project which might change its designation, he or she must notify the IRB who will determine whether the research is still exempt or must receive additional review.

Exempt research is subject to continuing review every three years.