**Exempt Research Categories**

The Department of Health and Human Services (HHS) and FDA regulations identify categories of research that are exempt. Exempt activities are those activities that are research involving human subjects, but meet criteria that exempt them from the full requirements of 45 CFR 46.  A list of six categories that are eligible for exemption as contained in 45 CFR 46.101(b) is given below. The ethical principles of study conduct still apply. Even though the research may be "exempt," at DeSales the determination of exemption must be made by the IRB. Exempt projects are different from Expedited or Full Board review in that they are not assigned an expiration date, do not have to undergo continuing review and are able to be modified in most cases without IRB approval.

In order to qualify for exemption, a research study must fall entirely within one or more of the six categories for exemption, and it cannot place subjects at greater than minimal risk. If the research involves prisoners, then it does not qualify for exemption from federal regulations and IRB review.

**Category 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 of or the comparison among instructional techniques, curricula, or classroom management methods.

Examples:

•Evaluating a new curriculum or delivery methodology

•A program evaluation of a continuing education workshop

**Category 2**

Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observations of public behavior unless: (i) information obtained is recorded in such a manner that human participants can be identified, directly or through identifiers linked to the participants; and (ii) any disclosure of the human participants' responses outside the research could reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, or reputation.

Notes about involving minors:

•Minors may be included when research will involve the use of educational tests (cognitive, diagnostic, aptitude, achievement) or when the investigator will observe public behavior but does not participate in that behavior or activity.

•Minors may not be included when research will involve the use of survey procedures, interview procedures, or observation of public behavior when investigators will be involved in the activity.

Examples:

•Conducting a quality of life survey

•Conducting a focus group about an experience or program

•Interviewing physicians about patient management practices

•Observing elementary children playground interactions, as long as the investigator has no involvement or does not manipulate the environment in any way

**Category 3**

Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observations of public behavior that is not exempt under #2 of this section, if: (i) the human participants 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.

Example:

•Interviewing public officials to determine opinions about new legislation

•Comparing public speaking strategies and techniques of state legislators

**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 participants cannot be identified, directly or through identifiers linked to the participants.

Note: Existing data means the items exist [are 'on the shelf'] before the research was proposed or were collected for any purpose prior to the research beginning.

Example:

•Analyzing tissue samples previously collected and stored, as long as the data are recorded without identifiers

•Comparing medical records of patients, as long as the data are all previously collected and recorded by the investigator without identifiers

**Category 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 programs; (iii) possible changes in or alternatives to those programs or procedures; (iv) possible changes in methods or levels of payment for benefits or services under those programs.

**Category 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 that contains a food ingredient at or below the level 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.