

**DECATUR MEMORIAL HOSPITAL
INSTITUTIONAL REVIEW BOARD**

SUBJECT: RESEARCH EXEMPT FROM IRB REVIEW

STANDARD: PATIENT RIGHTS AND ORGANIZATION ETHICS

EFFECTIVE: 4/08

POLICY:

Research activities in which the only involvement of human participants will be in one or more specific categories, which are listed below, may be exempt from IRB review. Determination of exemption must be based on regulatory and institutional criteria, and must be documented.

Specific Policies

Exempt Research Activities

Research activities in which the only involvement of human participants will be in one or more of the following categories are exempt from IRB review:

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,
 - ii. Research on the effectiveness of 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 a manner that human participants can be identified, directly or through identifiers, linked to the participants; and
 - ii. Any disclosure of the human participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, or reputation.
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, 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.
4. Research involving the collection 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.
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 programs;
 - iii. Possible changes in or alternatives to 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 acceptable 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 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 FDA or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

APPLICABLE TO:

These policies and procedures apply to all Investigator claims for exemption from IRB review.

RESPONSIBILITY:

The IRB Administrator is responsible for evaluating submissions that claim exemption from IRB review.

The IRB Co-Chair is responsible for providing his expertise in the review of claims of exemption.

APPROVED BY:

President and CEO