

**ST. VINCENT HOSPITAL RESEARCH & REGULATORY AFFAIRS
EXEMPT RESEARCH CATEGORIES FORM**

DIRECTIONS: This form is to be neatly typed and submitted to the IRB only when the investigator is contemplating the initiation of a research project which, in the investigator's judgment, is exempt from normal IRB review. The IRB will then determine whether the activity is covered by these regulations.

IRB Study Number:: Research Proposal Title::

Research activities are exempt from regulations for the protection of human research subjects when the **ONLY** involvement of human subjects falls within one or more of the categories below. **These exemptions do not apply to research involving prisoners, fetuses, pregnant women, human in vitro fertilization, or when there is additional involvement of human subjects beyond the categories listed below, when deception of subjects may be an element of the research, or when the activity might expose the subject to discomfort or harassment beyond levels encountered in daily life. The exemption of categories 2 or 3 below of exempt research does not apply when individuals under the age of 18 are subjects of the activity, except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed.**

Effective April 14, 2003, the Health Insurance Portability and Accountability Act (HIPAA) now clarifies policies and procedures relating to de-identification of health information. Considerations for research that is exempt must qualify based on previous regulations (45CFR46) as well as HIPAA regulations when protected health information is used.

Check the appropriate category(ies) that applies to your research project:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special educational instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. [45CFR46.101(b)(1)]

2. This category applies only when the information gathered about the individual does NOT pertain to his/her health. Otherwise, see #3 below.

Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless the following two conditions exist: (i) information obtained is recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the 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. For more details, see the 2nd list of categories below (#3). [45CFR46.101(b)(2)]

3. This category applies when the information gathered about the individual pertains to his/her health.

Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior as long as the subjects cannot be identified, directly or through identifiers linked to the subjects. (See the list of identifiers under 7.d. below for details). [45CFR46.101(b)(2)]

4. All research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey or interview procedures or observation of public behavior that is not exempt under categories 2 or 3 above, (i) if 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. [45CFR46.101(b)(3)]

5. Research and demonstration projects which are conducted by or subject to the approval of Department of Health and Human Services (DHHS), 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. [45CFR46.101(b)(5)]. The research or demonstration project must be conducted pursuant to specific federal statutory authority, must have no statutory requirement that an IRB review the project, and must not involve significant physical invasions or intrusions upon the privacy of the subjects.

IRB Study Number:
Research Proposal Title:

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 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. [45CFR46.101(b)(6)]
7. 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 subjects cannot be identified, directly or through identifiers linked to the subjects. [Note: *To qualify for this exemption ALL of the data, documents, records, or specimens must be in existence before the project begins*]. In addition, indicate which of the following apply(ies): [45CFR46.101(b)(4)]
- a. The data, documents, or records do NOT include health information.
- b. The existing data, documents, records, pathological specimens, or diagnostic specimens utilized were obtained by written legal permission prior to April 14, 2003 (e.g. through an informed consent, a waiver of informed consent, or other expressed written legal permission).
Please define:
- c. The health information pertains only to decedents.
- d. The health information is de-identified. (Note: to qualify for this exemption, either all identifiers must be removed or sufficient number of identifiers removed to be statistically de-identified. See the list of eighteen identifiers below or the Use and Disclosure of Health Information for Research Standard Operating Procedures for details.)
- De-identified data must have the following data removed:
- Name
 - All geographic subdivisions smaller than a state, including street address, city, county, precinct, zip codes if the geographic unit of combining all the same three initial digits contains more than 20,000 people
 - All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated in a single category of age 90 or older.
 - Telephone numbers
 - Fax numbers
 - Electronic mail addresses
 - Social security numbers
 - Medical record numbers
 - Health plan beneficiary numbers
 - Account numbers
 - Certificate/license numbers
 - Vehicle identifiers and serial numbers, including license plate numbers
 - Device identifiers and serial numbers
 - Web universal resource locators (URLs)
 - Internet protocol (IP) address numbers
 - Biometric identifiers, including finger and voice prints
 - Full face photographic images and any comparable images; and
 - Any other unique identifying number, character, or code.

If, after having completed the Exempt Research Checklist, the investigator still believes the study qualifies as exempt research, complete the rest of this page and submit the original to:

St. Vincent Research & Regulatory Affairs Department
8402 Harcourt Road, Suite 208
Indianapolis, IN 46260

Note that the study cannot be initiated until written acceptance for the IRB is given.

PLEASE ALLOW 5-10 WORKING DAYS FOR EXEMPT REVIEW PROCESSING.

SECTION I: INVESTIGATOR INFORMATION

Principal Investigator: _____ **Department:** _____
(Last, First, Middle Initial)

Address: _____ Phone: _____ E-Mail: _____

Contact Person: _____ Phone: _____ E-Mail: _____

If this is a Student Research Proposal, List Name of the Student: _____ Phone: _____

Research Proposal Title:

IRB Study Number:

Sponsor/Funding Agency: _____ PI on Grant: _____

Sponsor Proposal #/Grant #: _____ Period: From: _____ to _____

Sponsor Type: Federal; State; Industry Not-for-Profit Unfunded; Internally Funded

Grant Title (if different from research proposal title): _____

SECTION II: RESEARCH DESCRIPTION

Describe the general purpose, nature, and duration of the study, providing a description of the proposed research objectives and procedures below (in lay terms). Attach a copy of any research instruments (e.g. survey, questionnaire, interview guide).

Signature of Principal Investigator: _____ **Date:** _____

SECTION III: EXEMPT REVIEW DETERMINATION

Accepted

Denied

Authorized IRB Printed Name: _____

Authorized IRB Signature: _____ **Date:** _____