

**UNIVERSITY OF TENNESSEE HEALTH SCIENCE CENTER
INSTITUTIONAL REVIEW BOARD
EXEMPTION FROM IRB REVIEW: DETERMINATION**

I. PURPOSE

To document the procedures used by University of Tennessee Health Science Center Institutional Review Board to review and evaluate submissions for exempt status.

II. SCOPE

This SOP applies to the IRB Chairperson or designee.

III. BACKGROUND

Federal regulations provide for exemption from IRB oversight for certain kinds of research involving minimal risk. OHRP policy guidance requires that the determination that a study qualifies for exempt status be made by an entity other than the investigator. UTHSC IRB policy requires that the determination of whether a study qualifies for exempt status must be made by the Chairman or other senior member of the IRB. This determination is made through submission and review of Form 5, "Application for Exemption". Once a study has been determined to qualify for exempt status, no further oversight of the IRB is normally necessary. However, if revisions are made to a study originally approved for exempt status, then the IRB must determine that the study remains eligible for exempt status.

In Accordance With:

45CFR46.101(b) & 102(d) and (f).

OHRP Guidance on Exemptions for Research on Public Benefit and Service Programs located at <http://www.hhs.gov/ohrp/humansubjects/guidance/exmpt-pb.htm>.

Compliance with this policy also requires compliance with state or local laws or regulations that provide additional protections for human subjects.

IV. PROCEDURES

1. Unless otherwise required by Department or agency heads, research activities in which the only involvement of human subjects will be in one or more of the following categories will be assigned the status of exempt from further oversight by the UTHSC IRB:

- a. 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, curricular, or classroom management methods.
- b. 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 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 civil or criminal liability, or be damaging to the subjects' financial standing, employability or reputation.
 - c. 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 (b) 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.
 - d. 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.
 - e. Research and demonstration projects, which are conducted by or subject to the approval of the 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.
 - f. Systematic investigations that do not involve "research" as defined at 45CFR46.102(d).
 - g. Research that does not involve "human subjects" as defined at 45CFR46.102(f).
2. Upon receipt of an Application for Exemption (Form 5):
- a. The IRB Director or designee will assign an IRB number to the application.
 - b. The Form 1 application is forwarded to the electronic queue of an IRB analyst for determination of whether the application may qualify for exempt status.

3. If the study may qualify for exempt status, the Chairman or other senior member of the IRB is assigned the responsibility for reviewing the application.
4. The Chairman or other senior IRB member will review the application and consent documents according to applicable ethical principles, federal regulations and local IRB policies, and will complete the reviewer's form and make a determination of whether the study qualifies for exempt status.
5. The IRB Director or designee will prepare any correspondence for the investigator regarding the review and give it to the Chairman for electronic review and signature.
6. The correspondence regarding the results of the review is sent electronically to the applicant and is also retained in the study file.