UNIVERSITY OF TENNESSEE GRADUATE SCHOOL OF MEDICINE
INSTITUTIONAL REVIEW BOARD
EXEMPT DETERMINATION

I. PURPOSE

To document the procedures used by University of Tennessee Graduate School of Medicine Institutional Review Board Sections (UTGSM IRB) to review and evaluate submissions for exempt status.

II. SCOPE

This SOP applies to the IRB Chairperson, IRB Assistant Director or designee.

III. BACKGROUND

Federal regulations provide for exemption from IRB oversight for certain kinds of research meeting specific conditions. OHRP policy guidance requires that the determination that a study qualifies for exempt status be made by an entity other than the investigator. UTGSM IRB policy requires that the determination of whether a study qualifies for exempt status be made by the Chairperson or their designee. This determination is made through submission and review of the "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 the study as originally approved for exempt status, then the IRB must determine that the study remains eligible for exempt status.

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 are exempt from further IRB oversight:

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, curricular, 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:
   a. information obtained is recorded in such a manner that human subjects can be identified, directly or 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 civil or criminal liability, or be damaging to the subjects' 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 under #2 if:
   a. the human subjects are elected or appointed public officials or candidates for public office; or,
   b. 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 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.

5. Research and demonstration projects, which are conducted by or subject to the approval of federal department or agency heads, and which are designed to study, evaluate, or otherwise examine:
   a. public benefit or service programs;
   b. procedures for obtaining benefits or services under those programs;
   c. possible changes in or alternatives to those programs or procedures; or
   d. possible changes in methods or levels of payment for benefits or services under those programs.

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.

7. Systematic investigations that do not involve research as defined at 45 CFR 46.102(d).

8. Research that does not involve “human subjects” as defined at 45 CFR 46.102(f).

In Accordance With:

45 CFR 46.101(b) & 102(d) and (f)

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

IV. PROCEDURES

1. Upon receipt of an Application for Exemption, the IRB Assistant Director or designee will:
    a. Review the application for completeness and accuracy.
    b. Assign IRB Study Number

2. The Chairperson or the Chair's designee will review the documents and make a determination of exempt status.

3. If applicable, the Chairperson will consult with the UTMC Natural Medicine Formulary Subcommittee if the research falls under Category 6.

4. The IRB Assistant Director or designee will prepare and send any necessary correspondence for the investigator regarding the review.

5. At the discretion of the IRB, an annual summary of research may be required in some exempt studies.

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