IRB Policy 7: IRB Exempt Review

I. Summary Policy

The policy of both the East Tennessee State University Campus Institutional Review Board (ETSU IRB) and the East Tennessee State University/Veterans Affairs Institutional Review Board (ETSU/VA) IRB is to review human subjects research activities under its jurisdiction to determine whether the research meets one or more of the exemption categories described in the Federal Regulations (45 CFR 46.101(b)(1)-(6)), and additionally for the ETSU/VA IRB, the VHA Handbook 1200.5).

II. Determination of Exempt Status

In each instance, the investigator will make the initial request for exempt status and the IRB Chair will make the final determination. If the research is submitted by the IRB Chair, for non-VA studies, either the Vice Chair or the Vice Provost for Research at East Tennessee State University will review this determination. For VA studies, the Vice Chair will review this determination.

Neither the Chair nor the Vice Chair may review for approval research studies submitted for exempt or expedited review from their respective departments or divisions (for larger departments). For non-VA studies, in the absence of the Chair or Vice Chair, the Vice Provost for Research, will review the determination. For VA studies, the exemption status must be approved by the IRB Chair or an experienced IRB member designed by the Chair. If upon this review the determination of exemption is not upheld, the investigator will be informed and provided with the reasons for denial of exemption. The protocol will then be submitted for either expedited or full review, as appropriate to the level of risk, by the IRB.

The institution retains the option under the assurance to not claim the options provided for exempt status, but instead choose to require IRB review. If the Chair identifies ethical concerns in the research submitted for exemption, the study will not be exempted. Documentation for all exemptions will include citation of the specific category justifying the exemption and include enough information in the records to justify the exemption.

III. Categories
Only studies that meet the six specific categories of exempt activities as delineated by HHS Regulations 45 CFR 46 (101) (b) are eligible to be given exempt status.

NOTE: These categories do not apply to prisoners and categories 1-5 do not apply to FDA regulated research.

The six categories are:

(1) 45 CFR 46.101 (b)(1): Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as
   a. research on regular and special education instructional strategies, or
   b. research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) 45 CFR 46.101 (b)(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 criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation or insurability.

For 45 CFR 46 (101) (b)(2), the exemption for research involving survey or interview procedures or observations of public behavior DOES NOT apply to research covered by 45 CFR Part 46, Subpart D (Additional DHHS Protections for Children Involved as Subjects in Research), except for research involving observation of public behavior where the investigators do not participate in the activities being observed.

(3) 45 CFR 46.101(b)(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 45 CFR 46.101(b)(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) 45 CFR 46.101(b)(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 subjects cannot be identified, directly or through identifiers linked to the subjects.

To qualify for the above 45 CFR 46 (101) (b) category 4 exemption, data, documents, records or specimens must already exist at the time the research is proposed.

(5) 45 CFR 46.101(b)(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:
  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.

To qualify for Exemption 5 for Public Benefit Projects, which is for projects conducted by or subject to approval of federal agencies, the following criteria must be satisfied:

✓ The program under study must deliver a public benefit (e.g., financial or medical benefits as provided under the Social Security Act) or service (e.g., social, supportive or nutrition services as provided under the Older Americans Act)
✓ The research or demonstration project must be conducted pursuant to specific federal statutory authority
✓ There must be no statutory requirement that the project be reviewed by an IRB
✓ The project must not involve significant physical invasions or intrusions upon the privacy of participants
✓ Authorization or concurrence by funding agency

For VA studies, the determination of exempt status for research and demonstration projects meeting the criteria in this category must be made by the Under Secretary for Health on behalf of the Secretary of VA, after consultation with Office of Research and Development (ORD), Office of Research Oversight (ORO), Office of General Counsel (OGC), and other experts, as appropriate.

(6) 45 CFR 46.101(b)(6) and 21 CFR 56.104(d): Taste and food quality evaluation and consumer acceptance studies,
  a. if wholesome foods without additives are consumed or
  b. 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

IRB Policy 7 Exempt Review
the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the US Department of Agriculture.

IV. Ethical Standards

Studies submitted requesting exempt status will be reviewed by the Chair or Vice Chair to determine whether the research fulfills the organization’s ethical standards. The standards are as follows:

1. The research holds out no more than minimal risk to the participants.
2. The selection of participants is equitable.
3. If the study includes recording of identifiable information, there are adequate provisions to maintain the confidentiality of the data.
4. *When appropriate, if the study includes interactions with participants, there must be a consent process that discloses such information as:
   a. that the activity involves research
   b. a description of the procedures
   c. that participation is voluntary
   d. the name and contact information for the investigator

*When appropriate: always applies unless the IRB Chair determines that this requirement is not applicable. The IRB Chair may determine that this requirement is not applicable if both of the following criteria are true:
   a. that omission of this requirement will not adversely affect the rights and welfare of the participants
   And
   b. that the research could not practicably be carried out without omitting this requirement

5. The research has adequate provisions to maintain the privacy interests of participants.

If the Chair or Vice Chair identifies ethical concerns in the research submitted for exemption, the study will not be exempted.

V. Modifications

Any proposed changes to an exempt study must be submitted to the IRB for review and approval prior to implementation. (refer to modification policy)

V. Applicable Standards
Research that is determined to be exempt from IRB review is not exempt from protection of human subjects. All exempt research is subject to human subject protections and ethical standards.

VI. **Confidentiality**

Studies that meet exempt criteria may still be subject to the Privacy Act. Refer to Policy 14 for information regarding HIPAA.

References:
45 CFR 46. 101(b)  
45 CFR 46.401(b)  
OHRP Compliance Activities: Common Findings and Guidance- 7/10/02  
45 CFR 46.301(a)  
21 CFR 56.104  
VHA Handbook 1200.05 Appendix A.