IRB Policy 7: IRB Exempt Review
Revision Date February 16, 2008, revision October 7, 2009, revised January 27, 2011, revised January 3, 2014, revised February 9, 2015, revised April 2, 2018, revised January 24, 2019, revised Feb 7, 2019

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, 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). The exemption status must be approved by the IRB Chair or Vice-Chair, or an experienced IRB member designated 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.

In addition, for studies subject to the 2018 Common Rule, the IRB will conduct a limited review of the research as required.

III. Categories

Under the 1991 Common Rule:

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 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.

For studies subject to the 2018 Common Rule:

Only research activities in which the only involvement of human subjects will be in one or more of the six specific categories of exempt activities as delineated by HHS Regulations 45 CFR 46 (104) (d) are eligible to be given exempt status. ETSU has determined to not allow exemptions under category 7 or 8.

Categories 1-5 and 7-8 do not apply to FDA-regulated research.

Subpart B (pregnant women, fetuses and neonates): Each of the exemptions at this section may be applied to research subject to subpart B if the conditions of the exemption are met.

Subpart C (prisoners): The exemptions at this section do not apply to research subject to subpart C, except for research aimed at involving a broader subject population that only incidentally includes prisoners.

Subpart D (children): The exemptions at paragraphs (d)(1), (4), (5), (6), (7- not allowed at ETSU), and (8- not allowed at ETSU) of this section may be applied to research subject to subpart D if the conditions of the exemption are met. Paragraphs (d)(2)(i) and (ii) of this section only may apply to research subject to subpart D involving educational tests or the observation of public behavior when the investigator(s) do not participate in the activities being observed. Paragraph (d)(2)(iii) of this section may not be applied to research subject to subpart D.

Transnational: Laws and regulations in some countries do not allow exemptions. If the research is not eligible for an exemption under the laws of that country, even though the research may be covered by DHHS regulations, ETSU will not allow an exemption for research.

<u>The six categories are</u>**<u>:</u>**

1. Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

The exemption at Category 1 may be applied may be applied to research with children (research subject to subpart D) if the conditions of the exemption are met

2. Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

(i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

(iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by § (insert reference)__.111(a)(7)

Children (research subject to Part D):
Paragraphs (d)(2)(i) and (ii) of this section only may apply to research subject to subpart D involving educational tests or the observation of public behavior when the investigator(s) do not participate in the activities being observed. Paragraph (d)(2)(iii) of this section may not be applied to research subject to subpart D.

(3)(i) Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

(A) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(B) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be

damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

(C) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by § (insert reference)_.111(a)(7).

(ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

(iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

Benign behavioral interventions are:
• Brief in duration.
• Harmless
• Painless
• Not physically invasive
• Not likely to have a significant adverse lasting impact on the participants.
• The researcher has no reason to think the subjects will find the interventions offensive or embarrassing

(4) Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

(i) The identifiable private information or identifiable biospecimens are publicly available;

(ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

(iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of “health care operations” or “research” as those terms are defined at 45 CFR 164.501 or for “public health activities and purposes” as described under 45 CFR 164.512(b); or

(iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

(5) Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

(i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

For VA studies, the determination of exempt status for research and demonstration projects meeting the criteria for exempt category 5 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 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 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. Limited IRB Review

For studies subject to the 2018 Common Rule: Limited IRB review is a new requirement created under the revised DHHS regulations, and is unique to DHHS regulations. Limited IRB review will not be conducted by staff, but by a member of the IRB (IRB Chair or Vice-Chair or an experienced IRB member designated by the IRB Chair).

Research that requires limited review is as follows:

Category 2
• Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) where:
• The information obtained is recorded by the researcher in such a manner that the identity of human participants can be readily ascertained, directly or through identifiers linked to the participants and any disclosure of the human subjects' responses outside the research would reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation

The IRB must determine there are adequate provisions to protect the privacy interests of research participants and the confidentiality of identifiable date.

Category 3
• Research involving benign behavioral interventions in conjunction with the collection of information from adult participants through verbal or

written responses (including data entry) or audiovisual recording if the participant prospectively agrees to the intervention and where:

• The information obtained is recorded by the researcher in such a manner that the identity of human participants can be readily ascertained, directly or through identifiers linked to the participants. (§___.104(3)(i)(C)) and any disclosure of the human subjects' responses outside the research would reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation

For VA studies, exempt categories 2 and 3 require use of a limited IRB review if the information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects. The IRB is required to conduct a limited review to make the determinations.

The IRB must determine there are adequate provisions to protect the privacy interests of research participants and the confidentiality of identifiable data.

ETSU does not exempt research under categories 7 and 8.

a. Eligible research for limited review must be deemed to be no more than minimal risk.

If an IRB or EC member reviewing the research finds that research is greater than minimal risk, the reviewer must document the rationale for this determination and the rationale for review by the convened IRB or EC.

a. A complete new protocol submission xform with all relevant attachments (including but not limited to the proposed consent and all recruitment materials) must be submitted for an exempt determination, to include limited review as indicated.
b. IRB members conducting limited IRB review may not disapprove research.
c. When conducting limited IRB review, the IRB reviewer is responsible for making this determination: for exemption Categories 2 and 3, that there are adequate protections for privacy interests of participants and the confidentiality of identifiable data. If this criteria is not met, the study may not be issued an exempt determination/approval.
d. Exempt research under limited IRB review must still meet ETSU’s ethical standards (see following section)
e. Continuing review is not required for studies that qualify for a limited review.
f. ETSU retains the authority to suspend or terminate IRB approval of research approved with a limited review.

V. 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
    e. for studies subject to limited review, information about risk of loss of confidentiality

*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.

For VA studies: For exempt research activities involving the Investigator interacting with human subjects or obtaining information by educational tests, survey or interview procedures, or behavioral interventions, the following information must be given to the prospective human subject as applicable in writing or orally: (1) The activity is research; (2) Participation is voluntary; (3) Permission to participate can be withdrawn; (4) Permission for use of data can be withdrawn for exempt research activities involving the collection and use of identifiable data; and (5) Contact information for the VA Investigator.

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
45 CFR 46.401
OHRP Compliance Activities: Common Findings and Guidance- 7/10/02
45 CFR 46.301(a)
21 CFR 56.104
VHA Directive 1200.05