IRB Policy 7: 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, revised Oct 22, 2020, revised March 2, 2021

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 below, and if so, whether the research complies with applicable ethical standards. Researchers do not have the authority to make an independent determination that research involving human subjects is exempt and must obtain determination of exemption prior to beginning the research.

II. Determination of Exempt Status

For proposed research, the investigator provides the ETSU IRB study specific information by completing the New Protocol Submission xform and providing the required attachments. In each instance, the IRB Chair, or designee, will make the final determination regarding exempt status. 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 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, Vice-Chair, or an experienced IRB member designated by the Chair. The IRB Chair, or designee, may consult appropriate IRB members or others if additional expertise is needed to support the determination. If the reviewer determines that the study is not eligible for exemption, the protocol will be considered for either expedited or full board review, as appropriate. Reviewers may make the exemption determination, HIPAA privacy determination, request clarifications/ modifications, or refer the project for other appropriate level of review.

The IRB retains the option 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 may 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. Ethical 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. When considering studies for exempt status, the reviewer will determine whether the research fulfills the organization's ethical standards. The standards are as follows:

1. The research must present 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. The research has adequate provisions to maintain the privacy of participants.
5. The research is consistent with the ethical principles established by the Belmont Report.
6. *When appropriate, there is an agreement to participate that discloses adequate information for participants to make a voluntary decision regarding whether to participate in the research. This may include:
    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.

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.

IV. Exempt Categories

To receive an exempt determination, a protocol must satisfy the criteria under one or more of the following exemption categories.

Category 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.

“Commonly accepted settings” usually involve schools but also includes nonacademic settings where education of patients, professionals, clients or other populations is commonly conducted. Participation in research should not be a required part of the curricula. Students should be able to refuse participation without penalty.

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) 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.

Category 3
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:

(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.

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.

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.

Category 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 160 and 164, subparts A and E, for the purposes of “health care operations” or “research” as 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.

Category 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;
- 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.

For VA studies, the determination of exempt status 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.

Category 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 FDA or approved by the EPA or USDA.

V. Limitations for Exemptions

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 described above are eligible for exempt status. Category 7 and Category 8 as described at 45 CFR 46.104(d) have not been adopted as categories of research eligible for exemption by ETSU.

The following specific limitations must also be considered when determining whether a protocol is eligible for exemption:

- Categories 1-5 and 7-8 do not apply to FDA-regulated research.
- Prisoners: Exemptions do not apply, except for research aimed at involving a broader subject population that only incidentally includes prisoners, does not involve interaction with prisoners (including obtaining consent), and is not federally funded.
- Children: Exemptions do apply, except for Category 2, which is permitted only if the project involves educational tests or the observations of public behavior when the investigator does not participate in the activities being observed, and Category 3. Research involving children cannot be exempt under Category 2 if the research involves survey or interview procedures, or involves recording identifiable data requiring limited IRB review.
- Other vulnerable populations: Each of the exemptions may apply to research involving subjects who are economically/educationally disadvantaged, cognitively impaired, pregnant women, fetuses, if the conditions of the exemption are met.
- 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, ETSU will not allow an exemption for the research.

VI. Limited IRB Review

When the exemption requires the IRB conduct a limited IRB review, an IRB member must review and grant the exemption and determine there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data. As described in Section II of this policy, exempt categories 2 and 3 require 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.

Eligible research for limited review must be deemed to be no more than minimal risk. If the reviewer finds that the proposed research is greater than minimal risk, the reviewer must document the rationale for this determination and the rationale for review by the convened IRB, and the research would not be eligible for exemption. IRB members conducting limited IRB review may not disapprove research but can refer the proposed study for review by the convened IRB.

ETSU retains the authority to suspend or terminate IRB approval of research approved with limited IRB review.

VII. Subsequent Review

Continuing review is not required for studies that qualify for exemption status or that undergo limited IRB review. The IRB may require studies eligible for exemption to submit an annual administrative check-in xform to ascertain the status of ongoing research. Refer to Continuing Review policy.

Any proposed changes to an exempt study must be submitted to the IRB for review and approval prior to implementation. The changes are reviewed to ensure that they do not affect the exempt status of the research. Refer to modification policy.

References:

45 CFR 46.101, 401, 301(a)
OHRP Compliance Activities: Common Findings and Guidance, 7/10/02
21 CFR 56.104
VHA Directive 1200.05