Western Carolina University
Office of Research Administration
Institutional Review Board Standard Operating Procedures

SOP# 203.2	TITLE: Exempt and Limited IRB Review	Date Effective: 01/01/2022 Last Revision Date: 12/06/2022

I. Purpose

This sets forth the process for the determining whether a project meets the criteria for exempt determination and conducting limited review, if applicable.

II. Definitions

Certain categories of research described in the federal regulations are exempt from full board review and approval. However, exempt research is subject to institutional review by an individual reviewer and required to comply with the ethical principles outlined in the *Belmont Report*, including informed consent.

Projects may be determined exempt if the only involvement of human subjects in a study meets one or more of the following criteria 45 CFR § 46.104:

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 assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies as well as, research on the effectiveness or comparison among instructional techniques, curricula, or classroom management methods.

2. Research that includes only interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observations 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 responses outside the research would not reasonably place the subject at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; OR
    iii) The information 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 (as required at § 46.111(a)(7)) that there are adequate provisions to protect the privacy of subjects and maintain the confidentiality of data.

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 responses outside the research would not reasonably place the subject at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement or reputation; OR
iii. The information 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 (as required at 46.111(a)(7)) that there are adequate provisions to protect the privacy of subjects and maintain the confidentiality of data.

For the purposes of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing.

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.

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, 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.

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, EPA or USDA.

WCU is not currently implementing exemptions listed at 46.104(d)(7) and 46.104(d)(8) regarding storage and conduct of research where broad consent is required.

Projects that involve FDA regulated articles are only eligible for exempt category 6.

Research must also meet the following institutional criteria:
1. Research must present no more than minimal risk to participants
2. Projects that involve direct interaction with participants must
   - Adequately inform participants about the research project and obtain informed consent;
   - Use methods that will minimize coercion or undue influence in recruitment; and
   - Include provisions to protect the privacy and confidentiality of participants

Research not eligible for exemption include:
1. Projects involving prisoners as subjects
2. Projects involving the use of surveys, interview procedures, observations of public behavior, or benign behavioral interventions where participants are minors
3. Research involving deception, unless participants are prospectively notified that they are not being informed about the full purpose of the research

III. Procedure

Submission and Screening

1. Investigators must submit a *Request for Initial Review of Research* in InfoEd.

2. The research compliance office receives the package in InfoEd. The project is reviewed for completeness. The research compliance office will conduct a preliminary assessment to determine which review category is most appropriate for the project.

Assigning Reviewers

Qualified IRB members or research compliance office members may conduct exempt reviews.

IRB Exempt Determination

1. The exempt reviewer will be assigned the project in InfoEd by the research compliance office and all materials will be shared.
2. The reviewer will conduct an in-depth review to determine that all research procedures fit into one or more the exempt categories and meet all institutional requirements for exempt research.

3. The reviewer may request additional information to determine exempt status or may require modifications to the project before granting exemption. If the project requires modifications, the reviewer will reroute the submission in InfoEd back to the Investigator, and request specified modifications.

IRB Limited Review for Exemptions 2 & 3

1. Projects that meet the exemption criteria at 46.104(d)(2)(iii) and 46.104(d)(3)(i)(c) must undergo limited IRB review, conducted by an IRB member, to ensure the research plan makes adequate provisions to protect the privacy of subjects and maintain the confidentiality of data as described in 46.111(a)(7).
2. If the initial exempt review is conducted by IRB staff and is then determined to require limited IRB review, the IRB staff will share the project with an IRB member to finalize the review.
3. Once a project meets all the requirements of the exemption category, the reviewer will reroute the submission to the research compliance office with their approval. The research compliance office will issue a letter from InfoEd documenting the specific exemption category.
4. No expiration date will apply to submissions receiving exempt or limited exempt review determinations.
5. If the reviewer determines that the study does not qualify for exemption, then the review will proceed as outlined in SOP 204 - Expedited Research.
6. Exempt research is not subject to annual continuing review and it is the responsibility of the investigator to close the study when research is complete by emailing the research compliance office, who will change the status of the project in InfoEd to 'closed.'
7. Modifications to exempt projects must be submitted to the IRB, prior to implementation, to ensure the study continues to meet the exempt criteria.

IV. Responsibilities

Research compliance office, IRB members, Investigators

V. References

45 CFR §§ 46.104, 46.111
21 CFR § 56.104