Appalachian State University Research Protections and Institutional Review Board Standard Operating Procedures		
SOP #9 Rev. 2	Exempt Human Subjects Research	Date Effective:
Approved by IRB Chair	RBCrandy	Date 10/07/2021
Approved by RP Director	DA Paxton	Date 10.6.2021

I. PURPOSE

To describe policies and procedures for determining which human subjects research activities are considered exempt from IRB review and approval.

II. AUTHORITY

In accordance with federal regulations 45 CFR 46.104 and Appalachian State Policy 209 item 4.4.1, human subjects research that qualifies for exemption may be determined to be exempt from IRB review.

III. RESPONSIBILITY

1. Research personnel are responsible for requesting and obtaining an exemption determination prior to initiating exempt human subject research. Research personnel are also responsible for ensuring that research procedures are conducted in accordance with the ethical obligations to human participants as articulated in **The Belmont Report** and in disciplinary codes of professional conduct. Depending on the circumstances, researchers performing exempt research may be required to make provisions to obtain informed consent, protect confidentiality, minimize risks, and discuss problems or complaints with Research Protections (RP) staff.

2. RP staff is responsible for conducting exempt reviews, for requesting clarifications or changes to protocols that may qualify for exemption, and for providing official exempt determinations. The IRB Chair also reserves the right to determine that a study is exempt from IRB review.

3. A qualified IRB member (including, but not limited to, the RP Director or other RP Staff members) is responsible for conducting Limited IRB Reviews.

IV. DEFINITION OF EXEMPTION

Exempt research is human subjects research. Studies that are minimal risk and qualify for one or more exemption categories as stated in 45 CFR 46.104 may be considered exempt from the regulations and from IRB review.

- Studies that are subject to subpart C (research specifically involving prisoners) cannot be exempt.

- Studies that are subject to subpart D (research involving children) may not be allowable under certain exemption categories.
- Studies employing deception without prior authorization by participants cannot be exempt under exemption category 3.
- Studies subject to FDA oversight cannot be exempt.
- Certain studies which qualify for exemption may, at the discretion of RP staff, be required to undergo the expedited review and approval process.
- Studies that are exempt from IRB review and approval may still have other regulatory requirements that must be met, e.g. HIPAA or FERPA requirements.

V. PROCEDURES

1. Research personnel complete a Request for Initial Review in the Electronic Research Administration (eRA) system and mark the Request for Exemption section accordingly.
    a. A complete request may include, but is not limited to, the following:
        - The appropriate IRB application;
        - Copies of any recruiting materials or scripts;
        - Copies of informed consent documents and any relevant assent forms;
        - Uploaded copies and/or sufficiently detailed descriptions of all data collection instruments (e.g. surveys, interview questions);
        - Qualification of investigators (e.g. experience in the specific research area, certifications), if applicable and not currently on record with RP staff;
        - A Faculty Advisor (FA) if research is led by a student PI;
        - The Sponsored Projects number of any associated grant or contract; and
        - Disclosure of any Conflicts of Interest related to the proposed research.
    b. RP Staff is responsible for determining that a Request for Exemption is complete and whether the described study qualifies for exemption, using procedures from SOP #2.
    c. If the Request for Exemption is unclear, internally inconsistent, and/or missing pertinent information, RP staff may ask the investigator to amend the study documents and/or the IRB application.
    d. RP staff, the IRB Chair, or designee, are authorized to make the final determination whether the proposed research qualifies for exemption.
2. If the research qualifies for exemption, RP staff marks the study as exempt in the eRA system. The exempt determination is valid for the entirety of the research unless a change to the research is proposed that requires additional review.
    a. If the research does qualify for exemption, RP staff notifies the PI, and any research personnel designated to receive correspondence. Research personnel are responsible for revising the application as requested by RP staff and submitting the revisions for IRB review.

b. If the research qualifies for exemption after a Limited IRB Review, follow the procedures outlined in the Limited IRB Review section of this SOP.

3. External collaborators not affiliated with Appalachian State:
    a. External collaborators are responsible for securing all needed approvals and/or permissions from their sheltering institution(s) prior to conducting research procedures with human subjects. Appalachian State University does not provide oversight for collaborators who are affiliated with an external IRB. Collaborators with no affiliated IRB must complete an Individual Investigator Agreement, as described in SOP #2, before conducting any human subjects research procedures for projects under Appalachian State University oversight.
    b. If an external collaborator is affiliated with an IRB which requires that an Institutional Authorization Agreement (IAA) or other official reliance arrangement be in place, those requirements will be met within reason and as possible as described in SOP #2.
4. Requirement for Informed Consent:
    a. Studies exempt from 45 CFR 46 are not required to comply with the consent elements outlined in sections _.116 and _.117. However, it is best practice to provide some level of summary of the proposed research and receive acknowledgement from participants that they agree to be in the research.
    b. Studies subject to Limited Review may have a requirement for consent.
    c. Studies requiring additional regulatory oversight (e.g., HIPAA compliance, etc.) may have a requirement for consent.
    d. RP staff and/or the IRB Chair may require, at their discretion, that the exempt consent process be reviewed and modified, if needed, prior to providing an exempt determination for the project.
5. Closing Studies: Research personnel are responsible for informing RP staff when all human subject research associated with the study is complete, or when the principal investigator is no longer currently affiliated with Appalachian State University.

VI. LIMITED IRB REVIEW

1. Certain categories of exemption require a limited IRB review to ensure that adequate provisions are in place to protect the privacy of subjects and maintain confidentiality of data.
    a. RP staff determines whether a limited review is required.
2. Limited review must be performed by an authorized IRB member.
3. For exempt research subject to limited IRB review, the following criteria shall be applied:
    a. For exempt categories 2(iii) and 3(iii) (See Section 3.2), the IRB may approve the research when it determines that there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

b. For exempt category 7, the IRB may approve the research when it determines that the following criteria are satisfied:
    i. Broad consent for storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens is or was obtained in accordance with the requirements of 45 CFR 46.116(a)(1) - (4), (a)(6), and (d),
    ii. Broad consent is appropriately documented or waiver of documentation is appropriate, in accordance with 45 CFR 46.117, and
    iii. If there is a change made for research purposes in the way the identifiable private information or identifiable biospecimens are stored or maintained, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

4. Once limited review is complete and limited review approval has been granted, RP staff may issue an exempt determination for the study.

VII. POST EXEMPTION CHANGES REQUIRING REVIEW

1. Proposed changes to an exempted study require review if the change affects:
    i. The funding source,
    ii. The potential for a conflict of interest,
    iii. The contact information for the PI, or
    iv. The determination of exemption. Examples of changes which may affect the determination of exemption include, but are not limited to:
        i. Changes to subject population;
        ii. Changes to educational research with minors that extend beyond 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;
        iii. Proposed new research activities involving more than minimal risk, are not included in exempt categories (e.g., blood draws), or are subject to FDA regulations;
        iv. New knowledge is obtained which increases the risk level of the research;
        v. Change in the way identifying information is recorded (directly or indirectly) from existing data, documents, records, pathological specimens, or diagnostic specimens so that subjects can be identified; or
        vi. Change in the location of the research (i.e., another country, another school system, another off site location).

2. Proposed changes that require review must be submitted through the eRA system with a summary of the changes and any revised materials (e.g., consent forms, surveys, interview guide) in accordance with SOP #4. Proposed changes will be reviewed in the same manner as described in this SOP and SOP #4.
    a. Completion of IRB mandated training is verified for all newly added personnel; previously listed personnel are not required to update IRB ethics training for the purpose of a study modification, although it is a good practice that all research personnel complete the CITI refresher course before their certifications expire.

VIII. QUALIFYING FOR EXEMPTION

1. To be classified as exempt research, the research must meet the following criteria:
    a. The activities meet the HHS definition of "human subject" and "research" as defined in SOP #1.
    b. The research personnel assume responsibility for the protection of human subjects by ensuring that the research is performed with integrity and within accepted ethical standards. Exempt research must maintain compliance with the basic ethical principles for conducting human subjects research as outlined in the Belmont Report and other, pertinent regulatory requirements such as HIPAA.
    c. Unless it is not practical, basic information about the research is conveyed to subjects, which may include:
        i. a statement of the purpose of the research;
        ii. an explanation of the procedures of the study;
        iii. details of any foreseeable risks, benefits, and compensation;
        iv. a clear explanation that that participation is voluntary and that no penalty or loss of benefits to which the subject is otherwise entitled will occur should the subject either refuse to participate or decide to discontinue participation (at any time);
        v. Contact information for the principal investigator and faculty advisor if the investigator is a student.
    d. Research personnel are qualified to carry out the proposed research and have completed the required IRB training.
    e. There are adequate provisions in place to maintain data confidentiality and to protect participant privacy when applicable.
    f. All applicable local, state, university, and federal requirements have been met.
    g. The research poses minimal risks to research participants and falls under one or more of the Exempt Research Categories as outlined in 45 CFR 46.104 and described below.
2. The Exempt Research Categories as outlined in 45 CFR 46.104(d) are:

(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.

(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 §46.111(a)(7).

(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 §46.111(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.

(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.

(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) Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by §46.111(a)(8).

(8) Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:

i. Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with §46.116(a)(1) through (4), (a)(6), and (d);

ii. Documentation of informed consent or waiver of documentation of consent was obtained in accordance with §46.117;

iii. An IRB conducts a limited IRB review and makes the determination required by §46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and

iv. The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

IX. SUPPORT PROCEDURES

SOP #1 Determination of Activities that Need IRB Review
SOP #2 Requesting IRB Review
SOP #4 IRB Review of Modifications and Addendums
SOP #5 Expedited Review of Research

X. REFERENCES

45 CFR Part 46.104
ASU Policy 209
The Belmont Report (1979)