

Appalachian State University Research Protections and Institutional Review Board Standard Operating Procedures		
SOP #9 Rev. 1	Conducting Exempt and Limited Reviews	Date Effective: 1.21.2019
Approved by IRB Chair	<i>R. S. Grady</i>	Date 1/21/2019
Approved by RP Director	<i>Robin Swain</i>	Date 1/21/2019

### PURPOSE

To describe policies and procedures for determining what human research activities are considered exempt from IRB review and approval, how to conduct a Limited IRB Review, and the review process for exempt research.

### GENERAL DESCRIPTION

In accordance with federal regulations and institutional policy, human subject research that meet the Criteria for Exemption, or are approved for exemption after a Limited IRB Review, may be determined to be exempt from IRB review. The Principal Investigator (PI) is responsible for requesting an IRB exemption determination prior to initiating human subject research.

An exempt determination does not reduce 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 staff.

### RESPONSIBILITY

Execution of SOP: Principal Investigator (PI)/Study Personnel, Research Protections (RP) Staff, IRB Chair.

### DEFINITION OF EXEMPTION

Exempt research is human subjects research. Studies that are minimal risk and meet the criteria of one or more exemption categories as stated in 45 CFR 46.104 are considered exempt from the regulations and will not require an IRB review once exemption has been confirmed.

- 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.
- Studies subject to FDA oversight cannot be exempt.

## **PROCEDURES**

1. The PI completes a Request for Initial Review in IRB Information System (IRBIS) and marks the Request for Exemption section accordingly.
  - a. A complete request includes:
    - The appropriate IRB application
    - Copies of any recruiting materials or scripts
    - Copies of informed consent documents and any relevant assent forms,
    - All data collection instruments (e.g. surveys, interview questions),
    - Permission forms from other institutions involved in the research,
    - 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 AGrants number of any associated grant or contract
  - b. RP Staff is responsible for determining that an IRB application is complete and potentially qualifies for exemption, using procedures from SOP #2.
  - c. If it is unclear whether the study meets the Criteria for Exemption, RP staff may ask the investigator to amend the study documents to meet the Criteria for Exemption.
  - d. The Director of RP or IRB Chair, or their designees, make the final determination whether the proposed research meets the Criteria for Exemption.
2. If the research meets the Criteria for Exemption, RP staff conduct the exemption review in IRBIS. 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 not meet the Criteria for Exemption, RP staff notify the PI, and any research personnel designated to receive correspondence on the Exemption Form. The PI will revise the application in IRBIS and return to the IRB for review.
  - b. If the research meets the Criteria for Exemption after a Limited IRB Review, follow the procedures outlined below.
3. Exempt studies with collaborators not affiliated with Appalachian State will require confirmation from the nonaffiliated individual's IRB that no additional oversight is needed. Please refer to 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 parts 116 and 117. However, it is a good practice to provide

- some level of summary of the proposed research, and acknowledgement by participants to 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.
5. Closing Studies: PI are responsible for informing RP staff via email at [irb@appstate.edu](mailto:irb@appstate.edu) (referencing the Study ID number) when all human subject research associated with the study is complete, or when the researcher is no longer an Appalachian State employee or student and an alternative Appalachian State researcher has not been designated as the PI.

#### Conducting Limited IRB Review

1. Certain categories of exemption require review to ascertain that adequate provisions to protect the privacy of subjects and maintain confidentiality of data.
  - a. IRB administration determines whether limited review is required.
2. Exempt studies requiring limited review will be included in the procedures for SOP# 5, conducting expedited review.
  - a. Once limited review is complete and no further changes are needed to address provisions, the study is exempted.

#### Post-exemption Changes that Require Review

1. Proposed changes to an exempted study require review if the change affects:
  - a. The funding source,
  - b. The potential for a conflict of interest,
  - c. The contact information for the PI, or
  - d. 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 research activities involve 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

- vi. Change in 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 IRBIS with a summary of the change and any revised materials (e.g., consent forms, surveys, interview guide) in accordance with SOP#4.
3. Changes will be reviewed in the same manner as described in this SOP and SOP#2.

### **CRITERIA FOR EXEMPTION**

1. To be classified as exempt research, the research must meet the following criteria:
  1. The activities meet the DHHS definition of “human subject” and “research” as defined in SOP #1.
  2. The research follows the basic ethical principles for conducting human participant research as outlined in the Belmont Report and the PI assumes the responsibility for the protection of human participants in the research activities and ensures that the research is performed with integrity and within accepted ethical standards.
  3. Unless it is not practical, basic information about the research is conveyed to subjects, which may include:
    - a. a statement of the purpose of the research,
    - b. an explanation of the procedures of the study,
    - c. details of any foreseeable risks, benefits, and compensation;
    - d. 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).
    - e. Contact information for the investigator and faculty advisor if the investigator is a student
  4. Research personnel are qualified to carry out the proposed research and have completed the required IRB training.
  5. There are adequate provisions in place to maintain data confidentiality and to protect participant privacy when applicable.
  6. All applicable local, state and federal requirements have been met.
  7. The research poses minimal risks to research participants and falls under one or more of the Exempt Research Categories as outlined in 45 CFR 46.101 and described below.
2. The Exempt Research Categories as outlined in 45 CFR 46.101(b) 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.

## **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

## **REFERENCES**

45 CFR Part 46.104