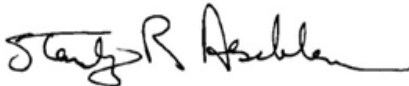



Appalachian State University Research Protections and Institutional Review Board Standard Operating Procedures		
SOP # 9 Revision #	TITLE: Exempt Review and Determination Process	Date Effective: 3/22/2013 Revision Date:
Approved By: IRB Chair	Signature 	Date: 3/20/2013
Approved By: RP Director	Signature 	Date: 3/20/2013

PURPOSE

To describe policies and procedures for determining what human research activities are considered exempt from IRB review and approval, 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 may be determined by Research Protections staff to be exempt from initial and continuing Institutional Review Board (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.

Definitions

1. *Minimal Risk*: Minimal Risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests [45 CFR 46.102(i)].
2. *Human subjects (FDA)*: An individual who is or becomes a participant in research either as a recipient of a test article or as a control or as an individual on whose specimen a device is used. A subject may be either a healthy individual or a patient [21 CFR 56.102(e)] (Drug, Food, Biologic).

RESPONSIBILITY

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

PROCEDURES

1. Research Protections (RP) staff maintain an IRB website with instructions for requesting an exempt determination of human subject research.
2. Principal Investigators (PI), or members of their research team, request IRB exemption by sending a complete request to irb@appstate.edu. A complete request includes:
 - an Exemption Request for Research with Human Participants form (Exemption form),
 - a copy of any recruiting materials or scripts,
 - a copy of an informed consent, and any relevant assent forms, if applicable
 - data collection instruments (e.g., survey, interview questions, interview guide), if applicable,
 - permission forms from other institutions involved in the research, if applicable,
 - a copy of any associated external grant or contract, and
 - the signature of the PI and faculty advisor (if the PI is a student).
3. Upon receipt of a review request, RP staff:
 - enter the request in an IRB management system,
 - acknowledge receipt of the request through an email to all research personnel designated to receive correspondence on the Exemption form,
 - confirm whether research personnel have completed any IRB mandated training,
 - confirm that the request is complete, and
 - follow procedures to determine that the activity meets the definition of human subject research.
4. If the review request is incomplete, RP staff notifies the PI (and any research personnel designated to receive correspondence on the IRB application) via email that the request is incomplete. If the request remains incomplete after 45 days, RP staff notifies the PI that the request will be withdrawn if there is no response within 7 days.
5. Generally within 7 working days, RP staff review complete requests for an exemption determination to confirm that the proposed research meets the Criteria for Exemption described below.
6. 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. The Director of RP or IRB Chair, or their designees, make the final determination whether the proposed research meets the Criteria for Exemption. RP communicates the decision of the IRB or RP staff to the investigator via phone, e-mail, or hard copy.

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7. If the research meets the Criteria for Exemption, RP staff sends an Exemption Determination Notice via email to the PI, and any research personnel designated to receive correspondence on the Exemption Form. The exempt determination is valid for the life 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, and follow SOP #2 for Initial Review.
8. Closing Studies: PI are responsible for informing RP staff via email at 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 employee or student and an alternative Appalachian researcher has not been designated as the PI.

Changes that Require Review to a Study Determined Exempt

1. Proposed changes to a study determined exempt 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 affect the determination of exemption, include, but are not limited to:
 - i. Changes to subject population to include either 1) vulnerable populations (i.e., children, prisoners, pregnant persons, or any population that may be incapable of protecting their interests through the informed consent process) or 2) minors (i.e., individuals under the age of 18) for research that does not meet exempt category 1 (educational research),
 - 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 or are subject to FDA regulations,
 - iv. New knowledge is obtained which increases the risk level of the research,
 - v. Proposed research activities include methods described in the Expedited review categories that do not meet the exempt criteria (e.g., blood draws). For information about Expedited review categories refer to SOP #5,
 - vi. 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,
 - vii. Addition of a data collection instrument, such as a survey or interview, that obtains information which is recorded so that (i) human subjects can be

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- identified, directly or through identifiers linked to the subjects; and (ii) a disclosure of the information outside the research could reasonably place the subject at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation, and
- viii. 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 sent to irb@appstate.edu with a summary of the change, proposed modifications highlighted in the Exemption Form, and any revised materials (e.g., consent forms, surveys, interview guide).
3. Changes will be reviewed in the same manner as the initial determination of exemption.

RESEARCH PERSONNEL AND TRAINING

Research personnel who 1) obtain informed consent of participants; 2) interact with participants for research purposes; or 3) have access to identifiable private information for research purposes, must be listed on the Exemption Form.

All research personnel must complete IRB-mandated training as well as any University-mandated training (e.g., Blood Borne Pathogen training) before the study will be approved or determined to be exempt. RP staff maintain instructions for IRB-mandated training on the IRB website. Deviations from the training requirements will be considered on a case by case basis with the IRB Administrator and/or IRB Chair.

SPONSORED RESEARCH

For sponsored research, RP staff:

- consult and follow any sponsor IRB review requirements,
- associate the Sponsored Program number with the IRB request for review,
- conduct a congruency analysis of the IRB request for review with any associated contract/grant, and
- add Sponsored Programs to IRB correspondence.

OFF-SITE RESEARCH, INTERNATIONAL RESEARCH, RESEARCH WITH NON-ASU ENTITIES

The term “off-site research” includes research conducted at sites that are not owned or operated by Appalachian State University (Appalachian), or at sites that do not fall under Appalachian IRB’s authority. RP staff coordinates the review of off-site research to define the responsibilities of each IRB, communicate among the responsible IRB committees, and manage information obtained in off-site research to ensure the protection of human subjects. To coordinate off-site research review, the IRB Administrator, in consultation with the Chief Research Officer and General Counsel as needed,

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considers the source of the funding, federal regulations, specific sponsor regulations, and institutional policy.

Appalachian may enter into formal agreement with other facilities, and/or personnel, which are not legal entities/employees of Appalachian to provide research review, to rely on other institutions for research review, or to cooperate in review. The IO, or designee, makes the final determination to rely on the review of another IRB and/or allow non-ASU entities/employees to rely on the oversight of the Appalachian IRB.

INSTITUTIONAL REVIEW

A research application may require institutional review in addition to IRB review (e.g., Conflict of Interest review, compliance with other University policies). The PI is responsible for informing RP staff about the need for any other institutional reviews. RP staff coordinates additional required reviews to ensure that the research is not conducted until all required reviews have been completed and approved.

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, information about the research is conveyed to subjects, including:
 - 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 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.

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2. The Exempt Research Categories as outlined in 45 CFR 46.101(b) are:
1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
 2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) 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.
 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 paragraph (b)(2) of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
 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.
 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: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) 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 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.

SUPPORT PROCEDURES AND PROCESSES

Determining Human Subject Research SOP #1

REFERENCES

21 CFR 56.102, 45 CFR 46.102