

Southeastern University Institutional Review Board Standard Operating Procedures		
Exempt Review	SOP #	RR 101
	Effective Date	1 January 2017
	Revision Date	
	Revision #	
	Approval: IRB	

1. POLICY

Southeastern University policy XXXX, Policy for the Protection of Human Subjects in Research, requires that, prior to initiation of any human subjects research related activities (i.e. prior to recruitment of subjects and data collection), all research involving human beings as subjects of research, including research with human material (e.g., pathological and diagnostic specimens) obtained from living individuals, be reviewed and approved by the IRB.

Research activities in which the only involvement of human subjects will be in one or more specific categories, which are listed in section 1.1 of this policy, may qualify for exempt status review. Determination of exempt status must be based upon regulatory and institutional criteria and the exemption decision must be documented. Determination of exempt status must be conducted by one or more of the Permanent Members (PMs), or their designee. **No investigator or department shall have the authority to make this decision.**

Exempt research must be of [minimal risk](#) to the subjects, have a sound research design, and be conducted ethically, meaning that at a minimum the principles outlined in the Belmont Report must be met. The IRB members making the exemption determination may require protections to meet these principles, including informed consent appropriate to the research, or review at a convened meeting of the IRB. No research involving, or potentially involving, prisoners as subjects may be classified as exempt under the categories listed below.

Specific Procedures

1.1 Determining Exempt Status

The following exemption categories are from Title 45, Part 46 of the Code of Federal Regulations for the Protection of Human Subjects (45 CFR 46).

1.1.1 Title 45, Code of Federal Regulations §46.101(b)(1) exempts research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:

- a. research on regular and special education instructional strategies, or
- b. research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

NOTE: *This category may be applied to research involving children.*

1.1.2 Title 45, Code of Federal Regulations §46.101(b)(2) exempts research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview

procedures, or observation of public behavior, *unless*:

- a. information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; *and*
- b. 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.

NOTE: *Research activities involving children that qualify for exempt status in this category are those involving educational tests and observation of public behavior where the investigator does not participate in the activity being observed. Research interviews or surveys with children cannot be exempt.*

1.1.3 Title 45, Code of Federal Regulations §46.101(b)(3) exempts 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 1.1.2 above, if

- a. human subjects are elected or appointed public officials or candidates for public office; *or*
- b. federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

1.1.4 Title 45, Code of Federal Regulations §46.101(b)(4) exempts 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.

NOTE: *To qualify for this exemption, the data must be in existence before the project begins. Identifiable records may be viewed, but data may only be recorded in a non-identifiable manner.*

1.1.5 Title 45, Code of Federal Regulations §46.101(b)(5) exempts research and demonstration projects that are conducted by or subject to the approval of department or agency heads, and that are designed to study, evaluate, or otherwise examine

- a. public benefit or service programs;
- b. procedures for obtaining benefits or services under those programs;
- c. possible changes in or alternatives to those programs or procedures; *or*
- d. possible changes in methods or levels of payment for benefits or services under those programs.

1.1.6 Title 45, Code of Federal Regulations §46.101(b)(6) exempts taste and food quality evaluation and consumer acceptance studies,

- a. if wholesome foods *without* additives are consumed; *or*
- b. 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 ([FDA](#)) or approved by the Environmental Protection Agency ([EPA](#)) or the Food Safety and Inspection Service of the US Department of Agriculture ([USDA](#)).

NOTE: *This category may be applied to children.*

1.2 Submission

1.2.1 The investigator makes a preliminary determination that a research application (herein after referred to as IRB application or an application) is eligible for exempt review based on the categories presented in 1.1. The IRB makes the final determination regarding whether an application qualifies for exempt status.

1.2.2 The investigator submits one copy of a completed IRB application form requesting review at the exempt level to the University IRB.

1.2.3 Upon receipt of the application form it is entered into the IRB tracking system and assigned an IRB number by the IRB Chair or Co-Chair.

1.3 Review

1.3.1 Research applications submitted by investigators who request exempt status review will be evaluated by one or more of the PMs, or their designee, who will document the exemption category for the project, if the project is deemed suitable for exemption.

1.3.2 If the protocol does not meet the criteria for exempt status review, the PM will change and initial the review designation on the application form, which will be processed for review at the appropriate level.

1.3.3 The reviewer makes one of the following determinations or recommendations by completing the IRB Review form:

Approved: The research procedures and associated documents meet the criteria for approval with no further revision needed.

Approved with Conditions: The research procedures and associated documents meet the criteria for approval with no further revision needed. However, final approval is contingent upon receiving external documentation as specified (i.e., school permissions, other committee approvals, second IRB approval documentation, etc.).

Pending Revision: Minor revisions which do not involve substantive issues must be made before the research can be approved. The investigator must submit the revisions for review.

Designated for expedited review or full board review: The reviewer determines that the application should be reviewed at a convened meeting of the IRB or via expedited review.

Disapproved: Disapproval of an application usually occurs when the risk of the proposed research outweighs any benefit expected to result from the research, or if the proposed research does not meet the federal criteria for IRB approval.

Not research involving human subjects: The proposed activity does not meeting the federal definition of research involving human subjects per 45 CFR 46.

1.3.4 When an application is placed in *Pending Revision* status, the IRB Chair or Co-Chair will document the approval status and any suggested revisions in the tracking system. The IRB Chair or Co-Chair will

generate an email to the investigator(s) transmitting the revisions requested by the IRB.

1.3.5 Investigators are responsible for submitting any requested revisions to the IRB. The IRB Chair or Co-Chair reviews the response to the request for revisions to determine if the investigator's response is appropriate. If the response is deemed appropriate, the IRB Chair or Co-Chair documents that the protocol is approved in the tracking system.

1.3.6 If the IRB Chair or Co-Chair determines that the revisions are inappropriate or insufficient, the investigator will be asked via email to make further revisions. This review and revision process will continue until the application is approved or reassigned to a different review level (e.g., expedited or full board).

1.3.7 When an application is approved with conditions, the IRB Chair or Co-Chair will generate a "conditionally approved" letter that will be sent to the investigator stipulating the documents that are needed prior to final approval. Upon receipt of the requested documentation, an approval letter will be issued as described in 1.3.8.

1.3.8 When an application is approved, the IRB Chair or Co-Chair will generate the approval letter with the IRB Chair signature and attach all recruiting, consent and debriefing documents (as applicable) with the IRB approval stamp affixed with the valid dates of IRB approval. The approval letter will state the expiration date, which will be 3 years from the date of approval. The IRB Chair or Co-Chair will send the signed approval letter and other appropriate documents to the investigator(s).

1.3.9 A report of all exempt determinations that have been approved since the previously convened meeting of the IRB will be posted to the IRB members' secure website prior to the next convened meeting of the IRB. The report will also contain lists of applications approved under expedited review procedures and continuing review procedures, as well as those applications for which modifications were approved since the previously convened meeting of the IRB.

1.3.10 The University Provost will be informed of IRB actions via email. Agendas for upcoming meetings will be posted to the IRB email account several days prior to each meeting. Minutes will be posted shortly after they have been approved by the IRB. By providing this information to the Provost, the IRB is meeting its obligation to inform the institution of its actions.

1.4 Approval Period

1.4.1 Applications reviewed and approved as exempt will not need to undergo annual review, but IRB personnel will check with the investigator 3 years after approval to determine if work with human subjects continues. If so, the study will continue to be listed as active in the IRB tracking system. The investigator must inform the IRB of any changes in the scope or design of the study prior to implementation of the changes to insure the study continues to meet exemption criteria.

1.4.2 Those investigators whose projects qualify for exemption will receive letters 60 and 30 days prior to the end of the 3 year time frame informing them of the need to apply for continuation of approval or

to notify the IRB that the application can be closed because the research has been completed. This will allow the IRB to know which research projects involving human subjects are being conducted under the auspices of the University's Federalwide Assurance.

1.5 Notification of the IRB

IRB applications that undergo exempt review are documented monthly by the IRB Chair or Co-Chair and a list is made available to all members via the IRB email and presented to the Board at the next convened meeting.

2. SCOPE

This procedure applies to research applications submitted for exempt status review.

3. RESPONSIBILITY

Investigators are responsible for making a preliminary determination that their applications are eligible for exempt status review. The IRB Chair or Co-Chair is responsible for receiving applications from investigators who are requesting exempt status review, tracking the application review, reviewing and documenting exempt status, reviewing and approving revisions, and generating correspondence. IRB Chair or Co-Chair is responsible for reviewing and documenting exempt status as needed, changing review level if appropriate, and reviewing and approving revisions.

4. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.101

5. REFERENCES TO OTHER APPLICABLE SOPS

This SOP affects all other SOPs

6. ATTACHMENTS

RR 101-A Documentation of Exemption

IRB Application # _____

This application qualifies for exempt review because it meets the conditions of the category marked below. To qualify for a category, the research must meet all of the conditions of the category.

- Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:
 - a. research on regular and special education instructional strategies, or
 - b. research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

NOTE: *This category **may** include research with children.*

- Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement) or observation of public behavior, where the researcher does not participate; and human subjects cannot be identified, directly or through identifiers linked to the subjects; *or* any disclosure of information would not be harmful to the individual's financial standing, employability, or reputation, or place at risk of criminal or civil liability.

NOTE: *This category **may** include research with children.*

- Research involving the use of survey procedures, interview procedures, or observation of public behavior, where the researcher does participate; and human subjects cannot be identified, directly or through identifiers linked to the subjects; *or* any disclosure of information would not be harmful to the individual's financial standing, employability, or reputation, or place at risk of criminal or civil liability.

NOTE: *This category **may not** include research with children.*

- Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt above, if
 - a. human subjects are elected or appointed public officials or candidates for public office; *or*
 - b. federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

- 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.

- Research and demonstration projects that are conducted by or subject to the approval of department or agency heads, and that are designed to study, evaluate, or otherwise examine
 - a. public benefit or service programs;
 - b. procedures for obtaining benefits or services under those programs;
 - c. possible changes in or alternatives to those programs or procedures; or
 - d. possible changes in methods or levels of payment for benefits or services under those programs.

- Taste and food quality evaluation and consumer acceptance studies,
 - a. if wholesome foods *without* additives are consumed; or
 - b. 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 ([FDA](#)) or approved by the Environmental Protection Agency ([EPA](#)) or the Food Safety and Inspection Service of the US Department of Agriculture ([USDA](#)).

NOTE: *This category **may** include research with children.*

Reviewer Signature

Date