1. GENERAL

Research involving human subjects may be exempt from federal regulations requiring IRB review. The Sam Houston State University Committee for the Protection of Human Subjects (PHSC) is responsible for determining whether research involving human subjects meets the criteria for exemption in accordance with applicable regulations. Investigators may not make this determination. Research that includes both exempt and non-exempt activities cannot be determined to be exempt.

2. PURPOSE

The purpose of this policy is to describe exempt research as defined by the Department of Health and Human Services (DHHS) regulations and the process by which the PHSC determines that research involving human subjects is exempt from the regulations and the requirements for IRB review.

3. DEFINITIONS

Go to the Glossary for definitions.

4. RESEARCH ELIGIBLE FOR EXEMPTION

4.01 Research that involves only activities listed in one or more of the categories specified in DHHS and/or Food and Drug Administration (FDA) regulations may be determined to be exempt.

4.02 Categories of Research That May Qualify for Exemption Under Federal Regulations-DHHS Categories of Exemption (45 CFR 46.101):

4.02.1 Research conducted in established or commonly accepted educational settings (e.g., schools, colleges, and other sites where educational activities regularly occur), 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.

4.02.2 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 participant; and

b. Any disclosure of the human subjects' responses outside the research could reasonably place the participants at risk of criminal or civil liability, or be damaging to the participants' financial standing, employability, or reputation.

Note: *The exemption above for research involving survey or interview procedures or observation of public behavior does not apply to research with children, except for research involving observations of public behavior when the investigator does not participate in the activities being observed.*

4.02.3 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 #4.02.2 above, if:

a. The human subjects are elected or appointed public officials or candidates for public office (Note: this applies to senior officials such as a mayor or school superintendent, rather than a police officer or teacher); or

b. Federal statute(s) requires(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

4.02.4 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 participants cannot be identified, directly or through identifiers linked to the participants.

4.02.5 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

d. Possible changes in methods or levels of payment for benefits or services under those programs

e. Additional requirements (all must apply):

(1) The programs under study must deliver a public benefit (e.g., financial or medical benefits as provided under the Social Security Act) or service (e.g., social, supportive, or nutrition services as provided under the Older Americans Act);

(2) The research or demonstration project must be conducted pursuant to specific federal statutory authority;

(3) There must be no statutory requirement that the project be reviewed by an IRB; and

(4) The project must not involve significant physical invasions or intrusions upon the privacy of participants.

4.02.6 Taste and food quality evaluation and consumer acceptance studies, if:

a. Wholesome foods without additives are consumed; or

b. 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.

5. RESEARCH INELIGIBLE FOR EXEMPTION

5.01 Research involving prisoners (with the exception of emergency use) may not be determined to be exempt.

5.02 Research that is subject to FDA regulations may not be determined to be exempt under DHHS exemption categories.

5.03 The exemption in DHHS regulations for research involving survey or interview procedures or observation of public behavior (Category 2) does not apply to research with children, except for research involving observations of public behavior when the investigator does not participate in the activities being observed.

5.04 Proposed research may not be greater than minimal risk to be determined exempt.

5.05 The regulatory exemption categories are not applied to proposed research (regardless of whether the research would otherwise be exempt) involving coercion, undue influence, deception, or any practice that does not uphold the ethical principles of respect for persons, beneficence, and justice as described in the Belmont Report.

6. EXEMPT DETERMINATIONS

Exempt determinations are made by the IRB Chair (or Chair's designee, typically, the ORSP's RCC) who has no direct involvement in the proposed activity. **Investigators are not permitted to make their own determinations of exemption.** Additionally, the ORSP's RCC must determine that the research meets the ethical standards described in the Belmont Report and that adequate participant protections are in place as described below.

6.01 Submission

Investigators must provide sufficient information about proposed research to determine exemption eligibility. The investigator will provide assurance that protections are provided to participants by submitting the Application for Exemption from Review by the Institutional Review Board, along with any required attachments. PHSC requirements for submission of non-exempt research

including Principal Investigator (PI) eligibility, completion of the CITI Training program, and meeting the basic requirements set forth by the Committee for the Protection of Human Subjects (PHSC), etc., also apply to exempt research.

6.02 Review

6.02.1 The criteria for exemption specified in DHHS regulations (45 CFR 46.101) are applied.

6.02.2 In addition to applying the applicable exemption criteria, the IRB Chair (or Chair's designee) will make the following additional determinations (as applicable) to ensure protection of potential participants:

a. The research involves no more than minimal risk

b. Selection of subjects is equitable

c. When identifiable information is to be recorded, there are adequate provisions to maintain the confidentiality of data

d. There are adequate provisions to maintain the privacy interests of participants

e. When there are to be interactions with participants, informed consent will be obtained by a process that will disclose adequate information, including that the activity involves research, participation is voluntary, a description of the procedures and investigator contact information is included.

6.02.3 Upon review, the IRB Chair (or Chair's designee) typically will make one of the following determinations:

a. The submission does not meet the federal definitions for research involving human subjects

b. The proposed research activity IS exempt and may be conducted without IRB review

c. The research is NOT exempt, and before performed, must be submitted for IRB review.

6.02.4 Up to two weeks may be required for processing applications. Additional time should be allowed for any modifications and/or clarifications that may be required as a result of review and for resubmission to the IRB for review in the event the research is determined not to be exempt.

6.03 Notification

Exempt research activities may not begin until PIs receive notification of the exempt determination in writing (or electronically). Notifications will include the exempt category or categories under which the determination was made. IRB members and institutional officials are notified of all research that is determined to be exempt. Determinations are documented in a summary that is posted and can be printed from the PHSC secure websites. Additionally, the designated Institutional Official (IO) will be notified of all exempt protocols via a report that will be generated within a week of scheduled IRB meetings.

6.04 Modifications

Modifications may not be made to exempt research, because of the possibility that proposed changes may change the research in a way that it no longer meets the criteria for exemption. A new application for exempt determination must be submitted and reviewed prior to modifying the research activity, unless the investigator believes that the change must be made to prevent harm to participants. All such changes must be reported to the ORSP's RCC or to the IRB.

6.05 Record Retention

Records of exempt determinations, including materials submitted and related correspondence, are retained by the Office of Research and Sponsored Programs in accordance with federal regulations (45 CFR 46.115). Records will include the exempt category or categories under which the determination was made or documentation as to why the research was judged not to be exempt.

7. APPLICABLE REGULATIONS/GUIDANCE

45 CFR 46.101, 45 CFR 46.115, 45 CFR 46.201, 45 CFR 46.301, 45 CFR 46.401, OHRP "Human Subject Regulations Decision Charts" (09/24/04), "OHRP Guidance on the Involvement of Prisoners in Research" (05/23/03), OHRP Guidance "Exempt Research and Research That May Undergo Expedited Review" (05/05/95), OHRP Guidance "Exemption for Research and Demonstration Projects on Public Benefit and Service Programs"

APPROVED: < signed >
Dana G. Hoyt, President

DATE: 6/17/15

CERTIFICATION STATEMENT

This academic policy statement (APS) has been approved by the reviewer(s) listed below and represents SHSU's Division of Academic Affairs' policy from the date of this document until superseded.

Original:	April 25, 2014	Review Cycle:	April 1, ENY*
Reviewer(s):	Council of Academic Deans Faculty Senate Academic Affairs Council	Review Date:	April 1, 2018

Approved: < signed > Date: 6/18/15
Jaimie L. Hebert
Provost and Vice President
for Academic Affairs

***ENY = Even Numbered Year**