1. GENERAL

Research involving human subjects may be exempt from federal regulations requiring Institutional Review Board (IRB) review. The Sam Houston State University Committee for the Protection of Human Subjects (henceforth referred to as the IRB) 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 IRB 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 46.104):

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.
c. The research activity must not adversely impact students' opportunity to learn nor the assessment of educators.

4.02.2 Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including video or auditory recording) if at least one of the following criteria is met:

a. Information obtained is recorded in such a manner that human subjects cannot be identified, directly or through identifiers linked to the participant; OR
b. Any disclosure of the human subjects' responses outside the research would not reasonably place the participants at risk of criminal or civil liability, or be damaging to the participants' financial standing, employability, educational advancement, or reputation; OR
c. Information is recorded with identifiers, and the IRB conducts a Limited Review to ensure that adequate measures are in place to protect the privacy and confidentiality of participants and the data.

Note: *This exemption category 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 Benign Behavioral Interventions (BBI) through verbal, written responses (including data entry or audiovisual recording) from adult participants who prospectively agree and ONE of the following criteria are met:

a. Recorded information cannot readily identify the participant; OR
b. Any disclosure of responses outside of the research would NOT reasonably place participants at risk (criminal, civil liability, financial, employability, educational advancement, reputation); OR
c. Information is recorded with identifiers and the IRB conducts Limited Review to ensure that adequate measures are in place to protect the privacy and confidentiality of participants and the data.

4.02.4 Research involving secondary research for which consent is not required and includes the use of identifiable information or identifiable biospecimens that have been or will be collected for some other 'primary' or 'initial' activity if ONE of the following criteria are met:

a. Biospecimens or information is publicly available; OR
b. Information is recorded so that participants cannot readily be identified (directly or indirectly/linked)' investigator does not contact participants and will not re-identify the participants; OR
c. Collection and analysis involving investigators' use of identifiable health information when such use is regulated by HIPAA "health care operations" or "research" or "public health activities and purposes"; OR
d. Research information collected by or on behalf of federal government generated or collected information obtained for non-research activities.

4.02.5 Research and demonstration projects that are conducted or supported by or subject to the approval of federal 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. The research or demonstration project must be posted to a publicly accessible federal web site prior to commencing the research involving 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.

4.02.7 Storage or maintenance of Identifiable Private Information or Identifiable Biospecimens for Secondary Research for which Broad Consent is required.

a. Information is recorded with identifiers, and the IRB conducts a Limited Review to ensure that adequate measures are in place to protect the privacy and confidentiality of participants and the data.

4.02.8 Secondary research involving use of Identifiable Private Information or Identifiable Biospecimens for Which Broad Consent was required.

a. Information is recorded with identifiers, and the IRB conducts a Limited Review to ensure that adequate measures are in place to protect the privacy and confidentiality of participants and the data.

5. RESEARCH INELIGIBLE FOR EXEMPTION

5.01 Research involving prisoners may not be determined to be exempt, unless the research is aimed at involving a broader participant population that only incidentally includes prisoners (i.e., prisoners are not the focus of the research).

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) who has no direct involvement in the proposed activity. **Investigators are not permitted to make their own determinations of exemption.** Additionally, the IRB Chair/Reviewer must determine that the research activities meet the exemption requirements outlined in 45 CFR 46.104 of the Federal Policy for the Protection of Human Subjects and as described above. For those exempt eligible research activities that require limited IRB review, the IRB Chair/Reviewer must determine that adequate measures are in place to protect the privacy and confidentiality of participants and the data.

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. IRB 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 IRB, etc., also apply to exempt research.

6.02 Review

6.02.1 The criteria for exemption specified in DHHS regulations (45 CFR 46.104) 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 IRB 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 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. 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.

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):	ORSP	Review Date:	April 1, 2020

Approved:_____ Date: 5-Feb-2019

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***ENY = Even Numbered Year**