

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 EH3in EH/F2 12 TaGo to the

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. could reasonably place the participants at risk of criminal or civil liability, 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.

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.

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 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 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 shou

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](#) [OHRP Guidance on the](#)
[Involvement of Prisoners in Research](#) [Exempt Research](#)
[and Research That May Undergo Expedited Review](#)
[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 superseded.

Original: April 25, 2014
Reviewer(s):

Review Cycle: April 1, ENY*