1. GENERAL

The IRB have the authority to suspend or terminate previously approved research that is not being conducted in accordance with IRB requirements or that has been associated with unexpected serious harm to subjects.

2. PURPOSE

This policy describes the conditions under which the IRB may suspend or terminate previously approved research and the procedures to be followed when suspending or terminating previously approved research.

3. DEFINITIONS

Go to the Glossary for definitions.

4. NON-COMPLIANCE

4.01 Screening Allegations of Noncompliance: Any allegation of noncompliance will be referred to the IRB. The IRB Chair (or designee) will conduct a preliminary screening of the allegation and gather information from involved parties (investigator, research staff, study participants, etc.). All materials and documents relevant to the allegation will be considered, along with the current IRB approval letter/certificate, the currently approved protocol application, the currently approved consent document, the grant proposal if applicable, and any other pertinent information (study materials, correspondence, etc.). Additional IRB members may be involved in the investigation and review if deemed appropriate or needed due to conflicts of interest. Following the initial screening, if allegations are determined not to have a basis in fact, no further action is taken under this policy. The IRB is informed at the next convened meeting.

4.02 Determination of Noncompliance: A determination of possible noncompliance is made initially by the IRB Chair (or designee) based on an initial screening. Upon determination that an allegation is based in fact, the IRB will gather any additional relevant information needed to determine whether noncompliance has occurred. The noncompliance information is then presented to the IRB Committee for consideration as to the determination of the type of noncompliance (non-serious, serious, and continuing) and necessary corrective actions or outcomes. The IRB will consider the necessary corrective actions or outcomes, as outlined in SOP 6 (section 6.03). IRB Committee consideration may occur at a convened meeting

and/or by preliminary discussions amongst IRB members prior to a convened meeting.

5. GENERAL INFORMATION ON SUSPENSIONS AND TERMINATIONS

5.01 Information indicating that research is not being conducted in accordance with IRB requirements (45 CFR 46) or that it has been associated with unexpected harm to subjects may arise from various sources, including (but not limited to) continuing reviews, event reports, allegations of potential noncompliance, and/or subject complaints.

5.02 When further investigation is required to determine whether suspension or termination is warranted, the investigation will be conducted as described in Section 5.03 of this SOP.

5.03 The IRB will report all suspensions or terminations of IRB approval to IRB members, investigators, regulatory agencies, and institutional officials as described in SHSU IRB's SOP #6 and #7 [Event Reporting – Unanticipated Problems and Suspensions and Termination of IRB-Approved Research].

a. Suspensions

(1) When there is reason to believe that research activities should be stopped, the IRB Chair or the convened IRB may suspend approval of any or all research activities in order to protect participants. The Institutional Official (IO) may also suspend research, as needed, on an urgent basis.

(2) When IRB approval of research is suspended, the IO, IRB Chair, or the convened IRB will consider actions such as the following to protect the rights and welfare of participants, as appropriate:

i. Notification of current and/or former participants

ii. Transferring responsibility for the research and participants to another investigator

iii. Continuation of participants in the research with an independent monitor

iv. Withdrawal of current participants from the research

v. Requiring arrangements for care of participants outside the research

vi. Requiring or permitting follow-up of participants (e.g., for safety reasons)

vii. Arranging for compensation of current and/or former participants

(3) When participants are to be withdrawn from the research, the IO, IRB Chair, or the convened IRB will evaluate whether the procedures for withdrawal consider the rights and welfare of enrolled participants.

(4) When study approval is suspended, the reason(s) will be communicated to the investigator(s), along with any actions required to protect the rights and welfare of current or past research participants. Other IRB responsible for oversight of the investigator(s)' research will also be notified, if applicable.

(5) Suspensions of approval may be lifted by the IO, IRB Chair, or convened IRB if there are no longer concerns about:

i. Potential harm to research participants

ii. Investigator or research staff noncompliance

iii. Other issues that were related to or resulted in suspension (e.g., drug manufacturer's recall, use of non-approved materials or procedures).

(6) Modifications made to the research (if any) as a result of the suspension will be reviewed by the convened IRB when changes represent more than minor changes, as defined by SHSU IRB's SOP #3 [Expedited Review Procedures].

(7) When the IRB Chair or IO suspends research, the suspension will be reported to the convened IRB at the next available meeting. The convened IRB will determine whether to continue the suspension, re-instate IRB approval, or terminate approval of the research.

b. Terminations

(1) The convened IRB may terminate previously approved research when the research is not being conducted in accordance with IRB requirements or

when the research is associated with unexpected serious harm to subjects as described in the SHSU IRB's SOPs #6 [Event Reporting]. Note: Similar actions taken by investigators or sponsors to stop research activities are not terminations as described by this policy.

(2) When IRB approval of research is terminated, the convened IRB will consider actions such as the following to protect the rights and welfare of participants, as appropriate:

i. Notification of current and/or former participants

ii. Transferring responsibility for research participants to another investigator

iii. Withdrawal of current participants from the research

iv. Requiring arrangements for care of participants outside the research

v. Requiring or permitting follow-up of participants (e.g., for safety reasons)

vi. Arranging for compensation of current and/or former participants

(3) When participants are to be withdrawn from the research, the convened IRB will evaluate whether the procedures for withdrawal consider the rights and welfare of enrolled participants.

(4) When study approval is terminated, the reason(s) will be communicated to the investigator(s), along with any actions required to protect the rights and welfare of current or past research participants. Other IRB responsible for oversight of the investigator(s)' research will also be notified, if applicable.

6. INVESTIGATOR RESPONSIBILITIES

6.01 Upon notification that research has been suspended or terminated by the IRB, the investigator(s) is responsible for the following:

a. Stopping enrollment and research activities as required by the IRB

b. Cooperating with any investigation conducted by the IRB or IRB Investigative Committee

c. Assisting with and/or carrying out actions required by the IRB to protect the rights and welfare of participants (e.g., notification, withdrawal, follow-up, etc.)

d. Reporting to the IRB any adverse events or outcomes encountered during suspension or termination of the research in accordance with SHSU IRB's SOP #6 [Event Reporting].

7. APPLICABLE REGULATIONS/GUIDANCE

45 CFR 46.103, 45 CFR 46.113, OHRP "Guidance on Reporting Incidents to OHRP" (06/20/11)

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**