1. GENERAL

The IRB Chair or one or more experienced IRB members designated by the Chair may use expedited review procedures to approve a limited class of research activities involving human subjects. Expedited IRB review procedures may be used for the following:

1.01 Initial or continuing review of research with minimal risk

1.02 Continuing review of research previously approved by the convened IRB, under specified circumstances

1.03 Review of minor changes to previously approved research

2. PURPOSE

This SHSU IRB SOP describes the situations in which research may qualify for expedited review, as well as the process by which the IRB reviews research by expedited procedures.

3. DEFINITIONS

Go to the Glossary for definitions.

4. RESEARCH ELIGIBLE FOR EXPEDITED REVIEW

4.01 Research activities that present no more than minimal risk to human subjects and are both consistent with 45 CFR 46.110 and involve only procedures listed in one or more of the categories delineated in Categories of Research That May Be Reviewed by the Institutional Review Board (IRB) through an Expedited Review (Office of Human Research Protections or OHRP).

4.02 Continuing review of research previously approved by the convened IRB may receive expedited review in any of the following situations:

a. The research is permanently closed to enrollment, all participants have completed all research-related interventions, and the research remains active only for long-term follow-up

b. No participants have been enrolled and no additional risks have been identified

c. The remaining research activities are limited to data analysis

4.03 The expedited procedure may also be used for continuing review of research that does not fit categories (1) through (7) of the Categories of Research That May Be Reviewed by the Institutional Review Board (IRB) through an Expedited Review Procedure or the conditions described above, when the IRB has determined and documented at a convened meeting that the research involves minimal risk and no additional risks have been identified.

4.04 Amendments to previously approved research during the period for which approval is authorized (one year or less) may be reviewed using expedited procedures.

4.05 Requirements for informed consent (or for waiver, alteration, or exceptions to the requirements for informed consent) apply regardless of whether the research is reviewed by the convened IRB or by an expedited procedure.

4.06 The expedited review procedure may not be used to review research in which identification of the participants and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are minimal.

4.07 Expedited review procedures may not be used for classified research involving human subjects.

4.08 The specific circumstances of the proposed research must be considered when determining that the research involves minimal risk to human subjects. The activities listed in Categories of Research That May Be Reviewed by the Institutional Review Board (IRB) through an Expedited Review Procedure should not be considered minimal risk simply because they are included on the list.

4.09 Additions to or extrapolations from the list of activities included in Categories of Research That May Be Reviewed by the Institutional Review Board (IRB) through an Expedited Review Procedure are not appropriate. Expedited review procedures may not be used unless the proposed research activities appear on the list, even when the research presents minimal risk.

5. SUBMISSION REQUIRMENTS

5.01 When submitting applications for initial review, continuing review, or amendment requests using the expedited procedure, investigators must submit all applicable materials listed in the SHSU IRB's SOP [IRB Submission and Pre-Review] for expedited review.

5.02 Upon receipt of an application for expedited review, the ORSP's Research Compliance Administrator (RCA), or Chair's designee pre-reviews the submission (e.g., to verify whether the materials are complete, required CITI training has been completed) and makes an initial determination as to whether the submission is eligible for expedited review.

6. EXPEDITED REVIEWER ASSIGNMENTS

6.01 ORSP's RCA (or Chair's designee) assigns expedited reviews to one IRB member from the pool of experienced reviewers designated by the IRB Chair (which may also include the IRB Chair).

6.02 When making expedited reviewer assignments, the ORSP's RCA (or Chair's designee) the following will be considered:

a. Reviewer's scientific and/or scholarly expertise

b. Reviewer experience

c. Reviewer's status as scientist or nonscientist

d. Reviewer workload

e. Potential conflicts of interest (both financial and personal/professional) as defined in the SHSU IRB's Glossary

f. The need for special representation (e.g., vulnerable populations)

6.03 ORSP's RCA (or Chair's designee) consults with the IRB Chair as necessary when making reviewer assignments.

6.04 ORSP's RCA (or Chair's designee) notifies IRB members of review assignments and confirms reviewers' availability and eligibility (e.g., no conflicting interests) to perform timely reviews.

7. EXPEDITED REVIEW PROCEDURES

7.01 Initial and Continuing Review

a. Assigned reviewer(s) will receive all information that the convened IRB would have received and will initially review the materials submitted to confirm that the research meets the applicability criteria and one or more categories of research eligible for expedited review.

b. For continuing review, the complete protocol file and relevant minutes from previous IRB review(s) will be available.

c. The expedited reviewer(s) will perform an in-depth review of all submitted materials, using the criteria for approval described in federal regulations and the SHSU IRB's SOP [Review of Research by the Convened IRB].

d. For continuing review, IRB reviewer(s) will determine the following:

(1) Whether the protocol needs verification from sources other than the investigators that no material changes occurred since previous IRB review, as described in the SHSU IRB's SOP [Review of Research by the Convened IRB]

(2) That the current consent document is still accurate and complete

(3) If any significant new findings relate to subjects' willingness to continue participation

e. Reviewer(s) will document the specific category or categories under which the research qualifies for expedited review and any finding(s) required by regulations, including protocol-specific information justifying the finding(s)

(for example, in an email to ORSP's RCA (or Chair's designee), the IRB reviewer will simply indicate, "Approved-Expedited, Category 7").

f. Reviewer(s) will forward to the next available meeting of the convened IRB research that does not meet the criteria for expedited review in the judgment of the IRB.

7.02 Amendments to Previously Approved Research

a. Assigned reviewer(s) will receive all information that the convened IRB would have received and will initially review the materials submitted to confirm that the amendment meets the criteria (i.e., a minor change) for expedited review.

b. The complete protocol file and relevant minutes from previous IRB review(s), as applicable, will also be available for review.

c. The expedited reviewer(s) will perform an in-depth review of all submitted materials, using the criteria for approval described in federal regulations and the SHSU IRB's SOP [Review of Research by the Convened IRB] when the modifications affect one or more regulatory criteria.

d. The reviewer(s) will also determine that any significant new findings relate to subjects' willingness to continue participation.

e. Reviewer(s) will document that the amendment represents a minor change(s) qualifying for expedited review and any finding(s) required by regulations, including protocol-specific information justifying the finding(s).

f. Research that in the judgment of the IRB reviewer(s) does not meet the criteria for expedited review (i.e., more than a minor change) will be forwarded to the next available meeting of the convened IRB.

8. OUTCOMES OF EXPEDITED REVIEW

8.01 When reviewing proposed research activities using expedited procedures, IRB reviewers may take one of the following actions:

a. Approved

b. Approved, with Conditions (conditions listed)

c. Modifications required (to secure approval)

8.02 An expedited reviewer can also request additional information and/or clarification from the investigator before taking one of the above actions.

8.03 When an expedited reviewer cannot take one of the actions above, the research will be referred for review by the convened IRB. Reviewers may not disapprove research by expedited review. Research can be disapproved only following review by the convened IRB as described in federal regulations and the SHSU IRB's SOP [Review of Research by the Convened IRB].

8.04 Research will be forwarded to the convened IRB for review when any of the following occur:

a. Expedited reviewer(s) cannot determine that the research meets the criteria for expedited review

b. Expedited reviewer(s) cannot approve the research or require modifications in the research to secure approval

c. Expedited reviewer(s) cannot approve the research for one year, based on the criteria described in the SHSU IRB's SOP [Review of Research by the Convened IRB]

d. Expedited reviewers (if more than one) cannot reach a consensus decision during the review process.

8.05 When an expedited reviewer refers research for convened IRB review, the submission materials, reviewer's comments, and any additional information obtained from the investigator are forwarded for consideration at the next available IRB meeting.

9. REVIEW OF INVESTIGATOR RESPONSES

9.01 When expedited reviewer(s) require modifications to research, investigators' responses will be reviewed as described in the SHSU IRB's SOP [IRB Actions and Communications] to verify that the conditions for approval have been satisfied. Depending on the nature of the modifications, this subsequent

review/verification may be performed by the IRB Chair, one or more IRB members, and/or the qualified ORSP's RCA (or Chair's designee).

9.02 Questions about whether the conditions for approval have been satisfied will be forwarded to the IRB Chair. When the conditions for approval are not met, the submission will be referred to the convened IRB for review (i.e., research cannot be disapproved except by convened review).

9.03 For expedited initial review, continuing review and review of amendments, the approval date of the research is the date that the IRB Chair, IRB member(s), and/or the ORSP's RCA (or Chair's designee) verifies that the conditions for approval have been met.

9.04 In certain cases investigators responses can be administratively reviewed by the ORSP's RCA (or Chair's designee) (as designated by the IRB reviewer). Specific examples of investigators' responses that can be administratively reviewed by the ORSP's RCA (or Chair's designee) are in Attachment 1.

10. COMMUNICATING EXPEDITED REVIEW ACTIONS

10.01 Investigator Correspondence

a. ORSP's RCA (or Chair's designee) will notify the principal investigator in writing (or electronically) of the action taken by the expedited reviewer(s) and any modifications required as a condition for IRB approval. Notifications of IRB approval by expedited procedures will include the specific category or categories under which the research qualifies for expedited review (as applicable).

b. When an expedited reviewer refers a submission for convened IRB review, the principal investigator will be notified of the referral and the scheduled convened meeting date.

10.02 Notification of IRB Members and Institutional Official

SHSU's Institutional Official and IRB members are notified of all research that is approved by expedited review procedures. Actions and findings are documented in a summary that is posted and can be printed from a secure folder on the T-drive.

11. RECORD RETENTION

Records of research undergoing expedited review, including materials submitted and related correspondence, are retained by the ORSP office. Records will include the expedited category or categories under which determinations were made, as applicable, and any finding(s) required by regulations, including protocol-specific information justifying the finding(s). ORSP's RCA (or Chair's designee) retains the aforementioned records in accordance with federal regulations (45 CFR 46.115).

12. APPLICABLE REGULATIONS / GUIDANCE

45 CFR 46.110, 45 CFR 46.115, "Categories of Research That May Be Reviewed by the Institutional Review Board (IRB) Through an Expedited Review Procedure" (63 FR 60364-60367, 11/09/98), OHRP "Guidance on IRB Continuing Review of Research" (11/10/10), OHRP "Guidance on IRB Approval of Research with Conditions" (11/10/10), OHRP "Guidance on the Use of Expedited Review Procedures" (08/11/03), OHRP "Guidance on Written IRB Procedures" (07/01/11)

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**