

1. GENERAL

When reviewing research, the convened IRB is responsible for determining the approval status and appropriate approval period (up to one year) of a study under review and must notify the investigator and institutional officials of its decisions.

2. PURPOSE

This policy describes actions that the convened IRB may take during review of research and communication of these actions, as well as the process for review of investigator responses to IRB determinations.

3. DEFINITIONS

Go to the [Glossary](#) for definitions.

4. ACTIONS OF THE IRB

4.01 When reviewing research, the convened IRB will take one of the following actions:

- a. Approved
- b. Modifications Required
- c. Tabled/Deferred
- d. Disapproved

4.02 These actions are applicable when the convened IRB conduct initial review, continuing review, or review of amendments to previously approved research. Actions that can be taken when reviewing research by expedited procedures are described in the SHSU IRB's SOP [Expedited Review Procedures].

4.03 When reviewing investigator appeals/request for reconsideration, the convened IRB will take one of the following actions:

- a. Approved
- b. Tabled/Deferred
- c. Disapproved

4.04 These actions are applicable when the convened IRB conducts a review of an investigator appeal/request for reconsideration. If the investigator appeal/request for

reconsideration is subsequently approved by the convened IRB, then it will reenter the Review of Research by the Convened IRB (IRB SOP 4) process.

5. IRB REVIEW

Initial and continuing review of research, review of amendments to previously approved research by the convened IRB, and investigator appeals/requests for reconsideration are conducted as described in the SHSU IRB's SOP [Review of Research by the Convened IRB]. Review of research by the expedited procedure is performed according to the SHSU IRB's SOP [Expedited Review Procedures].

6. IRB APPROVAL PERIOD

6.01 The IRB may approve research for a period of up to one year. The initial and continuing review approval periods for a study reviewed by either convened or expedited review are determined as described below.

6.02 Once a research protocol has been approved by the IRB, research may begin based on the date that is stipulated in the approval letter that will come from the IRB Chair and/or his or her designee, typically ORSP's RCA (or Chair's designee) [see section 9 of SOP 5].

6.03 For initial review, if modifications are required (to secure approval), the date that the modifications/conditions are met by the investigator is the "start date" for the approval period.

a. For example, if modifications were required for a study reviewed by the convened IRB on May 1, 2014, and the required modifications/conditions were met by the investigator on May 15, 2014, the maximum approval period is May 15, 2014, to May 14, 2015.

b. In the example above, the first date that the research can be performed (assuming that notification from the IRB is received) is May 15, 2014.

6.04 For continuing review, the date that research is re-approved or modifications are met by the investigator is the "start date" for the approval period.

a. For example, if modifications were required for a study reviewed by expedited procedures on May 1, 2014, and the required modifications/conditions were met by

the investigator on May 15, 2014, the maximum approval period is May 15, 2014, and ends May 15, 2015.

- b. In the example above, the first date that the research can be performed (assuming that notification from the IRB is received) is May 15, 2014.
- 6.05 The expiration date is the first date following the approval period, on which the IRB's approval of research has lapsed and research can no longer be performed.
- a. For example, the expiration date for research that was approved on June 1, 2014, with a continuing review frequency of one year is June 1, 2015.
 - b. In the example above, the last date that the research can be performed (unless the study is re-approved) is May 31, 2015.

7. FREQUENCY OF IRB REVIEW

- 7.01 The IRB will require continuing review at intervals appropriate to the degree of risk, but not less than once per year. The criteria used to consider whether more frequent review is required includes, but is not limited to, the following:
- a. High-risk research where there is concern about serious adverse events
 - b. Research where the potential risks in humans are unknown and may have the potential to be serious (e.g., phase I drug study, studies involving psychological harm, etc.)
 - c. Research being conducted in international or other off-site location(s) when a university IRB is serving as the IRB of record
 - d. Research in which an investigator has a potential conflict of interest that warrants more frequent reporting and review
 - e. Investigator/protocol has had compliance problems in the recent past
 - f. Other issue warranting more frequent review at the discretion of the IRB
- 7.02 Depending on the research, the following types of interval frequencies may be considered:

- a. Specified time period (such as annual, semi-annual, or quarterly review)
- b. Requirement to report back to the IRB after a specified number of participants have been enrolled or undergone study interventions
- c. Other point in the research meriting reporting and review (e.g., completion of phase I of a multi-phase study)

8. REVIEW OF INVESTIGATOR RESPONSES

- 8.01 When the IRB require modifications to research, investigators' responses will be reviewed 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 or a consultant with specific expertise, and/or qualified ORSP staff (who may or may not be IRB members).
- 8.02 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, investigators will be notified; and the submission will be referred to the convened IRB for review (i.e., research cannot be disapproved except by convened review). For specific details regarding the administrative review/verification of investigators' responses to modifications, see Attachment 1.
- 8.03 When research is deferred by convened review, only the convened IRB may reconsider the clarifications and/or modifications made to the submission. Whenever possible, the original IRB reviewer(s) will be reassigned review of the research.
- 8.04 When research is disapproved, an investigator will submit a new, revised application to request approval. Review of such applications will be by the convened IRB unless the research meets the criteria for expedited review, as described in the SHSU IRB's SOP [Expedited Review Procedures].
- 8.05 Investigator appeals of IRB decisions are reviewed by the IRB as described in the SHSU IRB's SOP [Review of Research by the Convened IRB].
- 8.06 For IRB actions that require response(s) from an investigator before the research can proceed, a reminder notice is sent if the response is not received within the time period specified by the IRB, or after 30 days (whichever is sooner). Two follow-up reminders are sent (i.e., at equivalent intervals or at 60 and 90 days). If the response is not received

within 90 days (or after three reminders, as applicable), the principal investigator will be notified that the submission has been administratively withdrawn.

9. COMMUNICATION OF IRB ACTIONS

9.01 After the IRB Chair (or designee) approves the minutes of the convened IRB meetings, the ORSP's RCA (or Chair's designee) will prepare notification letters to inform investigators of IRB actions. Note: Approval letters can be sent prior to completion of the meeting minutes.

9.02 Notification letters include (minimally) the following information:

- a. Date of review
- b. Type of submission reviewed (e.g., initial review, response to modifications, continuing review, or review of amendments to previously approved research)
- c. IRB action
- d. Approval and expiration date (when applicable)
- e. Applicable category for approval
- f. Any associated approvals requiring specific regulatory findings (e.g., waiver of the requirement for obtaining informed consent)
- g. Modifications or additional clarifications required, or other conditions that must be satisfied by the investigator, if any, for IRB approval
- h. For initial review, any conditions under which the research may be initiated
- i. For continuing review and amendments, any conditions that must be satisfied before an investigator can continue research activities
- j. For research that is deferred, a statement of the reasons for deferral and a description of how the investigator can respond
- k. For research that is disapproved, a statement of the reasons for disapproval and a description of how the investigator can respond

9.03 IRB members and the Institutional Official (IO) are notified of the IRB's actions and findings via summary documentation that is posted and can be printed from the secure IRB Members' folder on the T-drive.

10. APPLICABLE REGULATIONS/GUIDANCE

[45 CFR 46.111](#), OHRP "[Guidance on IRB Approval of Research with Conditions](#)" (11/10/10), 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
Reviewer(s): Council of Academic Deans
Faculty Senate
Academic Affairs Council

Review Cycle: April 1, ENY*
Review Date: April 1, 2018

Approved: _____ < signed > _____
Jaimie L. Hebert
Provost and Vice President
for Academic Affairs

Date: _____ 6/18/15 _____

***ENY = Even Numbered Year**