

(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

- 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 b **Qhe**

Sam Houston State University
Academic Policy Statement 140424

