

3.2.5. SHSU: Sam Houston State University

- 6.1. **Identify the necessity for LIRB**. This is accomplished through the standard IRB Analyst pre-review process. At the conclusion of pre-review, an expedited reviewer is assigned to conduct the LIRB.
- 6.2. Conduct the review.
  - 6.2.1. **Criterion for approval**. The application materials are reviewed against the applicable criterion for approval (45 CFR 46.111(a)(7)): When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
  - 6.2.2. Consent process and/or form. Exempt research is not required to have a formal consent process or form. The LIRB reviewer will not review any consent process or form provided with the application. However, it is an SHSU IRB requirement that studies that will interact with participants are expected to provide the participants with information about the study and what will be expected of participants (see established template for exempt-eligible studies).
  - 6.2.3. **Reliance arrangements** through which the SHSU IRB is providing the review for another organization or investigator. Establish the reliance agreement, following standard procedures and submit this agreement through Cayuse Human Ethics.
  - 6.2.4.**Possible outcomes**. The Common Rule allows only the following outcomes. **The application cannot be disapproved—this can only be accomplished at a full board meeting.** 
    - 6.2.4.1. Conditional approval (Revisions Required to Secure Approval (RRSA)). This is an intermediate step that must eventually result in approval or referral for standard IRB review.
    - 6.2.4.2. Approval (i.e., exempt—LIRB status).
    - 6.2.4.3. Referral for review by the expedited or convened IRB process.
    - 6.2.4.4. Determination that LIRB was not required because the activity qualifies for exempt status without LIRB or it is Not Research, Not Human Subjects, or Not Engaged.
- 6.3. Documentati(ppr-4 r)6(e 0)6(Wa.6h) a)92(v)2(a)1 (ed)2(t)-3(at)6(i)-46(ppr-4 r)Tw T1(u)2(i)2(y)22(uar-4 r)