

4.02.2

Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

4.02.7

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- d. There are adequate provisions to maintain the privacy interests of participants
- e. When there are to be interactions with participants, informed consent will be obtained by a process that will disclose adequate information, including that the activity involves research, participation is voluntary, a description of the procedures and investigator contact information is included.

6.02.3 Upon review, the IRB Chair (or Chair's designee) typically will make one of the following determinations:

- a. The submission does not meet the federal definitions for research involving human subjects
- b. The proposed research activity IS exempt and may be conducted without IRB review
- c. The research is NOT exempt, and before performed, must be submitted for IRB review.

6.02.4 Up to two weeks may be required for processing applications. Additional time should be allowed for any modifications and/or clarifications that may be required as a result of review and for resubmission to the IRB for review in the event the research is determined not to be exempt.

6.03 Notification

Exempt research activities may not begin until PIs receive notification of the exempt determination in writing (or electronically). Notifications will include the exempt category or categories under which the determination was made. IRB members and institutional officials are notified of all research that is determined to be exempt. Determinations are documented in a summary that is posted and can be printed from the IRB secure websites. Additionally, the designated Institutional Official (IO) will be notified of all exempt protocols via a report that will be generated within a week of scheduled IRB meetings.

6.04 Modifications

Sam Houston State University