SUL ROSS STATE UNIVERSITY

A Member of the Texas State University System

SRSU Policy: Institutional Review Board (IRB) Policy and Procedures
SRSU Policy ID: AMP 2.36
Policy Reviewed by: Assistant Vice President of Institutional Effectiveness
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1. Policy Statement and Purpose

Sul Ross State University respects the rights and dignity of all people. Therefore, it is the policy of Sul Ross University that all research involving human subjects conducted at the university will be in accordance with federal regulations including but not limited to the "Guidelines for Protection of Human Research Subjects" 45 CFR 46 established by the National Institutes of Health, and regulations to protect human subjects, 21 CFR 50, 312, 812 as established by the Food and Drug Administration.

To meet these regulations, SRSU will maintain an Institutional Review Board to ensure all research activities involving human subjects conducted at or sponsored by SRSU have adequate safeguards to protect the rights, dignity, and welfare of the human research subjects.

The mission statement of the Sul Ross University Institutional Research Board is to "ensure the protection of rights, privacy and welfare of all human participants in research programs conducted by Sul Ross State University and associated faculty, professional staff and students."

No research (including grant applications), development, or related activity involving human subjects may be undertaken unless the SRSU Institutional Review Board has reviewed and approved such proposed activity as outlined within this policy and procedures.

2. Scope

This policy applies to all institutional research involving human subjects.

Researchers will include SRSU employees, SRSU students, and external agencies.

3. Institutional Review Board

To meet the requirements of [45 CFR 46.103(b)(4)(i), 21 CFR 56.108(a)(1)]], the SRSU Institutional Review Board has developed and follows written procedures for conducting initial and continuing review of research and for reporting IRB findings and actions to the investigator and the institution as described below:

Institutional Review Board Membership

1. The IRB Committee members will be appointed by the Director of Institutional Research and approved by the President. Membership will consist of the following:

- No less than five members.
- Employees with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution.
- Membership of individuals who have primary concerns that are nonscientific.
- A minimum of three faculty members representing the College of Education & Professional Studies and the College of Literature, Arts, and Social Sciences, and the College of Agriculture, Life, and Physical Sciences.
- At least one faculty member representing Rio Grande College.
- The Director of Institutional Research (ex-Officio).
- One community member.
- Members will volunteer to serve on the committee.
- Input from outside experts may be solicited as needed.
- The Director of Institutional Research will serve as the committee chairperson.

- All members will complete the required IRB training within 30 days of Board appointment.
- No time limit shall be established for membership.

IRB Meeting Dates

The IRB will meet a minimum of once a month or as the need for review of the research being conducted requires. Additional special meetings may be called by the Chairperson.

IRB Conflict of Interest

No Board member shall be involved in the initial or continuing review of any activity in which the member has a conflict of interest, except to provide information as requested by the Board. The member may be allowed to provide the IRB information as requested; however, prior to IRB discussion and action, the Board member with a conflict of interest will recuse himself/herself from the meeting and leave the room. The IRB member with a conflict will be documented in the meeting minutes as being absent with an indication that a conflict of interest was the reason for the absence. Conflict of interest includes, but is not limited to involvement in the design, conduct or reporting of the research study, direct administrative powers over the investigators or the study, financial or ownership interest or compensation in the research, having personal relationships with the principal investigator, or for any reason the inability to be objective concerning a study.

IRB Records Will Be Maintained on the Sul Ross IRBNet Platform

Records shall be kept by the IRB of the following:

- A list of IRB members.
- Written IRB procedures.

- Minutes of IRB meetings
- Copies of research proposals reviewed.
- Sample informed consent forms.
- Reports of any injuries to human subjects.
- End of research study reports.
- Copies of all correspondence between the IRB and the investigators.

Records shall be kept three (3) years after the completion of research. Material provided to the IRB shall be considered privileged information, and the IRB shall assure the confidentiality of the data contained therein.

IRB Meeting Requirements

- The Board Chairperson will conduct the meetings. In the absence of the Chairperson, the members present shall elect a Chairperson pro temp to conduct the business of the meeting.
- A quorum (over 50%) of the IRB must be present at the IRB meeting for action to be taken. If a quorum is lost during a meeting, the IRB will dismiss the membership and reschedule for a later date.
- The IRB must review proposed research at convened meetings except in the case of an expedited review.
- A majority of the IRB members present must approve Board actions.
- Meetings may be held in person or through videoconferencing.

4. Research Proposal Application Requirements

The IRB has established a systematic process for researchers to submit the request to conduct research through the IRBNet platform.

Research proposals must contain, at a minimum, the following:

- Completion of all items on the IRB Protocol Form.
- Copy of survey if used in the research
  (following IRB approval, survey is reviewed by University Survey Committee)
- An Informed Consent Form.
- A signed letter of permission from an institutional representative, if research is to be conducted in an institution such as a school, hospital, or other agency. etc.
- Documentation that the researcher(s) have completed training approved by the Sul Ross State University IRB.

5. Research Application Reviews

The IRB will conduct meetings to review research applications in accordance with [45 CFR 46.108(b), 21 CFR 56.108(c)]. IRB application reviews will include the following:

- A review of all documents submitted for IRB review, including research proposals, informed consent forms, recruitment materials, survey(s)/hyperlinks, and all supplemental documents associated with the research request. A proposal will not be reviewed if one or more required items are incomplete or missing.

- All IRB members will have access to all review application materials.
- Reviewer will be designated by the chairperson from among the members of the IRB committee.
- Determination that the research application satisfies the following requirements requires that:

    - Risks to subjects are minimized. Research procedures should be designed such that subjects are not exposed to physical, psychological, or social risks significantly in excess of those normally encountered in daily life. Any possible risks imposed must be weighed against the scientific importance and the potential of the research.

    - The reviewer will consider whether the study involves subjects that are likely to be vulnerable to coercion or undue influence, and, if so, the reviewer will include additional safeguards to protect the rights and welfare of these subjects [45 CFR 46.111(b), 21 CFR 56.111(b)].

    - Selection of subjects is equitable, taking into account the purposes of the research and the setting in which the research will be conducted.

    - Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by 46.116. Translation of the informed consent form for non-English speaking subjects will be provided, when applicable.

    - Informed consent will be appropriately documented or appropriately waived in accordance with 46.117. Any potential exceptions from informed consent due to requirements for emergency research will be made in accordance with federal guidelines.

    - The research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects, when appropriate.

    - Adequate provisions to protect the privacy of the subjects and to maintain the confidentiality of data are made, when appropriate. Research procedures shall not disclose confidential information, including names and/or salient identifying characteristics, to other than the investigator(s) and their research staff. Further adequate provisions must be made to protect the confidentiality of information that is to be retained over an extended period of time.

    - Investigator and study staff qualifications, and the adequacy of the site where the research will be conducted, including any institutional requirements for sponsor-investigator studies will be reviewed, as applicable.

- The IRB will render a final decision regarding the application. The IRB may:

    - Approve the research:
    - Deny the research:
    - Table the decision: A decision may be tabled until requested documents are submitted.

- The effective date of the initial approval will be considered to be the date of the meeting in which the proposal was approved.

- The decision to approve a review application will include a determination of the approval period/continuing review interval of the proposed research, which will be based on the nature of the study, the risks posed by the study, and the vulnerability of the study population. This determination will be documented in the IRB meeting minutes in which the proposed research was discussed, and the results of this decision will be included in the email to the primary investigator and any researcher(s) indicated on the proposal.

6. Types of IRB Reviews

a. IRB Exemptions

Projects associated with university courses (other than capstone projects and graduate theses) are exempt from IRB review provided that the identity of research subjects is protected, and the subject is at minimal risk. The IRB recommends that departments conduct internal reviews on this type of research activity.

b. Expedited Review

A review may be expedited through a review by the chair of the IRB and/or one other member of the IRB for research that involves no more than minimal risk, or to review minor revisions in previously approved research, or review revisions for proposals that were approved with contingencies. All required documents must be submitted to the IRB. The IRB expedited reviewer may approve the application, table it until requested documents are submitted, or refer the application to the full Board for review.

c. Full Review

A review of proposals by the entire IRB is required for research that is conducted involving greater than minimal risk, or the research is of a psychologically sensitive nature.

d. Ceded Review

In some cases, the SRSU IRB may agree to rely on another institution's IRB for oversight of a project. The decision is made by the SRSU IRB Director on a case by case basis. A ceded review may apply, for example, to a SRSU faculty member who is doing advanced study through another institution. To apply for a ceded review, the principal investigator will complete the SRSU IRB protocol and upload it with any other pertinent documents onto the SRSU IRBnet site for review. Once the ceded review is approved, the SRSU IRB Director will forward a confirmation letter to the other institution for oversight of the project.

7. Investigator Responsibilities and IRB Action

Reporting Changes to Research Activities

The primary investigator is required to notify the IRB immediately, and receive prior authority, to make proposed changes to the research activities, except when such changes are necessary to eliminate apparent immediate hazards to subjects. If such a situation arises, the primary investigator must inform the IRB immediately upon making the adjustment.

Any expected changes in research must be reported to the IRB.

The IRB will conduct a review when changes are implemented without IRB approval and may disapprove the research or reaffirm the approval with specific requirements for monitoring the remainder of the research.

The IRB shall inform investigators of this requirement as part of the approval process.

Reporting Unanticipated Problems or Concerns

The primary investigator is responsible for promptly reporting in writing to the IRB, appropriate institutional officials, and, as applicable, any department or agency head, OHRP, and/or FDA any time unanticipated problems involving risks to human subjects or others, serious or continuing noncompliance, and or any suspension or termination of IRB approval. The report shall include a summary of the unanticipated problem(s), the outcome, and any steps taken to prevent the recurrence.

The IRB will conduct a full review and may disapprove the research or reaffirm the approval with specific requirements for monitoring the remainder of the research.

Noncompliance

The IRB will review the information received in the event of serious or continuing noncompliance with the regulations or IRB requirements. The primary investigator is responsible for promptly reporting in writing to the IRB the noncompliance, the outcome, and any steps taken to prevent recurrence.

The IRB will conduct a full review and may disapprove the research or reaffirm the approval with specific requirements for monitoring the remainder of the research.

8. Reviewing Changes in Research

a. Minor changes in research will entail consideration by the chair and primary reviewer on a case-by-case matter.
b. Documents submitted to the IRB for changes in research should consist of a written record of any substitutions made in any interview forms, surveys, participant selection process, etc. These documents should be submitted as a second package in IBRNet.
c. When significant changes are submitted, the original reviewer will review the change and submit his/her recommendation(s) to the full Board for a vote. The IRB may approve the change, deny the change or request a modification of the change.
d. In addition, the reviewer will assess whether the IRB-approved informed consent form requires revision based on the change proposed by the researcher.

9. Notifications to Other Offices or Agencies

The IRB will notify other offices or agencies (including the Office of Human Research Protections, HHS, or any equivalent office with the appropriate department or agency) of any unanticipated problems involving risks to subjects or others or any serious or continuing noncompliance with this policy or the requirements or determinations of the IRB AND any suspension or termination of the IRB approval.

10. Monitoring Research

The IRB shall maintain ongoing review of nonexempt human research with respect to subject's rights.

Investigators who report substantial changes that may impinge on human subjects may be subject to further review by the IRB. Such a review shall occur at the discretion of the IRB.

All investigators will be required to file a report upon completion or an interim report within one year following approval if project is not completed

11. IRB Communications Regarding Research

At a minimum, the IRB will communicate its investigation findings and actions through IRBNet to the primary investigator, any research associate as indicated on the proposal, and any member of the IRB not present at the meeting at the time the action was taken for the following:

a. Information regarding the research project's approval.
b. Information regarding any modifications or clarifications required by the IRB as a condition of approval.
c. Information regarding the IRB's decision to disapprove the requested research. The investigator will be given seven days to respond to the IRB chair concerning the decision in writing.

By September 30, the IRB committee will submit an annual report to be posted on the IRB Committee SRSU webpage.

12. Documentation

All documentation of research activities that have been approved by the SRSU IRB will be kept in the IRBNet platform by the IRB and will be kept separately by the primary investigator for a period of at least three years.

13. Suspension of Research Project

The IRB has the authority and the responsibility to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements, or that has been associated with unexpected serious harm to subjects.

The investigators will be notified in writing.

In the event that research subjects have already been enrolled in or have been active in a study that is now being suspended or terminated by action of the IRB, the IRB will communicate the reason(s) for the decision to the research subjects in writing.

14. Complaints

Anyone who believes that the rights of any human subject involved in a SRSU related research project are being violated is encouraged to inform the IRB of their concern. The IRB will investigate the complaint to determine if, in the Board's majority opinion, it is valid. If so, the IRB shall require either (1) the problem be remedied or (2) the research be discontinued.

Notification of such action will be forwarded to the investigators and any appropriate agencies and/or university personnel (e.g. president, dean, department head, etc.).