**SUL ROSS STATE UNIVERSITY**

*A Member of the Texas State University System*

**SRSU Policy: Protection of Human Research Subjects**

**SRSU Policy ID: APM 2.35**

**Policy Reviewed by: Executive Vice President and Provost**

**Approval Authority: President**

**Approval Date: September X, 2019**

**Next Review Date: September X, 2024**

**POLICY STATEMENT**

This policy describes Sul Ross State University's commitment to full compliance with the U. S. Department of Health and Human Services (HHS) regulations for the Protection of Human Research Subjects ([45 CFR 46](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html), June 18, 1991, as amended June 23, 2005 and thereafter) and describes and references procedures that the university takes to fulfill this commitment.

**ETHICAL PRINCIPLES**

The University is guided by the ethical principles regarding all research involving humans as subjects, as set forth in the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (entitled: [Ethical Principles and Guidelines for the Protection of Human Subjects of Research [the “Belmont Report”]](https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/)), regardless of whether the research is subject to federal regulation or with whom conducted or source of support (i.e., sponsorship).

**REGULATIONS AND PROCEDURES**

To fulfill this commitment, the University has developed and submitted to the HHS [Office for Human Research Protections](http://www.hhs.gov/ohrp/) (OHRP) a [Federalwide Assurance](http://www.hhs.gov/ohrp/assurances/assurances/filasurt.html) (FWA) for the Protection of Human Subjects, following the [Terms of the Federalwide Assurance](http://www.hhs.gov/ohrp/assurances/assurances/filasurt.html) specified by HHS. In addition, the University has registered with OHRP an Institutional Review Board (IRB), established in accordance with and for the purposes expressed in [45 CFR 46](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html).

This FWA delineates the following concepts and procedures:

a. institutional principles;

b. applicability of the terms of the FWA;

c. compliance with the federal policy for the protection of human subjects and other applicable federal, state, local, or institutional laws, regulations, and policies;

d. use of written procedures;

e. scope of the IRB’s responsibilities;

f. informed consent requirements;

g. requirement for assurances for collaborating institutions;

h. written agreements with independent investigators who are not otherwise affiliated with the institution;

i. the role of the institutional official;

j. institutional support for the IRB;

k. compliance with the terms of the assurance; and

l. a program of training in the protection of human research subjects.

All research covered by this policy will be reviewed and approved by the IRB except for those categories specifically exempted or waived by federal regulation as outlined in [45 CFR, Section 46.101 (b)(1-6) and Section 46.101 (i)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.101). The involvement of human subjects in research covered by this policy will not be permitted until the IRB has reviewed and approved the research protocol and informed consent has been obtained from the subject or the subject's legal representative as required by federal regulations ([45 CFR, Sections 46.111, 46.116 and 46.117](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html)).

The University assures that before human subjects are involved in nonexempt research covered by this policy, the IRB will give proper consideration to:

a. the risks to the subjects;

b. the anticipated benefits to the subjects and others;

c. the importance of the knowledge that may reasonably be expected to result; and

d. the informed consent process to be employed.

IRB approval for all federally-sponsored research involving human subjects will be submitted to the OHRP or appropriate federal department or agency. Compliance will occur within the time and in the manner prescribed for forwarding certifications of the IRB review to DHHS or other federal departments or agencies for which this policy applies. As required by [45 CFR, Section 46.119](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.119), in the event research is undertaken without the intention of involving human subjects but it is later proposed to involve human subjects in the research, the research shall just be reviewed by the IRB. Human research involvement will not be permitted until IRB approval is received by the appropriate federal department or agency.

As the institutional official named in the FWA, the Executive Vice President and Provost is responsible for monitoring amendments to these regulations and procedures and for proposing revisions to the FWA.

These regulations, procedures, concepts, and other relevant communications are published on the [SRSU IRB website](https://srinfo.sulross.edu/irb/irb/). Maintenance, revision and updates of this material are the responsibility of Executive Vice President and Provost.

**APPLICABILITY**

This policy applies to all research involving human subjects, and all other activities which even in part involve such research, regardless of sponsorship, if one or more of the following apply:

a. the research is sponsored by the university;

b. the research is conducted by or under the direction of any employee or agent of the university in connection with his or her institutional responsibilities;

c. the research is conducted using any property or facility of the university;

d. the research involves the use of the university's non-public information to identify or contact human research subjects or prospective subjects; or

e. the research is conducted to support a student thesis or dissertation.

All human subject research that is exempt under [45 CFR, Section 46.104 or 46.101 (i)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.101) will be conducted in accordance with:

a. [the Belmont Report](https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/);

b. the university's administrative procedures to ensure valid claims of exemption; and

c. IRB staff documentation of such activities.