

Sul Ross State University
 Institutional Review Committee
 Application for Review of Research Using Human Subjects

This application should be submitted to the Institutional Review Committee/Human Subjects Council to request review and approval, or exemption, of any research protocol involving human subjects. All applicable research projects must be reviewed and approved by the IRC before research begins.

Definition of Research: A systematic investigation (i.e. gathering and analysis of information) designed to develop or contribute to generalizable knowledge.

Definition of Human Subject: Living individual(s) about whom an investigator conducting research obtains: (1) data through intervention or interaction with the individual; or (2) identifiable private information. (Federal Policy 45 CFR 46.102(f))

Project Title:			
Investigator's Name	Investigator's Phone:	Investigator's Email:	
Project Start Date:		Date of IRC Request:	
If Student, Name of Faculty Supervisor	Faculty's Phone:	Faculty's Email	
If not employed or student at SRSU, List Name, College & Dept of SRSU Collaborator:	SRSU Collaborator Phone:	SRSU Collaborator Email:	
Will this project be funded externally? _Yes_No		Is the Investigator a Student? __ Yes __No	
If yes, name of funding agency:			
Status of Project:	Submitted on:	Funding Pending:	Funding Confirmed:

BY MY SIGNATURE BELOW, I ATTEST TO AN UNDERSTANDING OF AND AGREE TO FOLLOW ALL APPLICABLE SRSU, SPONSOR, TEXAS STATE AND FEDERAL POLICIES AND LAWS RELATED TO CONDUCTING RESEARCH WITH HUMAN SUBJECTS. If significant changes in investigative procedures are needed during the course of this project, I agree to seek approval from the IRC prior to their implementation. I further agree to immediately report to the IRC any adverse incidents with respect to human subjects that occur in connection with this project.

 Signature of Investigator Date

 Signature of Faculty Advisor (for student) or SRSU Collaborator (for External Investigator) Date

 Signature of Department Chair or Supervisor Date

Complete the attached Research Protocol Outline and attach this cover for with other required attachments.

Research Protocol Outline

Please complete this entire form (1 through 9). ENTER A RESPONSE FOR EVERY QUESTION. If a question does not apply to your project, please enter a "N/A". Answer all questions on this form, do not refer to your proposal attachment. Incomplete forms may result in the form being returned to you for completion and a resulting delay in approval of your project.

- 1) If you believe your project qualifies for Exemption, which exemption number(s) apply?
(Please see end of application for an explanation of exemption numbers.)
- 2)
- 3) Describe the research problem(s) your project addresses?

- 4) Describe the population sample for your project.
 - a. How many subjects will participate in this project?
 - b. How will these subjects be identified and selected for participation?

 - c. Describe the rationale for inclusion or exclusion of any subpopulation.

 - d. How will you recruit subjects?

 - e. Describe any incentives for participation you plan to use.

- 5) Will you include any of the following vulnerable populations in your research?

Children	yes	no
Prisoners	yes	no
Pregnant Women	yes	no
Mentally Ill	yes	no
Mentally Handicapped	yes	no
Fetuses	yes	no

If any of these populations are to be included, please address the following:

 - a. Rationale for selecting or excluding specific populations:

 - b. Description of the expertise of project personnel for dealing with vulnerable populations

 - c. Description of the suitability of the facilities for the special needs of subjects

 - d. Inclusion of sufficient numbers of subjects to generate meaningful data:

- 6) Describe the data collection process.
 - a. Will the data collected from human subjects be anonymous? Yes No
 - b. Will the data collected from human subjects be kept confidential? Yes No
 - c. Describe your procedures for ensuring anonymity and/or confidentiality.

 - d. How much time is required for each subject?

- e. **If subjects are students, will their participation involve class time?**
- f. **What methods, instruments, techniques, and/or other sources of material will you use to gather data from human subjects?**

- g. **Are you using a questionnaire, survey, and/or interview as part of your procedure?**
Yes No If yes, submit a copy

7) Describe potential risks to subjects:

- a. **Describe in lay language exactly what you will be doing to, or with, your subjects:**

- b. **Will you be carrying out procedures or asking questions that might disturb your subjects emotionally or produce stress or anxiety? Yes No If yes, describe your plans and criteria for counseling such subjects.**

- c. **Does your study involve deception of your subjects? Yes No If yes, describe the procedure you will use to debrief your subjects.**

- d. **Where appropriate, describe plans for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects.**

- e. **In three or four sentences, summarize the risk/benefit ratio of the proposed research, with regard to the human subjects, the risks to them, and the potential benefits to knowledge or society:**

8) Will you be seeking informed consent? Yes No

If yes, describe:

- a. **What information will be provided to prospective subjects?**

- b. **What (if any) information will be concealed prior to participation, and why?**

- c. **How will you ensure consent is obtained without real or implied coercion?**

- d. **How will you obtain and document consent?**

- e. **Who will be obtaining consent?**

9) Will this research be conducted at another University or site other than Sul Ross State University? Yes No

If yes, describe location and attach a copy of IRB approval from that institution.

10) Please attach a copy of your project description or proposal abstract.

RESEARCH USING HUMAN SUBJECTS

Summary

Individuals planning a project or applying for awards for research involving human subjects must either demonstrate that the research is exempt under University and Federal regulations, or they are required to provide written Assurances of Compliance with 45CFR Part 46 and to file a certification that the proposed research activity has been reviewed and approved by the Internal Review Board.

General

It is the policy of Sul Ross State University that all faculty, staff, and students conducting research using human subjects are required to have prior approval of the University. The researcher is responsible for the protection of rights and welfare any human subject involved in research, development and related activities. The researcher is expected to comply with the Federal Code (45 CFR part 46) on "Protection of Human Subjects". These regulations provide a systematic means, based on established ethical principles, to safeguard the rights and welfare of individuals who participate as subjects in research activities. A copy of the Federal Regulations is available at the office of the Vice President for Academic Affairs, or online at : www.med.umich.edu/irbmed/FederalDocuments/hhs/HHS45CFR46.html

The regulation exempts certain categories of research involving human subjects which normally involve little or no risk. The exemptions are listed in 45 CFR Part 46.101(b), and include educational testing and collection or study of data in which the subjects can not be identified. See below for details.

A human subject is defined as a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information. The regulations extend to the use of human organs, tissue, and body fluids for individually identifiable human subjects as well as graphic, written, or recorded information derived from individually identifiable human subjects.

Institutional Review Board

Sul Ross State University Policy and Federal Regulations require that research covered by 45 CFR Part 46 will not be allowed or funded unless it has been reviewed and approved by the Institutional Review Board (IRB). The IRB is an administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of Sul Ross State University. The IRB has the authority to approve, require modifications in, or disapprove all research activities that fall within the jurisdiction as specified by both the federal regulations and local institutional policy. Research that has been reviewed and approved by the IRB may be

subject to review and disapproval by officials of the University. However, these officials may not approve research if it has been disapproved by the IRB (45 CFR 46 Subpart A).

In order to approve research covered by the regulation, the IRB shall determine that all of the following requirements are satisfied. Risks to subjects are minimized by:

- Using procedure that are consistent with sound research design and do not unnecessarily expose subjects to risk.
- Whenever appropriate, using procedures already being performed on the s subjects for diagnostic or treatment purposes.
- Risks to subjects are reasonable in relation to expected benefits, if any, to subjects and the importance of the knowledge that may reasonable be expected to result.
- Selection of subjects is equitable. In making this assessment, the IRB should take into account the purposes of the research and the setting in which the research will be conducted.
- Informed consent is sought form each prospective subject or the subject's legally authorized representative in accordance with and to the extent required by the regulation.
- Informed consent is appropriately documented in accordance with and to the extent required by the regulation.
- Where appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
- Where appropriate, provisions are adequate to protect the privacy of subjects and to maintain the confidentiality of data.
- Where some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as persons with acute or severe physical or mental illness or person who are economically or educationally disadvantaged, appropriate additional safeguards are included in the study to protect the rights and welfare of these subjects.

Compliance

The Principal Investigator of the research project has primary responsibility for safeguarding the rights and welfare of individual human subjects involved in research activities. In regard to projects or grand awards, individuals planning a project or applying for awards for nonexempt human subject research are required to provide written Assurances of Compliance with 45 CFR Part 46 and to file with the application a

certification that the proposed research activity has been reviewed and approved by the IRB in compliance with 45 CFR Part 46.

Criteria for Exemption

Exemption categories are taken from the Code of Federal Regulations, Title 45, Public Welfare. Specifically, Part 46 describes procedures for the protection of human subjects. This material was issued by the Department of Health and Human Services on June 23, 2005. When claiming an exemption from review, please use the numbers from 1 to 6, corresponding to the categories below, in completing question one of the Research Protocol Outline.

(b) Unless otherwise required by department or agency heads, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from this policy:

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:

(i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and **(ii)** any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

(3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph **(b)(2)** of this section, if:

(i) the human subjects are elected or appointed public officials or candidates for public office; or **(ii)** federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

(4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

(5) Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate,

or otherwise examine:

(i) Public benefit or service programs; **(ii)** procedures for obtaining benefits or services under those programs; **(iii)** possible changes in or alternatives to those programs or procedures; or **(iv)** possible changes in methods or levels of payment for benefits or services under those programs.

(6) Taste and food quality evaluation and consumer acceptance studies, **(i)** if wholesome foods without additives are consumed or **(ii)** if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.