Southeast New Mexico College

Application Information and Instructions for the Use of Human Subjects in Research

Submission Information

What to Include in Your Submission?

a) Part A – Application Information.
b) Part B – Research Study Synopsis.
c) Part C – Assurance Document.
d) Part D – Summary of Research Proposal.
e) Part E – Consent Forms.
f) Part F – Research Instruments.

Deadlines.

The Institutional Review Board (IRB) meeting frequency depends on the number of applications we receive and the contingent on the nature of application. Proposals must be submitted a minimum of three weeks before the project start date.

Submission Information.

You must submit all materials requested. Incomplete submissions can significantly increase review and approval time.

Correspondence.

Notification concerning the IRB's decision will be made to the principal investigator via email/letter, unless otherwise requested.

Submit Proposals and Questions to:

Dr. Waheeb Al-Sharaabi, Chair (575) 234-9465 wal-sharaabi@senmc.edu Southeast New Mexico College 1500 University Drive, Carlsbad, NM 88220

General Information

Important Information for Submission.

Please read all directions and information provided. The information packet is intended to be used with the application form to help researchers fill out all needed information in a complete, accurate and detailed manner. Please submit the application and all additional materials required.

Application Form.

Part B is intended to be a brief description of the research. The boxes can be expanded but anything more than a few sentences is not necessary. However, Part D should include much more detailed and thorough responses to each section.

Proposal Reviews.

All faculty, staff, and students engaging in research that makes use of Human Subjects must have their proposal reviewed and approved by the Southeast New Mexico College Institutional Review Board (IRB).

Student Submission Information.

All Students: You must have your proposal reviewed and approved by your faculty sponsor prior to submission to the IRB. Submissions without faculty approval will not be accepted or reviewed.

Review Criteria.

In any review (Exempt, Expedited, or Full-Board), the reviewer(s) will determine whether (see p 29 –32 of IRB Handbook for definitions and conditions):

Involvement of human participants in the project is justified.

- Risks to subjects are minimized by using appropriate procedures and are justified in view of anticipated benefits.
- Research design is appropriate and will result in accurate and useful data. Wasting their time is a risk to subjects. Poorly or inappropriately designed research will not be approved.
- Appropriate supervision has been secured.
- Selection of participants is equitable and appropriate. Justification is required if the subject population is restricted to one gender or group.
- Adequate provision is made for a full declaration of confidentiality of data and anonymity of participants in any published record, as required by the approved level of review.
- Adequate provision is made for the rights and welfare of participants who are mentally, physically, economically, or educationally disadvantaged.
- Adequate provision is made for obtaining informed consent of the subjects, including those for whom English is not their first language.
- Those who are involved in the research are appropriately qualified to do the research.

Initial Review Time.

It will generally take three weeks to receive a response from the initial review depending on the type of review required. Initial review responses may include approval, request for changes, denial, or requests for more information before a review can take place. Incomplete applications will increase the review and approval time.

Approval Time.

Approval time depends on the quickness and thoroughness of the researcher's responses to requests by the Board. It will generally take three weeks, but the IRB cannot guarantee approval by any date. Please turn in submissions to the IRB in a timely manner if you are working with deadlines or on a strict schedule.

Vulnerable Populations.

Vulnerable populations, such as minors (under 18 years), persons with disabilities, prisoners, and those who are institutionalized, may require a subject advocate to be present at the full-board meeting. Please let the IRB chair know if you will be working with vulnerable populations so an advocate can be arranged as soon as possible. Failure to do this in a timely manner can delay the review and/or approval of your submission.

Part A -Application Information

Title of the Study.

The title of the study should be informative and relevant to the research being conducted.

Principal Investigator (PI).

The PI should be the person ultimately responsible for the research. Please include their contact information, i.e., address, phone number and email.

Co-Investigator(s).

Please list all co-investigators involved in the project and their college affiliation.

Research Originated By.

Please check only one box. It should be the main originator of the research.

Part B -Research Study Synopsis

Short Study Description.

This should be a brief paragraph describing the study in general. Please do not include more than a few sentences; more detailed responses are requested later in the application.

Study Length.

Provide the month and year of the start and end of the entire research study.

Location of the Study.

Include the main site of the study and any field sites to be used.

Subject Information.

Provide the total number of subjects desired, their gender and age range for all subjects involved.

Potentially Vulnerable Populations.

Please check any or all that apply. If "other" is checked, describe the vulnerable population and briefly why they are considered vulnerable.

Non-English-Speaking Subjects.

Briefly describe how researchers will communicate with any subjects that do not speak English. Also, please indicate what language(s) the consent form will be translated into. Please include both the English and the translated consent forms in Appendix E.

Dissemination of Research Findings.

Indicate both publication and presentation plans in general. It is understood that researchers may not know where these will occur. It is only necessary to indicate what the general intentions for distribution of the information are.

External Funding.

Please include not only whether funding is being sought, but also whether it has been received. Also provide the name of the agency to which the researchers have applied or who have provided the funding. Also include the dollar amount received or requested.

Method of Recruitment.

Check only those that apply. In Part D, researchers will be expected to provide a detailed description of the recruitment methods. Flyers, announcements, letters, etc. must be included with the submission for review as well.

Payment to Subjects.

Briefly address the questions asked. More detailed responses should be kept for Part D.

Extra Credit.

For those soliciting their own students to be research subjects, indicate if extra credit is offered and briefly describe the alternative available for those who do not wish to participate in the research to receive the same amount of extra credit.

Risks.

Briefly describe all risks/discomforts to the subjects. This can include, but is not limited to, emotional discomfort, breach of confidentiality, pain from procedures such as a blood draw, etc.

Benefits.

Briefly describe all benefits to participants and society in general.

Study Procedures.

This section should include brief but complete answers to all questions asked. The duration of the subjects' participation should be just their involvement in the study, not necessarily the total duration of the project. All procedures should be listed in section E. Include in section F a list of everything done just for the research (include all questionnaires, surveys, etc. in the appropriate appendix).

Informed Consent.

The IRB can approve alterations to signed informed consent if certain conditions are met. An alteration includes removing parts of signed informed consent (i.e. deception study where there is a debriefing at the end), seeking oral or phone consent rather than signed written consent or obtaining written unsigned consent.

Confidentiality.

Please be thorough in answering the questions in this section but no more than a few sentences for any one question.

Part C -Assurance Document

Signature of the Principal Investigator.

The signature of the PI is mandatory. Unsigned applications will not be accepted. By signing this section, the PI is agreeing to all of the requirements on the assurance document.

Faculty Sponsor Signature.

The faculty sponsor signature is required for all student research. Faculty should work with students to prepare a submission that is thorough, complete and ready for review by the IRB. They should also certify that they will be mentoring the student throughout the research project.

Part D -Summary of Research Proposal

Instructions: Please address these areas in a concise and informative manner. Part D should be 5 pages or less (not including instruments, consent forms, etc.). Please use 12pt font, page numbers and the headings noted below. Even if you have addressed an issue or particular information in another section of the application, it must be described here as well. Submissions that are incomplete or do not follow directions will significantly increase review and approval time.

Specific Aims.

What is the purpose of this research project?

Hypothesis.

Please briefly and succinctly state the hypothesis or questions to be tested. They should logically and clearly derive from the summary of background and significance.

Background and Significance.

This section should contain a brief review of appropriate literature with references and a statement of how the proposed project will relate to and differ from what has been accomplished previously.

Description of Subjects.

Describe subjects and the specific criteria that will be used to include or exclude persons from taking part in the study. If vulnerable subjects are included, justify their inclusion. Describe how subjects will be recruited into the study and how consent will be obtained.

Confidentiality.

Detail how confidentiality will be maintained. This includes a description of the secure storage of data (including notes, tapes, etc.) gathered in the study, what will happen to this information after the study (i.e., the tapes will be destroyed, materials will be donated to an archive, etc.), and who will have access to the data during the study and reporting.

Method or Procedures.

Describe in detail all methods and procedures, including research design. Instruments, questionnaires, surveys, interview questions, etc. should be attached in Part F. Include here a description of all instruments and questionnaires to be used. Any interventions, drawing of blood, or other procedures should be described including who will be doing the procedure and their qualifications. Be very specific about methods for obtaining the data.

Risks.

All potential risks to the participants should be listed. Potential risks may include emotional discomfort due to the nature of the questions being asked, breach of confidentiality, etc. If risks are minimal, then it should be stated. Describe protection measures used and method(s) of handling any potential adverse reactions to the data collection techniques.

Benefits.

All benefits to the subjects and to society should be listed. If there are no direct benefits to research subjects, state this and then describe the benefits to society.

Compensation.

Describe compensation to subjects, if any. This may include money, gift certificates, vouchers, drawings, and/or extra credit. Detail the method of providing compensation, if and how it will be prorated, and when it will be given. If extra credit is offered, describe a fair alternative to receive the same amount of credit.

References.

This should include the complete bibliography of any literature cited in the submission.

Qualifications.

Describe the duties and qualifications of all those involved in the research. Qualifications should be described in detail. The IRB will not approve of research unless researchers, and those who assist them, are appropriately qualified for their roles in the study.

Part E - Consent Forms

Please include a copy of all consent documents and include all the elements of informed consent including any script for oral consent if it is being requested. Include language translations if necessary.

Part F – Research Instruments

Please include copies of all Questionnaires, Surveys, Interview Questions, etc.