

SUU IRB PROPOSAL SUBMISSION FORM INSTRUCTIONS

The SUU IRB reviews all University research proposals involving human participants to determine if the research participants are placed at risk and if their rights and welfare are adequately protected.

The SUU IRB Proposal Submission form has been designed to provide the SUU IRB with the information it needs to evaluate your proposal. Complete each item carefully. Items that sometimes cause difficulty are clarified as follows:

- Item 2. **PRINCIPAL INVESTIGATOR.** This may be a faculty member, staff member, or student. The PI oversees and monitors the research on an on-going and continual basis.

- Item 3. **SUPERVISOR.** This refers to the faculty member who is responsible for supervising research conducted by students or staff. Faculty members do not need to name anyone as their supervisor.

- Item 5. **IRB TRAINING CERTIFICATES.** Online IRB training for principal investigators and supervisors (if applicable) can be found at the following URL: <http://phrp.nihtraining.com> Be sure to save an electronic copy of the completion certificate at the end of the course. This certificate must be on file with SUU's IRB and if applicable, with the Sponsored Programs, Agreements, Research and Contracts Office (SPARC) before a proposal will be reviewed. Individuals need only complete the training once, unless significant changes to federal regulations are made which would necessitate re-training.

- Item 9. **WHAT ARE YOUR RESEARCH QUESTIONS AND WHY ARE THEY IMPORTANT.** Many applicants interpret this requirement incorrectly. Research is a formal method of investigation used to answer *questions*. The IRB needs to know what questions for which you are seeking answers. The importance of the questions will be given more weight for full board reviews than for exempt or expedited reviews.

- Item 10. **DESCRIBE HOW PARTICIPANTS WILL BE RECRUITED AND ANY PROPOSED COMPENSATION OR INCENTIVE TO PARTICIPATE.** Be sure to describe the method of participant selection and recruitment in detail. For example, do not simply say that participants will be randomly selected for participation. Describe *how* this will be done.

- Item 11. **MATERIALS AND/OR APPARATUSES.** Describe any survey, interview, or questionnaire which will be administered to the participants. Include all questions to be asked in the IRB proposal. In the case of an unstructured or semi-structured interview, describe the general line of questioning and/or any restrictions which will be followed. Submit one copy of each research instrument. If one or more apparatus are to be used, include a full description of the equipment.

- Item 12. **DESCRIBE THE RESEARCH METHODOLOGY IN NON-TECHNICAL LANGUAGE.** The SUU IRB needs to know in nontechnical terms what will happen to and what will be expected of each research

participant. If any deception is planned, you need to explain why it must be included (i.e., rule out any alternatives). Deception involving more than minimal risk to participants will not be permitted.

Item 13. RISK/BENEFITS & PARTICIPANT INFORMATION. All applicants must complete and submit this *ASSESSMENT OF VULNERABILITY section*. This information is used by the IRB to determine the level of IRB review: exempt, expedited, or full board. Only the IRB can make this determination. If the magnitude and probability of harm to a participant are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests, then the protocol involves no more than minimal risk. If the protocol involves more than minimal risk, then you must carefully specify your procedures for protecting participants. Explain why the risk is justified.

Item 15. INFORMED CONSENT. Giving potential research participants all of the information that they might reasonably need to know in order to decide whether they will choose to participate, and the obtaining of their agreement to participate is known as the informed consent process. This process must be followed in all but extraordinary circumstances (e.g., in cases where participants' knowledge of the experiment/study would completely invalidate the research). SIGNED informed consent is required for research which involves more than minimal risk and/or tests a vulnerable population (e.g., minors, mentally or physically disabled, hospitalized/institutionalized individuals etc...). SIGNED consent must be obtained from legal guardians in cases where participants are not legally able to give their consent. SIGNED informed consent is also required if the data can be linked to individual participants and this information will be made public.

Note that no investigator may release or appear to release him/herself or SUU from liability for negligence.

PROCEDURE FOR SUBMITTING PROPOSALS TO THE IRB:

Submit the IRB application with all supporting document (e.g., all survey questions) to Michelle Grimes (michellegrimes(at)suu.edu).

Please type your name on the signature line of the application form and type the date. By doing this the Principal Investigator is providing their signature to the proposal. When the Principal Investigator is a student or staff member, a faculty supervisor must also sign the proposal.

Processing of your proposal may be faster if you read and adhere to the instructions above. Most proposals are delayed because of a need to make minor changes to the informed consent.

Properly completed proposals generally take 1-2 weeks to approve (if exempt or expedited), or 3-4 weeks to approve (if full board) after the monthly deadline (i.e., the 7th of each month). Please plan accordingly and be ready to anticipate unexpected delays.