

# Application for Human Subjects Research Proposals

# Scientific Merit Review

# Application to the Research Advisory Board

**For Information and Assistance:** Contact the RAB chair, Dr. Arben Lasku, a.lasku@sonoran.edu, at 480-858-9100 x324.

1. **RESPONSIBLE PROJECT INVESTIGATOR (RPI)** The RPI must be a non-visiting member of the Sonoran faculty or staff who will serve as project supervisor. **For other research team members [including those from other institutions], please complete the Research Team Attachment and provide with the completed application.** Include all persons who will be 1) directly responsible for the project’s design or implementation, 2) recruitment, 3) obtain informed consent, 4) involved in data collection, data analysis, or follow-up.

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| **Last Name:**  | First Name:        | Academic Degree(s):       |
| **Dept. or Unit:**  | Office Address:       |  |
| **Street Address:**  | City:       | State:       | Zip Code:       |
| **Phone:** | **Fax:** | E-mail:       |
| **Sonoran Campus Status: Nonvisiting member of (Mark One)** **[ ]  Faculty** **[ ]  Academic Professional/Staff** |
| **Training****[ ]  NIH Human Subjects Training, Date of Completion,****[ ]  Additional training, Date of Completion[[1]](#footnote-1),**  |

1. **PROJECT TITLE**

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SUMMARIZE THE RESEARCH

Describe the purpose, specific aims, or objectives. State the hypotheses to be tested. Describe the relevant prior experience and gaps in current knowledge. Describe any relevant preliminary data. Describe any limitations or difficulties anticipated.

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1. **RESEARCH PROCEDURES: S**pecifically describe what the participants (treatment groups and controls) will do and where the research activities will take place. Give approximate dates and durations for specific activities, including the total number of treatments, visits, or meetings required and the total time commitment. Include whether or not subjects will be randomized and if so, using what methods? Be sure to list principal and secondary outcome variables to be measured. Describe your plan for data analysis and statistics.

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1. **MEASURES** If subjects will complete questionnaires, surveys, interviews, psychological measures, or other measures, however administered, the IRB must review and approve the measures.

List all such measures here and attach complete, labeled copies (including translations, if applicable) to this application:

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| Measure 1: |       | [ ]  Attached [ ]  Will Follow |
| Measure 2: |       | [ ]  Attached [ ]  Will Follow |
| Measure 3: |       | [ ]  Attached [ ]  Will Follow |
| Measure 4: |       | [ ]  Attached [ ]  Will Follow |

List additional Measures on an attachment and check here: [ ]

**ANTICIPATED NUMBERS** How many subjects, including controls, will you study in order to get the data that you need?

If you plan to study disproportionate numbers of a given sex, race, or minority group, provide scientific rationale.

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| --- | --- | --- | --- |
| **Performance Site** | **# Male** | **# Female** | **Total** |
| 1. |       |       |       |       |
| 2. |       |       |       |       |
| 3. |       |       |       |       |
| **TOTALS** |       |       |       |

List Anticipated Numbers for additional Performance Sites on an attachment and check here: [ ]

1. **INCLUSION AND EXCLUSION CRITERIA** Address all four of the following items in explaining who will and will not qualify for participation and how that determination will be made: (1) Describe procedures to assure equitable selection of subjects. Justify the use of any special or vulnerable groups. Selection criteria that target one sex, race, or ethnic group require a clear scientific rationale. (2) List specific criteria for inclusion and exclusion of subjects in the study, including treatment groups and controls. (3) Name and attach copies of measures and protocols that will be used to screen applicants. (4) Explain how the inclusion/exclusion criteria will be assessed and by whom. If special expertise is required to evaluate screening responses or data, tell who will make this evaluation and describe their training and experience.

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1. **DATA COLLECTION** Explain how the data will be collected. If anonymous data collection is proposed, provide details of how investigators *will not have the ability to trace responses to subject identities.* For multiphase data collection or if multiple contacts will be made with subjects, specifically explain the subject tracking and coding systems.

Address the confidentiality of data collected via e-mail, databases, Web interfaces, computer servers, and other networked information, as applicable.

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1. **INFORMED CONSENT:** Sonoran policy requires the execution of a comprehensive, written document that is signed by the subject (or the subject’s authorized representative) as the principal method for obtaining consent from subjects. The language in the document must be understandable to the subject or the subject’s legally authorized representative.

Describe when and where voluntary consent will be obtained, how often, by whom, and from whom. If cognitively impaired subjects (including children under age 8) will be involved, explain how the subject’s understanding will be assessed and how often; include the questions that will be asked or actions that will be taken to assess understanding.

Describe any waiting period between informing the prospective subject and obtaining the consent. Describe steps taken to minimize the possibility of coercion or undue influence. Indicate the language used by those obtaining consent.

Indicate the language understood by the prospective subject or the legally authorized representative.

If the research involves pregnant women, fetuses, or neonates, indicate whether consent will be obtained from the mother, father, or both. If the research involves children, indicate whether consent will be obtained from: Both parents unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child; or from one parent regardless of the status of the other parent.

**SUBJECT REMUNERATION**

 Will subjects receive inducements or rewards before, during, or after participation?

 **[ ]**  Yes **[ ]**  No

If yes, will payment be prorated for partial participation?

**[ ]** Yes **[ ]**  No

1. As the principal investigator, I acknowledge that I am personally responsible for all aspects of this research proposal. I will be responsible for all communications with the RAB and will be responsible for submission of this project to the IRB once RAB approval is obtained.

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Signature of Principal Investigator Date

Attachments:

1. CVs of all personnel associated with the research
2. Questionnaires or surveys used as part of this research
3. Letters of association or cooperation with all entities involved in this research outside of Southwest College.
4. Statement of support from the Sonoran medical center or research department, as appropriate.
1. Additional training modules may be required depending on subject populations or types of research. These include: (i) research enrolling children; (ii) research enrolling prisoners; (iii) FDA regulated research; (iv) data collected via the internet; (v) research conducted in public elementary/secondary schools; and, (vi) researchers conducted in international sites [↑](#footnote-ref-1)