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| This Section is for Office Use Only | |
| Sonoran IRB Protocol No. |  |
| Exempt under 45 CFR §46.101(b) (1) (2) (3) (4) (5)  (6) | Reviewer 1: |
| Expedite, Category (1)(2)(3)(4)(5)(6)(7)(8)(9) | Reviewer 2: |

Initial Submission, date of submission

Revised New Protocol Application, date of revised New Protocol Application

Protocol has been reviewed and approved by the Sonoran RAB

**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: Non-visiting member of (Mark One)**  **Faculty**  **Academic Professional/Staff  Student** | | | | | | |
| **Training**  **NIH Human Subjects Training, Date of Completion,**  **Additional training, Date of Completion[[1]](#footnote-2),**  **Please attached a copy of the CV for each investigator or research team member.** | | | | | | |

**2. PROJECT TITLE**

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**3. FUNDING** Indicate whether this research is funded by, or application has been made for, a grant, contract, or gift.

**3A. STATUS**  Research is **not funded** and is **not pending** a funding decision (Proceed to Part 4).

Research is **funded** (funding decision has been made).

Funding decision is **pending**. Funding proposal submission date:

**3B. SOURCE(S)** If the research is funded or pending a funding decision, mark and name all sources:

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| **Type of Funding—check all that apply** | | **Name of Source** |
|  | **Federal**  (from federal agencies, offices, departments, centers) |  |
|  | **Commercial Sponsorship & Industry[[2]](#footnote-3)**  (from corporations, partnerships, proprietorships) |  |
|  | **State Department or Agency**  (from any state office or entity) |  |
|  | **Gift or Foundation (including SAGE)**  (public or private foundations, not-for-profit corporations, private gifts) |  |
|  | **Other** (please specify) |  |

**3C. PROPOSAL** Attach a complete copy of the funding proposal or contract.  Attached

Sponsor-assigned grant number, if known:

Title of Funding Proposal or Contract, if different from Project Title in Part 2:

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**3D. FUNDING AGENCY OFFICIAL, IF ANY, TO BE NOTIFIED OF IRB APPROVAL**

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| --- | --- | --- | --- | --- | --- | --- | --- |
| Last Name: | | First Name: | | Salutation: | | | |
| Agency: | | Office Address: | | | |  | |
| Street Address: | | City: | | | State: | | Zip Code: |
| Phone: | Fax: | | E-mail: | | | | |

**4. FINANCIAL INTERESTS:** Indicate below if any investigators or any members of their immediate families have any relationships, commitments, or activities with the sponsor of this research that might present or appear to present a conflict of interest with regard to the outcome of the research.

Ownership, equity or stock options

Personal compensation such as royalties, consulting fees etc.

Intellectual property such as patents, trademarks, copyright, licensing, etc.

Other conflict of interest:

No conflicts exist

5. SUMMARIZE THE RESEARCH.

In LAY LANGUAGE, summarize the objectives and significance of 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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**6. PERFORMANCE SITES**

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| Including Sonoran, sites,describe ALL the research sites for this protocol. For each non-Sonoran site, describe: Whether the site has an IRB. Whether the site has granted permission for the research to be conducted. Contact information for the site. If the site has an IRB, whether the site’s IRB has approved the research or planned to defer review to the Sonoran IRB. Each site has the most current version of the protocol, consent document and HIPAA authorization. Describe processes for communication with sites and safeguarding data at sites.  For Sonoran sites, documentation of IRB approval is: | | | |
| 1 |  | Attached  Will Follow  N/A |
| 2 |  | Attached  Will Follow  N/A |
| 3 |  | Attached  Will Follow  N/A |

List and describe any additional Performance Sites information on an attachment and check here:

**7. DESCRIBE THE HUMAN SUBJECTS**

**7A. SECONDARY DATA ONLY?** If this research *only* involves the analysis of data that *has already been collected* from human subjects and *no new data collection will occur,* check here:

**7B. MATERIALS OF HUMAN ORIGIN?** Will this research involve the collection, analysis, or banking of human biological materials (*e.g.,* cells, tissues, fluids, DNA)?  **Yes  No**

If yes attach **Appendix C**, the *Biological Materials Form.*

**7C. 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 in Part 11.

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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:

**7D. AGE RANGE** Mark all that apply. Researchers planning to include children in research projects involving *more than minimal risk* must provide written documentation of the benefits that are likely to accrue to a child participating in the project. This should include information gathered on adults, if it exists, or an explanation about why it does not exist.

0–7 years 8–17 years  18–64 years  65+ years

If applicable, written documentation of benefits for including children in ***more than minimal risk*** research is attached.

**7E. SPECIAL OR VULNERABLE POPULATIONS** Mark groups that will be targeted by design. Also indicate groups likely to be involved in the research even though they are not targeted by design.

None of the following special populations will be targeted

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| Children (age < 18 years) |  | | |
| Neonates | Mentally disabled or cognitively impaired persons | | |
| Fetuses *(in utero)* | Adults with legal guardians | | |
| *in vitro* fertilization subjects | Persons with limited civil freedom (*e.g.,* prisoners) | | |
| Pregnant or lactating women | Specific racial or ethnic group(s)— describe: |  | |
| Inpatients | Low income or economically disadvantaged persons | | |
| Outpatients | Students | |  |
| Elderly (age > 65 years) | Undocumented individuals | |  |
| Other (describe here): |  | | |

**7F.** if you checked any of the groups in question 7E, describe additional safeguards included in the protocol to protect the rights and welfare of special or vulnerable populations.

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**8. Recruitment**

**8A-1 RECRUItING Procedures** specifically describe the systematic procedures for finding and recruiting subjects or requesting pre-existing data or materials. 1) State whether any of the researchers are associated with the subjects (*e.g.,* subjects are students, employees, patients). 2) Name any specific agencies or institutions that will provide access to subjects or subject data. 3) Who will contact the prospective subjects? 4) Who gives approval if subjects are chosen from records? 5) Describe solicitation through the use of advertising (*e.g.,* posters, flyers, announcements, newspaper, radio, television, Internet), face-to-face interaction, direct mail or phone contact, classrooms, subject pools, health care registries, patient referrals, and institutional “gatekeepers,” as applicable.

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**8 A-2 Attach final copies of recruiting materials** including the final copy of printed advertisements and the final version of any audio/taped advertisements and check here:

Attached  Will Follow

**8B. WITHHELD INFORMATION** Do you propose to withhold information from subjects prior to or during their participation?

Yes  No

If yes, describe what will be withheld, justify the withholding (address risks, provide rationale), describe the debriefing plan, and attach a labeled copy of a written debriefing form, to be provided to subjects.

Debriefing Attached  Will Follow

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**8C. PROTECTED HEALTH INFORMATION (PHI)** The IRB must address the privacy and use of health information that is created, received, or housed by health care providers, health plans, or health care clearinghouses and that identifies or could be used to identify an individual. During *either recruiting or data collection*, will you use or have access to such information that is related to the past, present or future health or conditions of a *living or deceased* individual, provision of health care to the individual, or the payment for the provision of health care to the individual?  Yes  No

If yes, please obtain and utilize form: *AUTHORIZATION FORM FOR USE AND DISCLOSURE OF*

*PROTECTED HEALTH INFORMATION (PHI) FOR RESEARCH*

**9. 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 marked in Part 7E. 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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**10. RESEARCH PROCEDURES: Using LAYMAN’S LANGUAGE,** specifically describe what the participants (treatment groups and controls) will do and where the research activities will take place. Give 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? Describe your plan for data analysis and statistics.

(For schools-based research where class time is used, describe in detail the activities planned for nonparticipants and explain where (*e.g.,* in a classroom, in a private area) both participants and nonparticipants will be located during the research activities. Include a concise description of procedures, locations, time commitments, and alternate activities on the relevant consent and assent forms.)

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**11. EQUIPMENT** Will any physical stimulation or physiological data acquisition equipment be used with the subjects?

Yes  No If yes, attach **Appendix A**, the *Research Equipment Form.*

**12. DEVICES** Will any devices be used with the subjects?

Yes  No If yes, attach **Appendix B-1,** the *Device Form*.

**13. DRUGS AND BIOLOGICS** Will any drugs or chemical or biological agents be used with the subjects?

Yes  No If yes, attach **Appendix B-2**, the *Drug and Chemical Usage Form*.

**14. 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:

**15. 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

If remuneration will be given, for each subject group:

1. Specify the form of remuneration, including $, course credit, lottery, gift certificate, or other;
2. State the $ amount or the approximate $US value, or the course credit and its percentage of the final grade;
3. Explain the remuneration plan, including whether and how prorating will be made for partial participation;
4. For lotteries, include (a) the number of prizes, (b) the nature and value of each prize, (c) the approximate odds of winning, (d) the date(s) of the drawing(s), and (e) how winners will be notified, by whom, and by when; and
5. Include all this information on the relevant consent forms.

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**16. SUBJECT OUTLAY** Will subjects incur costs for research-related procedures (*e.g.*, longer hospitalization, extra tests), use of equipment, lost compensation, or transportation (over 50 miles)? Yes  No

If yes, describe here:

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**18. CONFIDENTIALITY OF DATA** Answer each of the following to describe methods that will ensure the confidentiality of individually identifiable data. Confidentiality is required unless subjects give express, written permission to have their identifiable information published, presented, or shared.

**18A. CHECK IF USED IN DATA COLLECTION:**  Audio tapes/digital voice  Video tapes

Still photos  Other imaging

**18B. 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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**18C. DATA SECURITY** Describe how and where the data be kept so that the data remain confidential.

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**18D. STAFF TRAINING** Describe the training and experience of all persons who will collect or have access to the data.

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**18E. DATA RETENTION** How long will the data be kept?

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**18F. DISSEMINATION OF RESULTS** what is (are) the proposed form(s) of dissemination (*e.g.,* journal article, thesis or academic paper, conference presentation, sharing within industry or profession)?

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**18G. PRIVACY** Describe provisions to protect the privacy interests of subjects.

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**18H. INDIVIDUALLY IDENTIFIABLE INFORMATION** Will any individually identifiable information, including images of subjects, be published, shared, or otherwise disseminated?  Yes  No

**If yes,** subjects must provide explicit consent or assent for such dissemination. Provide appropriate options on the relevant consent documents.

**19. 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.

An investigator may request a Waiver or Alteration of Informed Consent or a Waiver of Documentation of Informed Consent (e.g., online consent, oral consent). If requesting a waiver please complete the appropriate waiver form and submit it with the New Protocol Application form for review.

**Children must *assent*** (or voluntarily agree) to participation and a parent must separately consent on behalf of their child (*i.e.,* two different forms are generally required). Children under age 8 may assent either orally or passively, depending on their level of maturity. Children 8–17 years old should sign a written form unless the Sonoran IRB approves a different process.

**19A. TYPE OF CONSENT** Check all that apply and attach one copy of each relevant form, letter, or script on appropriate letterhead. Include translations, if consent will be obtained in a foreign language. Use headings, headers, or footers to uniquely identify each document and associate it with the subject group for which it will be used.

**Written** **informed consent (assent) with a document signed by**

adult subjects  parent(s) or guardian(s)  adolescents aged 8–17 years

**Waiver or Alteration of Informed Consent (Attach waiver form.)**

adult subjects  parent(s) or guardian(s)  adolescents aged 8–17 years

**Waiver of Documentation (signature) of Informed Consent (Attach waiver form.)**

adult subjects  parent(s) or guardian(s)  adolescents aged 8–17 years

**19B. USE OF PROXY** Will others (*e.g.,* next of kin, legal guardians, powers of attorney) act on behalf of adult subjects in giving consent to participate in this research?  Yes  No (if yes, describe in Section 19D.)

**19C. USE OF PROXY OUTSIDE THE UNITED STATES** If a proxy is used in research conducted outside Arizona, provide justification (e.g., statement of an attorney or copy of applicable law) that the proxy is authorized under the laws of the jurisdiction in which the research will be conducted to consent to the procedures involved in this protocol.

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**19D. CONSENT PROCESS** 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.

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**20. RISKS**

**20A. DESCRIPTION** specifically describe all known risks to the subjects for the activities proposed and describe the steps that will be taken to minimize the risks. Include any risks to the subject’s physical well-being, privacy, dignity, self-respect, psyche, emotions, reputation, employability, and criminal and legal status. Risks must be described on consent forms.

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**20B. RISK LEVEL:**

**No more than minimal risk**

(The probability and magnitude of harm or discomfort anticipated for participation in the proposed research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests).

**More than minimal risk**

**20C. Data Monitoring Plan:** If you checked that the research is more than minimal risk, describe the provisions for monitoring the data to ensure the safety of subjects (Who will periodically monitor harms and benefits experienced by subjects to ensure that the relationship of risks to potential benefits remains unchanged? How often will monitoring occur? What analyses will be performed? If appropriate, what criteria will be used to stop the research based on monitoring of the results?)

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**21. BENEFITS** Describe the expected benefits of the research to the subjects and/or to society.

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**22. RISK/BENEFIT ASSESSMENT** Weigh the risks with regard to the benefits. Provide evidence that benefits outweigh risks.

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If additional Risk/Benefit information is attached, check here:

**23.** Is this a multi-center study in which the Sonoran investigator is the lead investigator of a multicenter study, or Sonoran is the lead site in a multi-center study.

**Yes**  **No**

If yes, describe the management and communication of information obtained that might be relevant to the protection of subjects, such as: unanticipated problems involving risks to subjects or others, interim results and protocol modifications.

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**24. INVESTIGATOR ASSURANCES: The signature of the Responsible Project Investigator is required** (scanned or faxed signatures are acceptable). Other investigators are also responsible for these assurances and are encouraged to sign.

I certify that the information provided in this application, and in all attachments, is complete and correct.

I understand that I have ultimate responsibility for the protection of the rights and welfare of human subjects, the conduct of this study, and the ethical performance of this project.

I agree to comply with all Sonoran IRB policies and procedures, the terms of its Federal Wide Assurance, and all applicable federal, state, and local laws regarding the protection of human subjects in research.

I certify that

1. The project will be performed by qualified personnel according to the Sonoran IRB-approved protocol.
2. The equipment, facilities, and procedures to be used in this research meet recognized standards for safety.
3. No change will be made to the human subjects protocol or consent form(s) until approved by the Sonoran IRB.
4. Legally effective informed consent or assent will be obtained from human subjects as required.

Unanticipated problems, adverse events, and new information that may affect the risk–benefit assessment for this research will be reported to the Sonoran IRB Committee – [IRBchair@sonoran.edu](mailto:IRBchair@sonoran.edu).

1. I am familiar with the latest information concerning IRB regulations and policies, and I will adhere to the policies and procedures explained therein.
2. Student and guest investigators on this project are knowledgeable about the regulations and policies governing this research.
3. I agree to meet with the investigator(s), if different from myself, on a regular basis to monitor study progress.
4. If I will be unavailable, as when on sabbatical or other leave, including vacation, I will arrange for an alternate faculty sponsor to assume responsibility during my absence. I will advise the Sonoran IRB by letter of such arrangements.

I further certify that the proposed research has not yet been done, is not currently underway, and will not begin until IRB approval has been obtained.

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| Responsible Principal Investigator | Date |  | Investigator | Date |
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| Investigator | Date |  | Investigator | Date |

**25. (OPTIONAL) DEPARTMENTAL ASSURANCE** To be completed by the PI’s Departmental Chair or their designee.

The activity described herein is in conformity with the standards set by our department and I assure that the principal investigator has met all departmental requirements for review and approval of this research.

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| Departmental Executive Officer (or designee) | Date |

**\*** For units that conduct **scientific merit review, (RAB)** the signature above documents the following:

1. The research uses procedures consistent with sound research design.

2. The research design is sound enough to yield the expected knowledge.

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-2)
2. Clarify whether or not sponsor requires specific language in the contractual agreement that impacts human subjects research [↑](#footnote-ref-3)