**Red text is instructional. Delete all red text prior to submitting this form.**

**You are required to complete this form when the UA will be the IRB of Record for Human Subjects Research. The IRB will review your submission. If you have a sponsor protocol, this document is still required.**

**Use simple language for all items below. For more complete technical explanations, reference the title and page numbers for any items described in the sponsor’s protocol or other documents submitted with the application.**

|  |  |  |
| --- | --- | --- |
| **Basic Information** | | |
| **Title of Study:** |  |
| **Short Title:** |  |
| **Principal Investigator Name:** |  |
| **Principal Investigator’s Department/Unit:** |  |

# Background (Limit 1,000 words):

**Provide the scientific or scholarly background for the proposed Human Research. Discuss relevant prior experience or preliminary data (e.g., existing literature).**

# Lay Summary:

**Provide a brief description of the proposed research using terms that someone who is not familiar with the science or discipline can understand.**

# Purpose:

**Describe the purpose, specific aims, objectives, questions to be answered, hypotheses, and/or primary and secondary study endpoints of this Human Research protocol.**

# Funding Information:

**Indicate all sources of funding for the project, including gift funds, departmental funds, or other internal funding. For each funder, list the name of the funder, and the institutional proposal number or award number you received from Sponsored Projects.** **eIRB tip: For externally funded projects, the institutional proposal or award number provided must be linked in the “Study Funding Sources” section in eIRB.**

**HSPP charges fees for the review of industry funded research or for federally funded research requiring a single IRB. Review the HSPP Guidance** **[Fees for Human Research](https://research.arizona.edu/sites/default/files/Fees%20for%20Human%20Research%20v2021-09.pdf) and provide the IRB payment eDoc number. Submissions with an invalid or unfinalized eDoc number will not be reviewed until the payment is final.**

|  |  |
| --- | --- |
| **No Funding** | |
| **Federal Funding**, including flow-through federal funding (i.e., NIH, NSF, DoD, etc.) | Name of funding source: |
| Institutional Proposal or Award Number: |
| eDoc # (for multi-site projects): |
| **Industry Funding** | Name of funding source: |
| Institutional Proposal or Award Number: |
| eDoc #: |
| **Foundation Funding** | Name of funding source: |
| Institutional Proposal or Award Number: |
| **Department Funding** | Name of funding source: |
| **Gift Funding** | Name of funding source: |
| **Other** | Name of funding source: |

# Resources Available to Conduct the Human Research:

**Describe the resources (facilities, time, emergency resources, etc.) available to recruit, consent, conduct study procedures, and analyze data.**

# Study Population:

* 1. **Select all the categories of participants included in the research:**

|  |  |
| --- | --- |
| Healthy adults | Non-English-speaking subjects |
| Non-healthy adults | UA staff/faculty |
| Children (under 18 years old) \* | UA students |
| Pregnant women, neonates, and/or fetuses\* | Banner employees |
| Prisoners\* | Refugees |
| Native Americans, Alaskan Native, and Indigenous Populations\* | Other – please explain: Click or tap here to enter text. |
| Adults unable to consent (i.e., cognitively impaired adults) \* |

**\*Complete and attach the appropriate** [**HSPP Appendices**](https://research.arizona.edu/compliance/human-subjects-protection-program/HSPP-form/forms-index) **if your subjects include children, pregnant women, neonates, prisoners, cognitively impaired individuals, or Native Americans or Indigenous Populations. eIRB tip: appendices should be uploaded in the “Other Attachments” section in eIRB.**

* 1. **For each of the above selected categories, describe the inclusion and exclusion criteria. Indicate age range, gender, and ethnicity.**
  2. **Describe the total number of subjects to be enrolled locally under this IRB approval. If obtaining specimens, specify the maximum number of specimens needed for this project.**

# Recruitment Methods:

* 1. **Select the methods used to recruit individuals.**

|  |  |
| --- | --- |
| Email | Screening of the Electronic Medical Record (EMR) |
| Face to face | Social media |
| Flyers | SONA System |
| In person presentations | TV, Radio, Print |
| Online advertisements | Other – please explain: Click or tap here to enter text. |
| Phone calls |

**Refer to the HSPP Guidance,**[**Recruitment and Advertisements**](https://research.arizona.edu/sites/default/files/Recruitment%20and%20Advertisements%20v2023-07.pdf)**. Provide copies of any materials used to recruit subjects directly (e.g., recruitment scripts, emails, print/audio/visual advertisements, or online notices). Please ensure all recruitment materials state the project has been reviewed and approved by the University of Arizona IRB. eIRB tip: all recruitment material should be uploaded to the “Recruitment Materials” section in eIRB.**

* 1. **Explain the recruitment process. Describe how potential subjects will be identified, where recruitment will take place, when recruitment will occur, and the methods that will be used to recruit individuals.**

# Diversity, Equity, and Inclusion

* 1. **Explain how the research plan (recruitment, study population, data collection, etc.) is equitable and represents the demographic makeup for the location in which the research will be conducted.**
  2. **Describe whether non-English speaking subjects will be included in the study. If yes, please explain how your research team is prepared to meet the needs of the population. If not, please explain why non-English speakers will be excluded from the study population.**
  3. **What methods will you use to collect demographic information from participants? If you will not collect demographic information, please explain why not.**

# Consenting Process:

* 1. **Indicate the informed consent process(es) and/or document(s) for the study. Check all that apply.**

|  |
| --- |
| **Written Consent** |
| Informed Consent (ICF) – written or electronically signed form |
| Parental Permission – written or electronically signed form |
| Assent (participants under 18) – written or electronically signed form |
| Combined ICF/PHI Authorization – written or electronically signed form |
| Standalone Protected Health Information (PHI) HIPAA Authorization – written or electronically signed |
| Translated Consent/Assent – written or electronically signed form(s) |
| Short Consent Form – written or electronically signed form (see guidance on [**Short Form process**](https://research.arizona.edu/compliance/human-subjects-protection-program/HSPP-forms/consent-templates)) |
| Debriefing Script or Form – document used to properly inform subjects of the study’s purpose when intentionally deceived |

|  |
| --- |
| **Oral/Online/Unsigned Consent** **(Appendix for Alteration/Waiver of Consent or PHI is Required for upload into eIRB)** |
| Informed Consent – oral script/online/unsigned |
| Parental Permission – oral script/online/unsigned |
| Assent – oral script/online/unsigned |
| Translated Consent/Assent – oral script/online/unsigned |

|  |
| --- |
| **Waivers of Informed Consent and/or PHI Authorization** |
| Waiver of Consent |
| Full Waiver of PHI Authorization |
| Partial Waiver of PHI for Screening Purposes |

**Word versions of all consenting documents are required. Use HSPP** [**template consent forms**](https://research.arizona.edu/compliance/human-subjects-protection-program/HSPP-forms/consent-templates)**.** **eIRB tip: all consent forms should be uploaded in the “Consent Forms” section in eIRB.**

* 1. **Describe in detail the consent processes checked above, including any waiting period for subjects to sign the consent, steps to minimize the possibility of coercion or undue influence, and the language used by those obtaining consent.**
  2. **Where will the original signed consent and PHI authorization documents be stored?**
  3. **Acknowledgement of consent form storage.**

|  |
| --- |
| I will store original signed consent and/or PHI authorization documents for at least 6 years past the time the study is concluded. |
| For studies involving minors, I will store original signed consent and/or PHI authorization documents for at least 6 years after the youngest participant turns 18. |
| Not applicable – I am not collecting signed documents. |

# Research and Data Collection Procedures:

* 1. **Select the methods of data collection that will be used in this study (select all that apply):**

|  |  |
| --- | --- |
| Anthropometric measures (e.g., height, weight, waist circumference,  etc.) | Participant observation |
| Audio/video recording | Screening data |
| Benign interventions | Self-health monitoring (e.g., pedometers, food diaries, etc.) |
| Biological specimens – blood draws | Surveys – paper |
| Biological specimens – clinically discarded blood or specimens | Surveys – internet (including online and email-based data collection) |
| Biological specimens (urine/feces, tissue, saliva, skin, hair, nails, nasal swab) | Surveys – telephone |
| Clinical Data Warehouse (CDW) | Randomization with control and experimental groups |
| Cognitive or behavioral measures, including daily diaries | Records – billing |
| Data collected using other communication/electronic devices (e.g., cell phones, pagers, and texting devices) | Records – educational |
| Data previously collected for research purposes | Records – employee |
| Deception | Records – lab, pathology and/or radiology results |
| Instrumentation, equipment, or software not approved by the FDA | Records – mental health |
| Interviews – focus groups | Records – substance abuse |
| Interviews – in person | Research imaging protocols |
| Interviews – virtual/online | Recombinant DNA |
| Medical records review | Social networking sites |
| MRI/ultrasound with contrast | Stem cells |
| MRI/ultrasound without contrast | Radiation Scans (X-Ray, CT Scans, etc.) |
| Non-invasive instruments (e.g., external sensors applied to the body) | Other activities or interventions – describe: Click or tap here to enter text. |

**Attach all surveys, scripts, and data collection forms.** **eIRB tip: data collection tools should be uploaded in the “Other Attachments” section in eIRB.**

**If the study involves an investigational drug or device, complete and attach the Appendix for Drugs or the Appendix for Devices. Note: Drugs and devices may be used in research but may not be the purpose of the investigation (e.g., as an adjunct to a standard procedure or test for screening). Information about these drugs or devices must be included in this section so an assessment of risk and safety to subjects can be made. eIRB tip: under the “Study Scope” section in eIRB, if you are investigating drugs, biologics, food and dietary supplements, mark Question 1 “Does the study specify the use of an approved drug or biologic..?” as *YES* to ensure the appropriate Smart Form populates.**

* 1. **Description of research procedures.**

**Provide details of EACH research procedure in chronological order using simple language. Be clear when identifying which procedures are specifically for research, and which study population will be completing each study procedure. Include a description of all procedures already being performed on subjects for diagnostic or treatment purposes.**

**If there are plans for long-term follow-up (once all research related procedures are complete), describe what data will be collected during this period. For projects investigating drugs/devices or treatment plans, describe the tests and procedures that will be done to accomplish this. If applicable, discuss the randomization ratio, the dosages of drugs being used, and the investigational treatment plan.**

**If this is a multisite study where UArizona IRB will oversee an outside site, please briefly summarize what participating sites will be involved and what their role(s) will be.**

* 1. **Specify the total estimated time commitment for subject participation, and the estimated time commitment for each activity.**
  2. **If any biological specimens (blood, urine, tissue, etc.) are being collected for research, state the amount (ml/tsp/tbsp, etc.), method, frequency, and type of specimen to be collected and what the specimen will be used for.**
  3. **If the study is a** [**clinical trial**](https://grants.nih.gov/policy/clinical-trials/definition.htm)**:**

**a) Confirm registration with** [**https://clinicaltrials.gov/**](https://clinicaltrials.gov/) **has been completed:**

This study is not a clinical trial:

Registration complete:

Registration pending:

**b) If the Principal Investigator (PI) does not possess a medical license, describe the scope and nature of the PI’s previous clinical trial experience, including other studies they have led or participated in as Co-Investigator. If applicable, describe the previous clinical trial experience for the appointed Responsible Physician.**

**Note: Completion of the Collaborative Institutional Training Initiative (CITI) course on** [**Good Clinical Practice for Clinical Trials involving Investigational Drugs and Medical Devices**](https://arizona.sabacloud.com/Saba/Web_spf/NA7P1PRD161/app/me/ledetail;spf-url=common%2Flearningeventdetail%2Fcrtfy000000000003169%3Freturnurl%3Dcatalog%252Fsearch%2526searchText%253DGCP%252520for%252520clinical%252520trials%2526selectedTab%253DLEARNINGEVENT%2526filter%253D%25257B%25257D) **is mandatory for non-MD/DO PIs overseeing clinical trials.**

**In addition, all research coordinators listed on protocols overseen by non-MD/DOs supervising clinical trials must complete the**[***Clinical Research Coordinator***](https://arizona.sabacloud.com/Saba/Web_spf/NA7P1PRD161/app/me/learningeventdetail/cours000000000003527?regId=regdw000000000563181)**CITI training course. The HSPP will confirm completion of this training for all members of the study team that will be directly involved with research participants.**

# Potential Benefits to Subjects:

* 1. **Describe the anticipated benefits of this study to society, academic knowledge, or both.**
  2. **Describe any benefits that individuals may reasonably expect from participation (not including compensation, which cannot be considered a benefit of participation).**

# Risks to Subjects:

* 1. **Describe all physical, psychological, social, legal, and/or economic risks that could be associated with participation in this research.**

**Risks not directly related to the research need not be included in this section. However, nearly all human research has some minimal level of risk, such as a loss of confidentiality when identifiable data is collected.**

* 1. **Discuss what steps will be taken to minimize risks to subjects/data.**

# Costs, Compensation, and Injury:

* 1. **Describe any costs, monetary and non-monetary, that subjects may incur. This includes time.**
  2. **Discuss the amount of compensation (monetary and/or non-monetary) subjects may receive. Describe if compensation will be prorated.**

# Privacy of Subjects and Confidentiality of Data:

* 1. **Describe steps, if any, to protect the privacy of the subjects throughout their participation (e.g., during the recruitment process, consent process, and/or research procedures).**
  2. **Will data/specimens be kept for future research, including unspecified future research and genetics? Yes  No**

**\*If your funder requires a Data Management Plan, additional information will be collected below.**

* 1. **If yes to the above question, describe future use plans here, including unspecified research, any storage in a repository (if applicable), and what data will be retained/reused.**
  2. **Discuss how study results will be shared with subjects, families, and/or the institution, both immediately and long-term.**
  3. **Indicate if the research team will be accessing any of the following records.**

|  |
| --- |
| Substance abuse records (HIPAA and [**42 CFR Part 2**](https://www.samhsa.gov/about-us/who-we-are/laws-regulations/confidentiality-regulations-faqs)) |
| Medical records (HIPAA) |
| Educational records (FERPA)\* |
| Employee records ([**ABOR Policy 6-912**](https://hr.arizona.edu/sites/default/files/ABOR-Policy-6-912.pdf))\* |
| Other, specify: Click or tap here to enter text. |

**\*Access to information from a University of Arizona employee record or FERPA information requires the written permission of the participants.**

* 1. **For each record source selected above, list the data elements to be accessed, who will access them, and how the information will be obtained.**
  2. **Indicate where data will be stored:**

|  |  |
| --- | --- |
| Box@UA | OnCore |
| Box@UA Health | PACS medical imaging software |
| Clinical Data Warehouse (CDW) | Password Protected Drive |
| Cloud Server | REDCap |
| Department Drive | Transmitting/receiving subject data to/from an outside group |
| Department Office | UA Records Management & Archives |
| Encrypted Drive | Banner Server/Platform, specify: |
| External Drive (hard drive, USB, disk) | [Soteria](https://soteria.arizona.edu/) |
| Google Suite for Education |
| [HIPAA Research Computing Service](https://uarizona.service-now.com/sp?id=sc_cat_item&sys_id=32755b2d1bcb28107947edf1604bcbd1) | Other, specify: Click or tap here to enter text. |

* 1. **For EACH of the storage locations checked above, discuss the type of data to be stored, including if the data will be identifiable, coded, or de-identified upon storage.**

**If data will be coded, specify who will maintain the code, where it will be stored, and when it will be destroyed. If data will be de-identified, explain if there is any possibility that the data could be re-identified.**

**Definitions:**

* **Identifiable: The identity of the subject is or may be readily ascertained.**
* **Coded: Data are separated from personal identifiers through use of a code. As long as a link to identifiers exists, data is considered identifiable and not de-identified.**
* **De-identified: A record in which all identifying information is removed.**
  1. **If collecting biological specimens, please describe the storage location for the specimens, including if they will be identifiable, coded, or de-identified upon storage.**

* 1. **Storage of research records (research records should be maintained for whichever of the following time periods is the longest, select one):**

|  |
| --- |
| I will store research records for at least 6 years past the time the study is concluded. |
| For studies involving minors, I will store research records for at least 6 years after the youngest participant turns 18. |
| I will store research records for the length of time required by law or study sponsor, please specify: Click or tap here to enter text. |

* 1. **Describe what security controls (e.g., administrative, physical, technical) are in place to make sure data/specimens are secure.**
  2. **Indicate how data/specimens will be shared with collaborating entities:**

|  |
| --- |
| Data and/or specimens will not be shared between UA and any outside group or collaborating entity. |
| Data/or specimens will be transmitted and/or disclosed to an outside group or a collaborating entity. |
| Data and/or specimens will be received from an outside group or a collaborating entity. |
| PHI will be transmitted to or received from an outside group or a collaborating entity. \* |
| A Limited Data Set will be transmitted or received from an outside group or a collaborating entity. \* |
| Data/specimens will be sold to pharmaceutical companies. |

**\*If you will be transmitting or receiving any PHI, or a** [**Limited Data Set**](https://research.arizona.edu/sites/default/files/hipaa_data_reference_guide_12.21.2016.pdf)**, as a part of your project, please go to the following link to review the** [**Data Use Agreement (DUA)**](https://research.arizona.edu/faq-type/data-use-agreement) **from the HIPAA Privacy Program.**

* 1. **Describe what information will be shared, who it will be shared with, and how it will be shared (e.g., secure file transfer, REDCap, etc.). Also include information about future use sharing and repositories. Specify if the shared data will be identifiable, coded, a limited data set, or de-identified.**

# Additional Questions (complete as applicable):

* 1. **Subject Injury: If the research involves more than minimal risk to subjects, describe the provisions for medical care and available compensation in the event of research related injury. If the Human Research has a clinical trial agreement, this language should reflect what is stated in the agreement.**
  2. **Withdrawal of Subjects: Discuss how, when, and why subjects may be removed from the study. If abrupt withdrawal is necessary, discuss how subjects will be withdrawn so that they are not put at increased risk. Discuss what happens if a subject is withdrawn from one part of the study but asked to continue with other parts, such as ongoing follow-up.**
  3. **Monitoring for Subject Safety: Provide a brief lay discussion of your plan to monitor for subject safety. Describe what safety information will be collected, including serious adverse events, how safety information will be collected, and the frequency of collection including a timeline of when the data and review(s) will occur, who will review the information, and the plan for reporting findings.**

**If there will not be a way to monitor for subject safety, please explain.**

* 1. **Data Management Plan: Please discuss the data management plan, if required by your funder. For additional resources, reference the HSPP** [**Data Management webpage**](https://research.arizona.edu/compliance/human-subjects-protection-program/resources-investigators/data-management)**.****If your sponsor/funding agency requires a Data Management Plan, please upload the approved copy in eIRB. This section and the informed consent form should contain all pertinent information including:**
* **What data/metadata will be shared (imaging, survey; raw data or derived; protocol, data form; etc.)**
* **What repository will be used (if known)**
* **How will data be stored (in a de-identified or identifiable format)** 
  1. **International Research: Describe site-specific regulations or customs affecting the research, local scientific and/or ethical review structures that differ, and if community advisory boards are involved. If so, describe their composition and involvement. For research being conducted outside of the US, please explain any local laws, regulations, or customs the IRB needs to be aware of.**

**Authorization from sites where research will take place is required with the application. Permission to conduct research outside of the country requires review by the** [**UA Travel Registry**](https://ua-risk.terradotta.com/)**.**

**Additional items needed for review:**

* Word versions of applicable subject materials: Consent Forms, Recruitment Materials, Data Collection Materials, Participant Materials
* Current PI CV or biosketch
* Advisor approval (if the PI is a student or medical resident)
* Department/Center/Section Review approval

* [Scientific/Scholarly review](https://research.arizona.edu/sites/default/files/Other%20Approvals%20Required%20v2023-10.pdf) approval
* Responsible physician approval and CV (if the PI is conducting medical procedures for which he/she is not clinically certified to perform)
* Additional approvals, as needed (e.g., [RAP/Banner feasibility](https://research.uahs.arizona.edu/clinical-trials/research-intake-form), Export Control, Radiation, COI, CATS, SRC, school district approval, tribal approval, etc.)

**Other items as applicable:**

* HSPP Appendices
* Data Monitoring Plan or Data Management Plan
* Drug/Device information
  + Applicable Drug or Device Appendix
  + Investigator's Brochure, drug product sheet, device manual, user's manual, instructions for use, package insert, IND/IDE documentation, FDA 1572 form, 510k indication, FDA exemption, sponsor determination of device risk, etc.
* Sponsor Protocol and MOPs that are used in the study