**This form is required when the UA will be the IRB of Record for Human Subjects Research. The UA IRB requires a summary of your research project. This form is the protocol summary, in lay terms, for the IRB to review. If you have a sponsor protocol, this document is still required.** **The red text is instructional and should be deleted prior to submitting this form to the IRB.**

**Depending on the nature of your study, some sections may not be applicable to your research. If so, mark as “N/A” and explain why the section does not apply.**

**Use lay terms 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 the Human Research.**

# Funding Information:

**Please 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 the award number that you received from Sponsored Projects. For externally funded projects, the information below should match the Study Funding Sources in eIRB.**

**HSPP charges fees for the review of industry funded research or for federally funded research requiring a single IRB. Please 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.**

|  |  |
| --- | --- |
| **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: |
| Adults unable to consent (i.e., cognitively impaired adults) \* |

**\*Complete and attach the appropriate HSPP Appendices if children, pregnant women, neonates, prisoners, cognitively impaired individuals, or Native Americans or Indigenous Populations will be enrolled.**

* 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 accrued locally. 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: |
| Phone Calls |

**Refer to the HSPP Guidance,**[**Recruitment and Advertisements**](https://research.arizona.edu/sites/default/files/Recruitment%20and%20Advertisements%20v2021-09.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.**

* 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.**

# 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 |
| Protected Health Information (PHI) 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 |

|  |
| --- |
| **Oral/Online/Unsigned Consent** **(Appendix for Alteration/Waiver of Consent or PHI is Required)** |
| 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 |

**Provide copies of all consenting documents in a Word format. Utilize HSPP** [**template consent forms**](https://research.arizona.edu/compliance/human-subjects-protection-program/HSPP-forms/consent-templates)**.** **If data or specimens will be stored for future use, include a separate section in the informed consent that reflects the future use and storage.**

* 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.**

**If subjects who do not speak English will be enrolled, describe the process to ensure that the oral and written information provided to those subjects will be in that language.**

* 1. **Where will the original signed consent and PHI authorization documents be stored?**
  2. **Acknowledgement of consent form storage.**

|  |
| --- |
| I will store original signed consent and 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 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. **Please select the methods of data collection that will be employed 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: |

**Attach all surveys, scripts, and data collection forms. 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.**

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

**Please provide details of EACH research procedure in chronological order using lay 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.**

* 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, method, frequency, and type of specimen to be collected and what the specimen will be used for.**

# 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. Note, compensation cannot be considered a benefit of participation.**

# Risks to Subjects:

* 1. **Describe all physical, psychological, social, legal, and/or economic risk you feel are 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. Please note, time is considered a cost.**
  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 in the Human Research (e.g., during the recruitment process, consent process, and/or research procedures).**
  2. **Describe if data or specimens will be kept for future research, including unspecified future research and genetics.** **If data or specimens will be stored in a repository, indicate who holds the repository and what information will be sent to the repository. Ensure this information is reflected in the subject’s informed consent form.**
  3. **If appropriate, discuss how immediate and/or long-term study results will be shared with subjects, families, and/or the institution.**
  4. **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://public.azregents.edu/Policy%20Manual/6-912-Access%20to%20or%20Disclosure%20of%20Personnel%20Records%20or%20Information.pdf))\* |
| Other, specify: |

**\*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, summarize the data elements to be accessed, who will access them, and how the information will be obtained.**

* 1. **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) | Other, specify: |
| ☐ Google Suite for Education |  |

* 1. **For EACH of the storage locations checked above, discuss the type of data to be stored, including if the data is identifiable, coded, or de-identified upon storage. Discuss who may have access to the data and how long the data will be kept.**

**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.**

**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.**

* 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. |
| ☐ Transmitting and/or disclosing any subject data and/or specimens to an outside group or a collaborating entity. |
| ☐ Receiving any subject data and/or specimens from an outside group or a collaborating entity. |
| ☐ Transmitting or receiving PHI to or from an outside group or a collaborating entity. \* |
| ☐ Transmitting or receiving a Limited Data Set to or 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/compliance/HIPPA-privacy/data-use-agreements/faqs) **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.):**

# 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 the plan to monitor for subject safety. Describe what safety information will be collected, including serious adverse events, how safety information will be collected, 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 funding agency. For additional resources, reference the HSPP** [**Data Management webpage**](https://research.arizona.edu/compliance/human-subjects-protection-program/resources-investigators/data-management)**.**
  2. **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: Consents, PHI Authorization Form(s), Recruitment Materials, Data Collection Materials, additional Participant Materials
* Current PI/Co-PI CVs 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_approvals_required_v2020-01.pdf) approval
* Responsible physician approval (if the PI is conducting medical procedures for which he/she is not clinically certified to perform)
* Additional approvals, as needed (e.g., [RIA/Banner feasibility](https://research.uahs.arizona.edu/clinical-trials/research-intake-form), Export Control, Radiation, COI, UA travel registry, CATS, SRC, school district approval, tribal approval, etc.)

**Other items as applicable:**

* HSPP Appendices, as applicable
* Data Monitoring Charter and 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.
* Multi-site information (for sites engaged in research where the UA is the IRB of record)
  + Appendix for Multi-site Research
  + Documentation of reliance
  + Copy of the site's human subjects training policy
  + CV and medical license (if applicable) of site PI
* Sponsor protocol, if separate from this form