**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, and where the project is limited to a review of identifiable data or specimens ONLY. If the project involves recruitment, interaction, or consent, do NOT use this form. Instead, use the *IRB Protocol for Human Subjects Research* form.**

**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%20v2022-09.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 criteria that define who will be included or excluded in your final study sample. Indicate age range, gender, and ethnicity.**

# Number of Specimens/Records to be Reviewed Locally:

* 1. **Describe the maximum number of specimens needed for this project.**
	2. **Specify the date range of records to be reviewed. (e.g., data will be reviewed from October 1, 2020 – July 31, 2023).**

# Research and Data Collection Procedures:

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

|  |
| --- |
| [ ]  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))\* |
| [ ]  Previously collected biological specimens |
| [ ]  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. **Select the appropriate box indicating where the information/specimens were or will be collected/obtained (i.e., identify the source of data/specimens):**

|  |
| --- |
| [ ]  Banner University Medical Center- Medical Records**For** [**Collaborative Activities with Banner Health**](https://research.arizona.edu/compliance/human-subjects-protection-program/collaborative-activities-banner-health)**, review the additional information needed for Non-Research Projects** |
| [ ]  Data Warehouse, specify:  |
| [ ]  Business Associate or Collaborator |
| [ ]  Other, explain:Click or tap here to enter text. |

* 1. **List the data elements or specimens to be reviewed for this protocol. Alternatively, you can upload a data abstraction sheet which lists all data elements to be collected/reviewed to the “Other Attachments” section in eIRB.**

# Potential Benefits to Subjects:

**Describe the anticipated benefits of this study to society, academic knowledge, or both.**

# Risks to Subjects:

* 1. **Describe all social, legal, and/or economic risks that could be associated with 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.**

# Privacy of Subjects and Confidentiality of Data:

* 1. **Will data/specimens be kept for future research, including unspecified future research and genetics? Yes**[ ]  **No**[ ]
	2. **If yes to question 11.1, please describe future use plans here, including unspecified research, any storage in a repository (if applicable), and what data will be retained/reused.**
	3. **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, and who may have access to the data.**

**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 obtaining 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.).** **Specify if the shared data will be identifiable, coded, a limited data set, or de-identified.**

**Additional items needed for review:**

* 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
* Additional approvals, as needed (e.g., [RAP/Banner feasibility](https://research.uahs.arizona.edu/clinical-trials/research-intake-form), Export Control, COI, SRC, tribal approval, etc.)

**Other items as applicable:**

* HSPP Appendices
* Sponsor protocol, if separate from this form