**This form should be used for Human Subjects Research projects where the UA will be the IRB of Record, and where the project is limited to a review of data or specimens ONLY. If the project will involve recruitment, interaction, or consent, do not use this form. Instead, use the *IRB Protocol for Human Subjects Research* form.**

**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 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 approximate date range of records to be reviewed.**

# 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://public.azregents.edu/Policy%20Manual/6-912-Access%20to%20or%20Disclosure%20of%20Personnel%20Records%20or%20Information.pdf))\* |
| [ ]  Previously collected biological specimens |
| [ ]  Other, specify:  |

**\*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):**

**Note: Provide a separate list of the specific data points, variables, and/or information that will be collected and/or analyzed (i.e., data abstraction form).**

|  |
| --- |
| [ ]  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: |

* 1. **Describe the data elements or specimens to be reviewed for this protocol. Alternatively, you can attach a data abstraction sheet which lists all data elements to be collected/reviewed.**

# 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 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.**

# Privacy of Subjects and Confidentiality of Data:

* 1. **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.**

* 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 items needed for review:**

* 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
* Additional approvals, as needed (e.g., [RIA/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, as applicable
* 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 of site PI
* Sponsor protocol, if separate from this form