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

**You are required to complete this form when an External IRB will be the IRB of Record. The UA IRB will review your submission. If you have a sponsor protocol, this document is still required.** **Depending on the nature of your study, some sections may not be applicable to your research. If so, mark as “N/A” and, optionally, explain why the section does not apply.**

**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:** |  |

# 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: |

# Scope of Ceded Activities

* 1. **Briefly summarize the research activities the local UArizona investigators will perform.**  **If applicable, you may indicate that this site will perform all procedures described in the sponsor protocol.**
	2. **Specify the type of subject populations to be involved, and the expected number of local subjects to be enrolled in the study.**
	3. **If applicable, describe the location for storage and dispensing of drugs/biologics/devices.**

# Recruitment Methods

* 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.**

**Refer to the HSPP Guidance,**[**Recruitment and Advertisements**](https://research.arizona.edu/sites/default/files/Recruitment%20and%20Advertisements%20v2023-07.pdf)**.**

# Consenting Process:

* 1. **Describe the consenting processes in detail. Specify the method of documenting HIPAA authorization (if applicable).**

# Privacy of Subjects and Confidentiality of Data

* 1. **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.**
	2. **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. **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 and/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.**

**Items needed for approval:**

* Word version of Consent Forms
* IRB of record approval (for non-commercial IRBs)
* Sponsor Protocol (if applicable)
* Current PI CV or biosketch
* Advisor approval (if the PI is a student or 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, Radiation, COI, CATS, SRC, school district approval, tribal approval, etc.)
* If applicable, Appendix for Waiver or Alteration of Consent or PHI Authorization