**This form is required when an External IRB will be the IRB of Record. 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:** |  |

# 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: |

# Scope of Ceded Activities

* 1. **Specify the type of subject populations to be involved, and the expected number of local subjects to be enrolled in the study.**
  2. **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%20v2021-09.pdf)**.**

# 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://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.**
  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) | 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. **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.):**

**Items needed for approval:**

* Word Version of Application
* Word Versions of Consents and PHI Authorization Form(s)
* Protocol
* Current PI/Co-PI CVs 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_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, Radiation, COI, UA travel registry, CATS, SRC, school district approval, tribal approval, etc.)
* If applicable, Appendix for Waiver or Alteration of Consent or PHI Authorization