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

**This form is required when the project is being reviewed by the convened IRB, or when information is needed to explain outstanding items that occurred during the previous continuing review period.**

|  |  |  |
| --- | --- | --- |
| **Basic Information** | | |
| **Title of Study:** |  |
| **Short Title:** |  |
| **Principal Investigator Name:** |  |
| **Principal Investigator’s Department/Unit:** |  |

# Provide a brief description of the research.

**Briefly summarize the research.**

# Subject Demographics:

**Complete the following information related to enrollment of participants in your study.**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Basic Enrollment Information** | | | | | | | |
|  | IRB Approved | Since activation | Since last approval | Male (total) | Female (total) | Other (total) | Undeclared (total) |
| # subjects enrolled locally: |  |  |  |  |  |  |  |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Subject Race** | | | | | | |
|  | White | Black | Asian/ Pacific Islander | American Indian/ Alaska Native | Other | Undeclared |
| # subjects enrolled locally: |  |  |  |  |  |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Subject Ethnicity** | | | | |
|  | Hispanic or Latino | Not Hispanic or Latino | Other | Undeclared |
| # subjects enrolled locally: |  |  |  |  |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Special Populations** | | | | | | | |
|  | Children | Prisoners | Fetuses | Pregnant | Student/ Employee | Cognitively Impaired | Other |
| # subjects enrolled locally: |  |  |  |  |  |  |  |

# Additional Questions:

* 1. **Provide the eDoc # for industry-sponsored projects. Refer to the HSPP Guidance on** **[Fees for Human Research](https://research.arizona.edu/sites/default/files/Fees%20for%20Human%20Research%20v2022-09.pdf).**

eDoc #:

N/A, not industry sponsored.

* 1. **List all unexpected or unanticipated problems since the last renewal period. Add additional lines as necessary.**

|  |  |  |
| --- | --- | --- |
| **RNI submission ID:** | **RNI approval date:** | **Brief description of reportable item:** |
|  |  |  |
|  |  |  |

N/A, no unexpected or unanticipated problems have occurred.

* 1. **Since the last IRB review, have any subjects withdrawn or been withdrawn from the research?**

No

Yes. Explain how many subjects withdrew, and why each subject withdrew:

* 1. **Since the last IRB review, have there been any publications in the literature or any other relevant information regarding this study, especially regarding risks or potential benefits?**

No

Yes. Provide a thorough summary of the information and reference the relevant publications:

* 1. **Since the last IRB review, have there been any interim findings, multi-center trial reports, or data safety monitoring reports?**

No

Yes. Provide a copy of the findings or reports, and clarify there are no issues that need to be addressed:

* 1. **Since the last IRB review, have there been any regulatory actions that could affect safety and risk assessments?**

No

Yes. Describe the regulatory actions taken and provide copies of any relevant correspondence or documentation:

* 1. **In the opinion of the PI, have the risks and potential benefits changed?**

No

Yes. Describe the changes to the risks and potential benefits:

* 1. **Have there been any changes to the data security/ storage or protection of data, or any other modifications to the protocol that were not submitted to the IRB?**

**The IRB must review and approve all changes to previously approved research prior to implementing the change. Refer to the HSPP Guidance,**[**Modifying Approved Research**](https://research.arizona.edu/sites/default/files/Modifying%20Approved%20Research%20v2021-09.pdf)**.**

**The only exception to this policy is when a change is needed to eliminate apparent immediate hazards to human subjects. If a change occurs to eliminate immediate risk, the IRB must be notified within five (5) days as outlined in the HSPP Guidance,**[**Reportable New Information**](https://research.arizona.edu/sites/default/files/Reportable%20New%20Information%20v2023-04.pdf)**.**

**For modifications that have not yet been implemented, these can be submitted jointly with the renewal application under a “Modification and Continuing Review” submission in eIRB. NOTE: If you previously selected “Continuing Review” for this submission, you will need to discard the submission, and create a new submission under “Modification and Continuing Review.”**

No

Yes. Describe whether or not a change has already been implemented and provide justification for why this was not previously submitted to the IRB:

* 1. **Have any problems that required prompt reporting NOT been submitted as required?**

No

Yes. Describe the reportable event and provide justification for why this was not previously submitted to the IRB:

**Submit a Reportable New Information in** [**eIRB**](https://eirb.arizona.edu/IRB) **and note the RNI submission ID in this section.**