**HRP 503 – TEMPLATE – EXPEDITED/FULL BOARD**

**BASIC PROTOCOL INFORMATION:**

**Title:** *Include the full protocol title.*

**Version:**

**Version Date:** Click or tap to enter a date.

**Other IRBs associated with this project:**

**FUNDING INFORMATION:**

Check all that apply.

|  |
| --- |
| [ ]  Not funded by any source. |
| [ ]  Internal funding. Provide the source/mechanism of internal support:  |
| [ ]  U.S. Federal government funding (i.e., DoD, NIH, NSF, etc.) via one or more direct awards or a sub-award. Provide the source of federal support:  |
| [ ]  Other sources of funding (please specify): |

**PRINCIPAL INVESTIGATOR:**

**Name:**

**Department:**

**Telephone Number:**

**Email Address:****Department Head/Chair Name:**

[ ]  PI is not a student.

[ ]  I have read the PI eligibility statement and confirm that the above named PI meets criteria to be a PI on an IRB protocol at AU.

***\*\*ALL KEY STUDY PERSONNEL MUST BE ADDED THROUGH ‘LOCAL STUDY TEAM MEMBERS’ IN ENDEAVOR.*** ***PLEASE ENSURE THAT ALL PERSONNEL HAVE COMPLETED THE NECESSARY MODULES TO CONDUCT RESEARCH AS SPECIFIED IN HRP-103 – INVESTIGATOR MANUAL. YOU CAN CHECK THE STATUS OF CITI TRAINING BY CLICKING ON THE ‘TRAINING’ TAB IN ENDEAVOR. TRAINING THAT OCCURS OUTSIDE OF CITI MUST BE UPLOADED UNDER THE ‘LOCAL SITE DOCUMENTS’ SECTION OF YOUR PROTOCOL.\*\****

Table of Contents

[1.0 Study Summary 3](#_Toc173310560)

[2.0 Objectives 3](#_Toc173310561)

[3.0 Background\* 3](#_Toc173310562)

[4.0 Study Intervention/Investigational Agent 3](#_Toc173310563)

[5.0 Procedures Involved\* 3](#_Toc173310564)

[6.0 Data and Specimen Banking\* 4](#_Toc173310565)

[7.0 Sharing of Results with Participants\* 4](#_Toc173310566)

[8.0 Study Timelines\* 5](#_Toc173310567)

[9.0 Study Endpoints\* 5](#_Toc173310568)

[10.0 Inclusion and Exclusion Criteria\* 5](#_Toc173310569)

[11.0 Local Number of Participants 5](#_Toc173310570)

[12.0 Vulnerable Populations\* 5](#_Toc173310571)

[13.0 Recruitment Methods 6](#_Toc173310572)

[14.0 Withdrawal of Participants\* 6](#_Toc173310573)

[15.0 Risks to Participants\* 6](#_Toc173310574)

[16.0 Potential Benefits to Participants\* 6](#_Toc173310575)

[17.0 Data Management\* and Confidentiality 6](#_Toc173310576)

[18.0 Provisions to Monitor the Data to Ensure the Safety of Participants\* 7](#_Toc173310577)

[19.0 Compensation for Research-Related Injury 8](#_Toc173310578)

[20.0 Economic Burden to Participants 8](#_Toc173310579)

[21.0 Consent Process 8](#_Toc173310580)

[22.0 Process to Document Consent in Writing 8](#_Toc173310581)

[23.0 Setting 8](#_Toc173310582)

[24.0 Resources Available 8](#_Toc173310583)

[25.0 Multi-Site Research\* 8](#_Toc173310584)

# Study Summary

# Objectives

* 1. **Describe the purpose, specific aims, and objectives.**
	2. **State the hypotheses to be tested.**

# Background\*

* 1. **Describe the relevant prior experience and gaps in current knowledge.**
	2. **Describe any relevant preliminary data.**
	3. **Provide the scientific or scholarly background for, rationale for, and significance of the research based on the existing literature and how will it add to existing knowledge**.

# Study Intervention/Investigational Agent

* 1. **Description:**
	2. **Drug/Device Handling**:
	3. **If the drug is investigational (has an IND) or the device has an IDE or a claim of abbreviated IDE (non-significant risk device), include the following information:**
		+ **Identify the holder of the IND/IDE/Abbreviated IDE.**
		+ **If your test article meets the criteria for a waiver of IND or IDE, please describe**
		+ **Explain procedures followed to comply with sponsor requirements for FDA regulated research for the following:**

|  |  |  |  |
| --- | --- | --- | --- |
| **FDA Regulation** | **IND Studies** | **IDE studies** | **Abbreviated IDE studies** |
| **21 CFR 11** | **X** | **X** |  |
| **21 CFR 54** | **X** | **X** |  |
| **21 CFR 210** | **X** |  |  |
| **21 CFR 211** | **X** |  |  |
| **21 CFR 312** | **X** |  |  |
| **21 CFR 812** |  | **X** | **X** |
| **21 CFR 820** |  | **X** |  |

# Procedures Involved\*

* 1. **Describe and explain the study design.**
	2. **Provide a description of all research procedures being performed and when they are performed, including procedures being performed to monitor participants for safety or minimize risks.**
	3. **Describe procedures or methods in place to lessen the probability or magnitude of risks.**
	4. **Describe all drugs and devices used in the research and the purpose of their use, as well as their regulatory approval status.**
	5. **Describe the source records that will be used to collect data about participants**.
	6. :**What data will be collected during the study and how will that data will be obtained?**

|  |  |
| --- | --- |
| **Data source(s):** [ ] New Data[ ] Existing Data | **Will recorded data directly or indirectly identify participants?**[ ] Yes[ ] No |
| **Data collection will involve the use of:*** + - * [ ]  Educational Tests (cognitive diagnostic, aptitude, etc.)
			* [ ]  Internet / Electronic
			* [ ]  Interview
			* [ ]  Audio
			* [ ]  Observation
			* [ ]  Video
			* [ ]  Locations or Tracking Measures
			* [ ]  Photos
			* [ ]  Physical / Physiological
			* Measures or Specimens
			* [ ]  Digital Images
			* [ ]  Surveys / Questionnaires
			* [ ]  Private records or files
			* [ ]  Other (please specify):
 | **Will study data be stored within a HIPAA covered facility?** [ ] Yes[ ] NoIf yes, which facility(ies)? (To determine AU HIPAA covered entities, please refer to [Auburn University’s HIPAA page](https://www.auburn.edu/administration/oacp/hipaa.php)):  |

* 1. **If there are plans for long-term follow-up (once all research related procedures are complete), what data will be collected during this period?**

# Data and Specimen Banking\*

* 1. **If data or specimens will be banked for future use, describe where the specimens will be stored, how long they will be stored, how the specimens will be accessed, and who will have access to the specimens.**
	2. **List the data to be stored or associated with each specimen.**
	3. **Describe the procedures to release data or specimens, including: the process to request a release, approvals required for release, who can obtain data or specimens, and the data to be provided with specimens.**

# Sharing of Results with Participants\*

* 1. **Describe whether results (study results or individual participant results, such as results of investigational diagnostic tests, genetic tests, or incidental findings) will be shared with participants or others (e.g., the participant’s primary care physicians) and if so, describe how the results will be shared**.

# Study Timelines\*

* 1. **Describe:**
		+ **The duration of an individual participant’s participation in the study.**
		+ **The duration anticipated to enroll all study participants.**
		+ **The estimated date for the investigators to complete this study (complete primary analyses).**

# Study Endpoints\*

* 1. **Describe the primary and secondary study endpoints.**
	2. **Describe any primary or secondary safety endpoints.**

# Inclusion and Exclusion Criteria\*

* 1. **Describe the targeted population.**
	2. **Describe how individuals will be screened for eligibility**.
	3. **Describe the criteria that define who will be included or excluded in your final study sample.**
	4. **Indicate specifically whether you will include or exclude each of the following special populations:**

|  |  |  |  |
| --- | --- | --- | --- |
| [ ]  Pregnant people/fetuses | [ ]  Known interpersonal relationships | [ ]  At risk for/Experiencing substance use disorder | [ ]  LBGTQIA+ |
| [ ]  Minors | [ ]  At risk of/Experiencing homelessness | [ ]  Refugees | [ ]  American Indian/Alaskan Native |
| [ ]  Prisoners/Justice-Involved | [ ]  Persons with economic disadvantages | [ ]  Disabled people/People with disabilities | [ ]  AU faculty, staff, students |
| [ ]  Persons with educational disadvantages | [ ]  Decisionally or intellectually impaired | [ ]  Unauthorized immigrants | [ ]  Non-AU Students |

# Local Number of Participants

* 1. **Indicate the total number of participants to be accrued locally.**
	2. **If applicable, distinguish between the number of participants who are expected to be enrolled and screened, and the number of participants needed to complete the research procedures (i.e., numbers of participants excluding screen failures.)**

# Vulnerable Populations\*

* 1. **If the research involves individuals who are vulnerable to coercion or undue influence, describe additional safeguards included to protect their rights and welfare.**

# Recruitment Methods

* 1. **Describe when, where, and how potential participants will be recruited.**
	2. **Describe the source of participants.**
	3. **Describe the methods that will be used to identify potential participants.**
	4. **Describe materials that will be used to recruit participants**.
	5. **Describe plans to compensate participants, keeping in mind the institutional policies set forth by Procurement and Business Services. Be sure to include the amount and timing of any payments to participants**.

# Withdrawal of Participants\*

* 1. **Describe anticipated circumstances under which participants will be withdrawn from the research without their consent.**
	2. **Describe any procedures for orderly termination.**
	3. **Describe procedures that will be followed when participants withdraw from the research, including partial withdrawal from procedures with continued data collection.**

# Risks to Participants\*

* 1. **List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the participants related the participants’ participation in the research**.
	2. **If applicable, indicate which procedures may have risks to the participants that are currently unforeseeable.**
	3. **If applicable, indicate which procedures may have risks to an embryo or fetus should the participant be or become pregnant.**
	4. **If applicable, describe risks to others who are not participants (e.g., risks to ethnic or cultural groups, risks to sexual partners of participants, etc.).**

# Potential Benefits to Participants\*

* 1. **Describe the potential benefits that individual participants may experience from taking part in the research.**

# Data Management\* and Confidentiality

Data will be collected:

|  |  |
| --- | --- |
| [ ]  | Anonymously with no direct or indirect coding, link, or awareness by key personnel of who participated in the study |
| [ ]  | Confidentially, but without a link to participant’s data to any identifying information (collected as “confidential” but recorded and analyzed “anonymous”) |
| [ ]  | Confidentially with collection and protection of linkages to identifiable information. |

* 1. **Describe the data analysis plan, including any statistical procedures. Provide a power analysis as necessary.**
	2. **Describe the steps that will be taken to secure the data (e.g., training, authorization of access, password protection, encryption, physical controls, certificates of confidentiality, and separation of identifiers and data) during storage, use, and transmission.**
	3. **Describe any procedures that will be used for quality control of collected data.**
	4. **Describe how data or specimens will be handled study-wide.**
	5. **Describe the steps that will be taken to protect participants’ privacy interests.**
	6. **If data are collected with identifiers and coded or linked to identifying information, describe the identifiers and how identifiers are linked to participants data. Provide the rationale for coding or linking the data with identifying information.**
	7. **Describe how and where identifying data and/or code lists will be stored. Be specific (building, room number, AU Box, etc.). Describe how the location where the data is stored will be secured. For electronic data, describe security measures. If applicable, describe where IRB-approved and participant signed consent documents will be kept on campus for 3 years after the study ends.**
	8. **Describe how and where data will be stored (e.g., hard copy, audio/visual files, electronic data, etc.), and how the location where data is stored is secured. If data is separated from identifying data, please indicate that. For electronic data, describe data security.** Note that use of a flash drive or portable hard drive is not appropriate if identifiable data will be stored.
	9. **Indicate the latest date that identifying information will be retained and how the information or links will be destroyed.**

# Provisions to Monitor the Data to Ensure the Safety of Participants\*

* 1. **Describe:**
		+ **The plan to periodically evaluate the data collected regarding both harms and benefits to determine whether participants remain safe. The plan might include establishing a data monitoring committee and a plan for reporting data monitoring committee findings to the IRB and the sponsor.**
		+ **What data are reviewed, including safety data, untoward events, and efficacy data.**
		+ **How the safety information will be collected (e.g., with case report forms, at study visits, by telephone calls with participants).**
		+ **The frequency of data collection, including when safety data collection starts.**
		+ **Who will review the data.**
		+ **The frequency or periodicity of review of cumulative data.**
		+ **The statistical tests for analyzing the safety data to determine whether harm is occurring.**
		+ **Any conditions that trigger an immediate suspension of the research.**

# Compensation for Research-Related Injury

* 1. **If the research involves more than Minimal Risk to participants, describe the available compensation in the event of research related injury.**
	2. **Provide a copy of contract language, if any, relevant to compensation for research-related injury.**

# Economic Burden to Participants

* 1. **Describe any costs that participants may be responsible for because of participation in the research.**

# Consent Process

* 1. **Indicate whether you will you be obtaining consent, and if so describe the consent process.**

# Process to Document Consent in Writing

* 1. **Describe whether you will be following HRP-091 - SOP - Written Documentation of Consent. If not, describe whether and how consent of the participant will be documented in writing.**
	2. **Will participants be asked to sign the consent document?** [ ]  **Yes** [ ]  **No**
	3. **Will you use an electronic consent document?** [ ]  **Yes** [ ]  **No**

Please complete the table below:

|  |  |
| --- | --- |
| [ ]  | Waiver of Consent (Including existing de-identified data) |
| [ ]  | Waiver of Documentation of Consent (Use of Information Letter, rather than consent form requiring signatures) |
| [ ]  | Waiver of Parental Permission (in Alabama, 18 years-olds may be considered adults for research purposes)  |

 **Provide the rationale for the waiver request, if applicable:**

# Setting

* 1. **Describe the sites or locations where your research team will conduct the research.**

# Resources Available

* 1. **Describe the resources available to conduct the research.**

# Multi-Site Research\*

* 1. **Study-Wide Number of Participants\***
	2. **Study-Wide Recruitment Methods\***
		+ If this is a multicenter study and participants will be recruited by methods not under the control of the local site (e.g., call centers, national advertisements) describe those methods.
		+ Describe when, where, and how potential participants will be recruited.
		+ Describe the methods that will be used to identify potential participants.
		+ Describe materials that will be used to recruit participants.
		+ If this is a multi-site study where you are the lead investigator, describe the processes to ensure communication among sites.
	3. **Describe the method for communicating to engaged participating sites.**
	4. **If this is a multicenter study where you are a participating site/investigator, describe the local procedures for maintenance of confidentiality.**

**As a reminder, please upload all additional materials supporting your protocol to ‘Local Site Documents’ in Endeavor. This includes, but is not limited to:**

* Data collection instruments
* Letters of support/permission
* Debriefing forms
* Vendor vetting documentation
* Scripts
* Data use agreements
* Conflict of Interest (COI) management plans
* Referral lists
* Emergency Action Plans (EAPs)
* Data Safety Monitoring Board (DSMB) plans
* Data security plans
* Recruitment materials (i.e., flyers, social media posts, etc.)
* Additional training certificates that are external to CITI (i.e., phlebotomy certificates, youth protection training, etc.)
* Clinical trial registration confirmation
* Relevant appendices (i.e., mental health safety plan, MRI appendix (HRP-901), anonymous data collection assurance (HRP-902), etc.)