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

**INSTRUCTIONS[[1]](#endnote-1):**

* Use HRP-503 - TEMPLATE PROTOCOL to prepare a document with the information from following sections. HRP-503 should be used for **expedited** and **full board protocols**. HRP-503a should be used for **exempt** level research. To determine if your research falls under an exemption category, please consult HRP-312 WORKSHEET: Exemption Determination and/or the [HHS decision chart for exemption](https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts-2018/index.html#c2) determination.
* Depending on the nature of your study, some sections may not be applicable to your research. If so mark as “NA”.
* While you will be able to download a copy of the protocol from the system, you should always keep an electronic copy. When making changes, we strongly recommend that you download the most recent copy of your protocol directly from Endeavor. This will allow you to make changes that will be detected by Endeavor for ease of reviewing. Failure to do so may delay the review process.
* As you are writing the protocol, remove all instructions in orange italics (or sections that are in orange italics that are not relevant to your protocol) so that they are not contained in the final version of your protocol (or use the version without instructions available on the IRB website, the Endeavor IRB Canvas site, or through Endeavor) and use this copy as a guide).

**BASIC PROTOCOL INFORMATION:**

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

**Version:** *Include the protocol version and date. Version numbers should go up sequentially (i.e., 1 then 2 then 3).*

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

**Other IRBs associated with this project:** *List any IRBs associated with the current protocol. This may include previously approved studies, related studies, or IRBs at other institutions. If the latter, please include the IRB from the other institution in the Local Site Documents section of Endeavor.*

**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:**

***Please Note:*** *Undergraduate and graduate students are not allowed to be the Principal Investigator on a research study. For further information on who is eligible to serve as a Principal Investigator, see HRP-103 – INVESTIGATOR MANUAL.* *Please be sure to list all key study personnel in the “Local Study Team Members” within Endeavor. If personnel are not auto populated, please contact* [taylomm@auburn.edu](mailto:taylomm@auburn.edu)*. All study team members must have appropriate CITI training as specified in HRP-103 – INVESTIGATOR MANUAL. All emails \*must\* be original AU email addresses, and not aliases (i.e., abc1234@auburn.edu, not uniqueid@auburn.edu).*

**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.\*\****

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# Study Summary

Provide a brief summary/abstract of the study methodology, including design, population, and variables of interest. Include how the results of the study will be used (e.g., presentations, publications, thesis, dissertation, or other dissemination products). (350 word maximum, in language understandable to someone who is not familiar with your area of study.)

# Objectives

* 1. **Describe the purpose, specific aims, and objectives.** It is helpful to begin sentences with “The purpose of this study is…”, “The specific aims of this study are…”, and “The objective of this study is…”.
  2. **State the hypotheses to be tested.**

# Background\*

* 1. **Describe the relevant prior experience and gaps in current knowledge.** Citations should be included at the end of this document (for ease of use with citation managers).
  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**. **IMPORTANT:** Please do not copy and paste your grant background/significance section. Be sure that this section is readable by someone outside of your area of expertise.

# Study Intervention/Investigational Agent

* 1. **Description:** *Describe the study intervention and/or investigational agent (e.g.,*

*drug, device) that is being evaluated.*

* + - Please note that the Auburn University IRB will not review any research that falls under FDA regulations (21 CFR). If you have a question as to whether your research would fall under FDA regulations, please contact [irbadmin@auburn.edu](mailto:irbadmin@auburn.edu) prior to continuing with this form.
  1. **Drug/Device Handling**: If the research involves drugs or a device, describe your plans to store, handle, and administer those drugs or devices so that they will be used only on participants and be used only by authorized investigators.
     + If the control of the drugs or devices used in this protocol will be accomplished by following an established, approved organizational SOP (e.g., Research Pharmacy SOP for the Control of Investigational Drugs, etc.), please reference that SOP in this section.
  2. **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** (see WORKSHEET: Drugs (HRP-306) or WORKSHEET: Devices (HRP-307) for guidance):
     + **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**. Upload all surveys, scripts, and data collection forms under ‘Local Site Documents’ in Endeavor.
  6. :**What data will be collected during the study and how will that data will be obtained?** Please provide a detailed list and narrative of data collection instruments in addition to completing the table. Any data collection sheets, surveys, tests, interview scripts, or other recording instruments that will be used for the project should be attached under Local Site Documents 🡪 Other Attachments in Endeavor. Data collection instruments that are participant facing (i.e., not completed by the study team such as a Qualtrics surveys) must be provided in their final form.

|  |  |
| --- | --- |
| **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  No  If 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.** Please be sure to include HRP-584 – TEMPLATE – Data Repository Consent/Assent as necessary with your protocol. Note: A separate IRB protocol may be required to support a research repository.
  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**. If test results may include sensitive information, please be sure to include detailed plans of how the information will be delivered and by whom, and what resources will be available to the participant.

# 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**. Be sure to include any participant facing screening materials in their final form in the Local Site Documents upload in Endeavor.
  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:** (You may not include members of the above populations as participants in your research unless you indicate this in your inclusion criteria.)

|  |  |  |  |
| --- | --- | --- | --- |
| 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.**
     + If the research involves pregnant women, review HRP-412 - CHECKLIST - Pregnant Women to ensure that you have provided sufficient information.
     + If the research involves neonates of uncertain viability or non-viable neonates, review HRP-413 - CHECKLIST - Non-Viable Neonates or HRP-414 - CHECKLIST - Neonates of Uncertain Viability to ensure that you have provided sufficient information.
     + If the research involves prisoners, review HRP-415 - CHECKLIST - Prisoners to ensure that you have provided sufficient information.
     + If the research involves persons who have not attained the legal age for consent to treatments or procedures involved in the research (“children”), review the HRP-416 - CHECKLIST - Children to ensure that you have provided sufficient information.
     + If the research involves cognitively impaired adults, review HRP-417 - CHECKLIST - Cognitively Impaired Adults to ensure that you have provided sufficient information.

# Recruitment Methods

* 1. **Describe when, where, and how potential participants will be recruited.** If applicable, describe procedures for oral or written communication with the prospective participant or legally authorized representative that will be done for purposes of screening, recruiting, or determining eligibility..Please keep in mind that recruitment materials must follow the University distribution policies as well as individual building policies. Please refer to HRP-315 – WORKSHEET – ADVERTISEMENTS for guidance.
  2. **Describe the source of participants.**
  3. **Describe the methods that will be used to identify potential participants.** If applicable, describe procedures for accessing records or stored identifiable biospecimens for purposes of screening, recruiting, or determining eligibility.
  4. **Describe materials that will be used to recruit participants**. (Attach copies of these documents with the application under ‘Local Site Documents’ 🡪 Recruitment Materials’. For advertisements, attach the final copy of printed advertisements. When advertisements are taped for broadcast, attach the final audio/video tape. You may submit the wording of the advertisement prior to taping to preclude re-taping because of inappropriate wording, provided the IRB reviews the final audio/video tape.)
  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**. If compensation will require participants to register as a vendor, include information about this process in the consent form (i.e., inform participants that they will need to provide tax identification information which may include their social security number).

# 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**. Include as may be useful for the IRB’s consideration, a description of the probability, magnitude, duration, and reversibility of the risks. Consider physical, psychological, social, legal, coercive, and economic risks. Please note that if an investigator is using or accessing confidential or identifiable data, breach of confidentiality is always a risk. Other potential risks include use of deception or exposure. Following the description of each risk, include plans to mitigate the risk.
  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.** Include as may be useful for the IRB’s consideration, the probability, magnitude, and duration of the potential benefits. Indicate if there is no direct benefit. Do not include benefits to society or others.

# 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. |

*Note: Attach HRP-902 – APPENDIX – Anonymous Data Collection Assurance under Local Site Documents 🡪 Other Attachments when you will be collecting anonymous data that is sensitive in nature or could be considered more than minimal risk if it were to be identifiable.*

* 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.** Please be sure to include additional relevant information, including appropriate permissions and protection, if your data collection will include Protected Health Information (PHI), Family Educational Rights Privacy Act (FERPA), or Protection of Pupil Rights Amendment (PPRA) data.
     + What information will be included in that data or associated with the specimens?
     + Where and how data or specimens will be stored?
     + How long the data or specimens will be stored?
     + Who will have access to the data or specimens?
     + Who is responsible for receipt or transmission of the data or specimens?
     + How data or specimens will be transported?
     + Indicate how the research team is permitted to access any sources of information about the participants.
  5. **Describe the steps that will be taken to protect participants’ privacy interests.** “Privacy interest” refers to a person’s desire to place limits on whom they interact or whom they provide personal information.
  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\*

This section is required when research involves more than Minimal Risk to participants. If your protocol requires a Data Safety Monitoring Board or Plan, please submit the appropriate documents. Please see the [NIH Policy for Data and Safety Monitoring](https://grants.nih.gov/policy/humansubjects/policies-and-regulations/data-safety.htm) and the [NIAAA Guidelines](https://www.niaaa.nih.gov/research/guidelines-and-resources/data-and-safety-monitoring-guidelines) for establishing and operating a DSMB. You may delete this section if it is not applicable to your study.

* 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.**
     + Where will the consent process take place.
     + Any waiting period available between informing the prospective participant and obtaining the consent.
     + Any process to ensure ongoing consent.
     + Whether you will be following HRP-090 - SOP - Informed Consent Process for Research. If not, describe:
       - The role of the individuals listed in the application as being involved in the consent process.
       - The time that will be devoted to the consent discussion.
       - Steps that will be taken to minimize the possibility of coercion or undue influence.
       - Steps that will be taken to ensure the participant’s understanding.

**Non-English Speaking Participants**

* + - Indicate what language(s) other than English are understood by prospective participants or representatives.
    - If participants who do not speak English will be enrolled, describe the process to ensure that the oral and written information provided to those participants will be in that language. Indicate the language that will be used by those obtaining consent.

**Waiver or Alteration of Consent Process (consent will not be obtained, required information will not be disclosed, or the research involves deception)**

* + - Review the HRP-410 - CHECKLIST - Waiver or Alteration of Consent Process to ensure you have provided sufficient information for the IRB to make these determinations.
    - If the research involves a waiver of the consent process for planned emergency research, please review the HRP-419 - CHECKLIST - Waiver of Consent Process for Emergency Research to ensure you have provided sufficient information for the IRB to make these determinations.

**Participants who are not yet adults (infants, children, teenagers)**

* + - Describe the criteria that will be used to determine whether a prospective participant has not attained the legal age for consent to treatments or procedures involved in the research under the applicable law of the jurisdiction in which the research will be conducted.
      * For research conducted in the state of Alabama, review HRP-013 - SOP - LARs, Children, and Guardians to be aware of which individuals in the state meet the definition of “children.”
      * For research conducted outside of the state, provide information that describes which persons have not attained the legal age for consent to treatments or procedures involved the research, under the applicable law of the jurisdiction in which research will be conducted. One method of obtaining this information is to have a legal counsel or authority review your protocol along the definition of “children” in HRP-013 - SOP - LARs, Children, and Guardians.
    - Describe whether parental permission will be obtained from:
      * Both parents unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.
      * One parent even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child.
    - Describe whether permission will be obtained from individuals other than parents, and if so, who will be allowed to provide permission. Describe the process used to determine these individuals’ authority to consent to each child’s general medical care.
    - Indicate whether assent will be obtained from all, some, or none of the children. If assent will be obtained from some children, indicate which children will be required to assent.
    - When assent of children is obtained describe whether and how it will be documented.

**Cognitively Impaired Adults**

* + - Describe the process to determine whether an individual is capable of consent. The IRB allows the person obtaining assent to document assent on the consent document and does not routinely require assent documents and does not routinely require cognitively impaired adults to sign assent documents.

**Adults Unable to Consent**

* + - List the individuals from whom permission will be obtained in order of priority (e.g., durable power of attorney for health care, court appointed guardian for health care decisions, spouse, and adult child).
      * For research conducted in the state of Alabama, review HRP-013 - SOP - LARs, Children, and Guardians to be aware of which individuals in the state meet the definition of “legally authorized representative.”
      * For research conducted outside of the state, provide information that describes which individuals are authorized under applicable law to consent on behalf of a prospective participant to their participation in the procedure(s) involved in this research. One method of obtaining this information is to have a legal counsel or authority review your protocol along the definition of “legally authorized representative” in HRP-013 - SOP - LARs, Children, and Guardians.
    - Describe the process for assent of the participants. Indicate whether:
      * Assent will be required of all, some, or none of the participants. If some, indicated, which participants will be required to assent and which will not.
      * If assent will not be obtained from some or all participants, an explanation of why not.
      * Describe whether assent of the participants will be documented and the process to document assent. The IRB allows the person obtaining assent to document assent on the consent document and does not routinely require assent documents and does not routinely require participants to sign assent documents.

# 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:**

*If your research presents no more than minimal risk of harm to participants and involves no procedures for which written documentation of consent is normally required outside of the research context, the IRB will generally waive the requirement to obtain written documentation of consent. (If you will document consent in writing, attach a consent document. If you will obtain consent, but not document consent in writing, attach a consent script. Review HRP-411 - CHECKLIST - Waiver of Written Documentation of Consent to ensure that you have provided sufficient information. You may use HRP-502 - TEMPLATE CONSENT DOCUMENT to create the consent document or script.)*

# Setting

* 1. **Describe the sites or locations where your research team will conduct the research.**
     + Identify where your research team will identify and recruit potential participants.
     + Identify where research procedures will be performed. Include room numbers. Be sure to also include an Emergency Action Plan (EAP) for all research locations. EAPs should be uploaded under “Local Site Documents” within Endeavor.
     + Describe the composition and involvement of any community advisory board.
     + For research conducted outside of the organization and its affiliates describe:
       - Site-specific regulations or customs affecting the research for research outside the organization.
       - Local scientific and ethical review structure outside the organization.

# Resources Available

* 1. **Describe the resources available to conduct the research:** For example, as appropriate.
     + Justify the feasibility of recruiting the required number of suitable participants within the agreed recruitment period. For example, how many potential participants do you have access to? What percentage of those potential participants do you need to recruit?
     + Describe the time that you will devote to conducting and completing the research.
     + Describe your facilities.
     + Describe the availability of medical or psychological resources that participants might need as a result of an anticipated consequence of the human research. For research involving psychological risks, please include a mental health safety plan, as necessary.
     + Describe your process to ensure that all persons assisting with the research are adequately informed about the protocol, the research procedures, and their duties and functions.

# Multi-Site Research\*

* 1. **Study-Wide Number of Participants\***

*If this is a multicenter study, indicate the total number of participants to be accrued across all sites. If this is not a multi-site research study, you may delete this section.*

* 1. **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.** Local recruitment methods are described later in the protocol.
     + **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.** (Attach copies of these documents with the application. For advertisements, attach the final copy of printed advertisements. When advertisements are taped for broadcast, attach the final audio/video tape. You may submit the wording of the advertisement prior to taping to preclude re-taping because of inappropriate wording, provided the IRB reviews the final audio/video tape.)
     + **If this is a multi-site study where you are the lead investigator, describe the processes to ensure communication among sites**. See HRP-830 - WORKSHEET - Communication and Responsibilities. All sites have the most current version of the protocol, consent document, and HIPAA authorization.
     + If research is being conducted at sites other than Auburn University or in cooperation with other entities, a permission letter from the site/ program director must be included indicating their cooperation or involvement in the project. NOTE: If the proposed research is a multi-site project, involving investigators or participants at other academic institutions, hospitals or private research organizations, please contact the AU IRB office for guidance (irbadmin@auburn.edu).
     + All required approvals (initial, continuing review and modifications) have been obtained at each site (including approval by the site’s IRB of record).
     + All modifications have been communicated to sites and approved (including approval by the site’s IRB of record) before the modification is implemented.
     + All engaged participating sites will safeguard data, including secure transmission of data, as required by local information security policies.
     + All local site investigators conduct the study in accordance with applicable federal regulations and local laws.
     + All non-compliance with the study protocol or applicable requirements will be reported in accordance with local policy.
  2. **Describe the method for communicating to engaged participating sites.** (see HRP-830 - WORKSHEET - Communication and Responsibilities):
     + Problems (inclusive of reportable events).
     + Interim results.
     + The closure of a study.
  3. **If this is a multicenter study where you are a participating site/investigator, describe the local procedures for maintenance of confidentiality.** (See HRP-830 - WORKSHEET - Communication and Responsibilities.)
     + Where and how data or specimens will be stored locally?
     + How long the data or specimens will be stored locally?
     + Who will have access to the data or specimens locally?
     + Who is responsible for receipt or transmission of the data or specimens locally?
     + How data and specimens will be transported locally?

**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.)

1. This template satisfies AAHRPP elements 1.7.B, I.8.B, I-9, II.2. A, II.2.I, II.3.A, II.3.B, II.3.C-II.3.C.1, II.3.D-F, II.4.A, III.1.C-F, II.2.D [↑](#endnote-ref-1)