**INSTRUCTIONS:**

* All referenced Checklists, Worksheets and SOPs are available to the research team in the Library located on the electronic database. Additional guidance may be found on the Human Subjects/IRB website, accessible through the UH Division of Research Compliance webpage.
* Use the following template (“TEMPLATE SITE SUPPLEMENT TO SPONSOR PROTOCOL (HRP-508)” to provide the IRB with information supplemental to the sponsor’s protocol.
* Depending on the nature of what you are doing, **some sections may not be applicable to your research and may be deleted as indicated within the template. If not indicated as a section that can be deleted, mark as “N/A.”**
* Attach the entire sponsor’s protocol. Unless otherwise specified, provide only site-specific information below.
* When you write a single site supplement, keep an electronic copy. This is a “living document: and you will need to modify this copy when making changes to submit to the IRB.
* **As you are writing the site supplement, remove all instructions in blue italics so that they are not contained in the final version of your site supplement.**

**PRINCIPAL INVESTIGATOR:**

*Name*

*Department*

*Telephone Number*

*Email Address*

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# 

# Inclusion and Exclusion Criteria

* 1. Describe any inclusion or exclusion criteria that will differ for your local site compared to the sponsor’s protocol. For example, if the sponsor’s protocol allows the enrollment of children but your site will not enroll children, indicate that here.

# 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 “CHECKLIST: Pregnant Women (HRP-412)” to ensure that you have provided sufficient information.
     + If the research involves neonates of uncertain viability or non-viable neonates, review “CHECKLIST: Neonates (HRP-413)” or “HRP-414 – CHECKLIST: Neonates of Uncertain Viability (HRP-414)” to ensure that you have provided sufficient information.
     + If the research involves prisoners, review “CHECKLIST: Prisoners (HRP-415)” 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 “CHECKLIST: Children (HRP-416)” to ensure that you have provided sufficient information.
     + If the research involves cognitively impaired adults, review “CHECKLIST: Cognitively Impaired Adults (HRP-417)” to ensure that you have provided sufficient information.
     + Students for whom you have access to or influence over their grades are also vulnerable to undue influence and special protections should be in place. In most cases, investigators should not be the individual recruiting or obtaining consent from students in their own courses. A study team member without access to/influence on grades may be acceptable. (Call IRB office for guidance).

# Local Number of Subjects

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

# Local Recruitment Methods

*This section is for recruitment methods under the control of the local site and not central recruitment managed by the sponsor.*

* 1. Describe when, where, and how potential subjects will be recruited.
  2. Describe the source of subjects.
  3. Describe the methods that will be used to identify potential subjects.
  4. Describe materials that will be used to recruit subjects.
     + Submit copies of these documents with the application as an attachment to the SmartForm.
     + For advertisements, attach the final copy of printed advertisements. Guidance for advertisements is provided on the IRB website. When advertisements are taped for broadcast, a script may be provided prior to taping, however the final audio/video tape file may not be used until it has been reviewed/approved by the IRB (submit via a modification and attach to the SmartForm).

# Setting

* 1. Describe the sites or locations where your research team will conduct the research.
     + Identify where research procedures will be performed.
     + Describe the composition and involvement of any community advisory board.
     + For research conducted outside of the United States:
       - Site-specific regulations or customs affecting the research for research outside the organization.
       - Local scientific and ethical review structure outside the organization.
       - See International Research Policy on the IRB website
  2. Include, as an attachment to the SmartForm, any applicable Letters of Support/Cooperation, IRB Approval(s), School District Approvals, etc. to recruit potential subjects and/or conduct research at these specified sites

# Drugs or Devices

* 1. If the research involves drugs or device, describe your plans to store, handle, and administer those drugs or devices so that they will be used only on subjects and be used only by authorized investigators.

# Withdrawal of Subjects

* 1. Describe procedures that will be followed locally, if different than the sponsor’s protocol, when subjects withdraw from the research.

# Costs/Payments to Subjects

* 1. Describe any costs that subjects may be responsible for due to their participation in the described research.
  2. Describe the amount and timing of any payments or inducements to subjects.
     + Include the mode of payment (gift card, check, extra credit, etc.). If using a gift card, the gift card type(s) must be stated.
     + If a physical gift is provided (for example, a coloring book for child participants), estimate monetary value.
     + Indicate if subjects will need to complete all measures/procedures prior to receiving any remuneration, or if the payment will be pro-rated.

# Compensation for Research-Related Injury

* 1. If the research involves more than Minimal Risk to subjects, 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.

# Confidentiality

* 1. Describe the local procedures for maintenance of confidentiality.
  2. Describe what direct identifiers will be obtained and any coding systems that will be used for study data (and specimens, if applicable). Note that:
     + The key to the code should be stored separate from the consent forms and study data.
     + Audio is considered an identifier.
     + Only indicate that study is anonymous if no identifying data (including consent forms, contact information, etc.) will be collected and subjects will not be seen in person.
  3. Will anyone outside the research team have access to the identifiers?
  4. How long will the key to the study code be maintained? If not destroyed following data collection, provide justification for maintaining.
  5. If audiotaping is conducted, will the recordings be destroyed upon transcription? If not, provide justification.

# Provisions to Protect the Privacy Interests of Subjects

* 1. Describe the steps that will be taken to protect subjects’ privacy interests. “Privacy interest” refers to a person’s desire to place limits on whom they interact or whom they provide personal information.
  2. Describe what steps you will take to make the subjects feel at ease with the research situation in terms of the questions being asked and the procedures being performed. “At ease” does not refer to physical discomfort, but the sense of intrusiveness a subject might experience in response to questions, examinations, and procedures.

# Informed Consent Process

Informed consent must be obtained from all subjects, unless a waiver or alteration is approved by the IRB (see below).

* 1. Indicate whether you will you be obtaining consent, and if so describe:
     + Where and when the consent process takes place
     + Any waiting period available between informing the prospective subject and obtaining the consent
     + Any process to ensure ongoing consent.
     + Whether you will be following “SOP: Informed Consent Process for Research (HRP-090).” 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 subjects’ understanding

**Non-English Speaking Subjects**

Delete section if not applicable

* + - Indicate what language(s) other than English are understood by prospective subjects or representatives.
    - If subjects who do not speak English will be enrolled, describe the process to ensure that the oral and written information provided to those subjects will be in that language. Indicate the language that will be used by those obtaining consent.
      * Non-English speaking should be included in the inclusion/exclusion criteria.
      * Consent documents must be submitted to the IRB, as an attachment to the SmartForm, in English and the language of the potential subjects.
      * A Translation Assurance form must be submitted, as an attachment to the SmartForm, for documents translated into a language other than English.

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

Delete section if not applicable

* + - Review the “CHECKLIST: Waiver or Alteration of Consent Process (HRP-410)” 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 “CHECKLIST: Waiver of Consent for Emergency Research (HRP-419)” to ensure you have provided sufficient information for the IRB to make these determinations.

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

Delete section if not applicable

* + - Describe the criteria that will be used to determine whether a prospective subject has or 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. (E.g., individuals under the age of 18 years.)
      * For research conducted in the state of Texas, review “SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)” to be aware of which individuals in the state meet the definition of “children.”
      * For research conducted outside of the state of Texas, 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 with the definition of “children” in “SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013).”
    - 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**

Delete section if not applicable

* + - Describe the process to determine whether an individual is capable of consent.

**Adults Unable to Consent**

Delete section if not applicable

* + - 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, review “SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)” 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 subject 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 “SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013).”
    - Describe the process for assent of the subjects. Indicate whether:
      * Assent will be required of all, some, or none of the subjects. If some, indicated, which subjects will be required to assent and which will not.
      * If assent will not be obtained from some or all subjects, provide an explanation of why not.
      * Describe whether assent of the subjects will be documented and the process to document assent. The IRB Office can work with you to allow the person obtaining assent to document assent on the consent document.

# Process to Document Consent in Writing

* 1. Describe whether you will be following “SOP: Written Documentation of Consent (HRP-091).” If not, describe whether and how consent of the subject will be documented in writing.
  2. If you will document consent in writing, attach a consent (and/or parental permission/assent) document (s) as an attachment to the SmartForm.
  3. You may use “TEMPLATE CONSENT DOCUMENT (HRP-502)”to create the consent document or script if a sponsor consent is not provided. The IRB may request modifications be made to a sponsor consent document.

# HIPAA

Delete this section if not applicable.

Indicate if you will be obtaining, creating, using, and/or disclosing individually identifiable health information associated with a HIPAA-covered component or entity in the course of the research.

* 1. In most cases, written authorization is required. You may use the TEMPLATE HIPAA AUTHORIZATION to create the subject authorization and attach it to the SmartForm.
  2. If a HIPAA Waiver of Authorization is requested, review your protocol along with the waiver criteria in the “CHECKLIST: HIPAA Waiver of Authorization (HRP-441)” document. Address all requirements outlined in the checklist for the IRB/Privacy Board to make this determination:
     + Indicate why the use or access is necessary for the research.
     + Provide an adequate plan to protect the identifiers from improper use and disclosure.
     + Provide an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law.
     + Provide adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of protected health information for which an authorization or opportunity to agree or object is not required by 45 CFR 164.512.
     + Indicate how the research could not practicably be conducted without the waiver.
     + Describe why the research could not practicably be conducted without access to and use of the protected health information.

# Data Management

* 1. 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.
  2. Describe any procedures that will be used for quality control of collected data.
  3. Where will data be stored?
  4. How long will the data be stored?
  5. Who will have access to the data?
  6. Who is responsible for receipt or transmission of the data?
  7. How will data be transmitted locally?
  8. If a multi-site study,
     + Who is responsible for receipt or transmission of the data to other sites/the sponsor?
     + How will data be transmitted to other sites/the sponsor?
     + How long will data be stored study-wide?
  9. Will data be banked for future use? (Ex. establishment of a recruitment database?)
     + Indicate that appropriate consent for data banking has been obtained from the subject via the consent process.

# Specimen Use and Banking

*Delete this section if the research does not utilize/collect specimens.*

* 1. The sponsor’s protocol may require banking specimens for future use and both storage and use will be determined by the sponsor. If additional specimens will be banked locally 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 banked locally.
  3. Describe the procedures to release locally banked 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 Subjects

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

# Resources Available

* 1. Describe the qualifications (e.g., training, experience, oversight) of you and your staff as required to perform their role. When applicable describe their knowledge of the local study sites, culture, and society. Provide enough information to convince the IRB that you have qualified staff for the proposed research.
  2. Describe other resources available to conduct the research: For example, as appropriate:
     + Justify the feasibility of recruiting the required number of suitable subjects within the agreed recruitment period. For example, how many potential subjects do you have access to? What percentage of those potential subjects 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 subjects might need as a result of an anticipated consequences of the human research.
     + 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.

# Additional Approvals

* 1. Describe any approvals that will be obtained prior to commencing the research. (E.g., school, external site. funding agency, laboratory, radiation safety, or biosafety approval.)