***BIOMEDICAL TEMPLATE WITH INSTRUCTIONS:***

* *Use this protocol template for BIOMEDICAL research.*
* *Depending on the nature of what you are doing, some sections may not be applicable to your research. If a section is not applicable, mark NA.*
* *When you write the protocol, keep an electronic copy. You will need to modify this copy when making changes.*
* If your study will ONLY involve secondary use of data and/or specimens. See **HRP-503b TEMPLATE** **SECONDARY USE PROTOCOL**.
* Remove all instructions in red before submitting to the IRB or use the version WITHOUT instructions available on the IRB website and use this copy as a guide.

# PROTOCOL TITLE: (Include the full protocol title.)

Protocol Version Date:

|  |
| --- |
| [ ]  Check if this research has U.S. Federal government funding via one or more direct awards or a sub-award. Provide the source of federal support:  |
| [ ]  All other sources of funding: |

# PRINCIPAL INVESTIGATOR:

*Name*

*Department*

*Telephone Number*

*Email Address*

#  Co- INVESTIGATORS:

*Name*

*Department*

*Email Address*

# Objectives:

(*Describe the purpose, specific aims, or objectives. State the hypotheses to be tested*.)

*If you are uploading a funding proposal that has this information, indicate applicable pages.*

# Background:

*(Describe the relevant prior experience and gaps in current knowledge*.)

(*Describe any relevant preliminary data*.)

(*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*.)

# Inclusion and Exclusion Criteria:

(*Describe how individuals will be screened for eligibility*.)

(*Describe the criteria that define who will be included or excluded in your final study sample*.)

(*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*.)

* *Adults unable to consent*
* *Minors (infants, children, teenagers)*
* *Pregnant women*
* *Prisoners*

# Number of Local Participants:

(*Indicate the total number of participants to be accrued locally*.)

(*If applicable, include a break-down of participants by procedure group*.)

(*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*.)

# Study-Wide Number of Participants:

(*If this is a multi-center study for which you are the lead investigator, indicate the total number of participants to be accrued across all sites*.)

# Study Timelines:

(*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:

(*Describe the primary and secondary study endpoints*.)

# Procedures Involved:

(*Describe and explain the study design*.)

(*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*.)

(*Describe*:

* *Procedures performed to lessen the probability or magnitude of risks.*
* *All drugs and devices used in the research and the purpose of their use, and their regulatory approval status.*
* *The source records, including medical or educational records that will be used to collect data about participants. (Attach all surveys, scripts, and data collection forms.)*

(*What data will be collected, including long-term follow-up*.)

# Data and Specimen Banking:

(*If data or specimens will be banked for future use, describe where the specimens will be stored, how long they will be stored, when they will be destroyed (if ever), how the specimens will be accessed, and who will have access to the specimens*.)

(*List the data to be stored or associated with each specimen*.)

(*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, including whether those data will be identifiable to others*.)

*Note: a separate IRB protocol may be required to support a research repository*

# Data and Specimen Management:

(*Describe the data analysis plan, including any statistical procedures. Provide a power analysis, if necessary*.)

(*Describe the steps that will be taken to secure the data to maintain confidentiality (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*.)

(*Describe any procedures that will be used for quality control of collected data*.)

(*Describe how data and specimens will be handled study-wide*:

* *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 (role on the study) will have access to the data or specimens?*
* *Who (role on the study) is responsible for receipt or transmission of the data or specimens?*
* *How data and specimens will be transported?)*

# Provisions to Monitor the Data to Ensure the Safety of Participants:

(*This section is required when research involves more than Minimal Risk to participants.)*

*(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.)*

# Withdrawal of Participants:

(*Describe anticipated circumstances under which participants will be withdrawn from the research without their consent, including stopping participation for safety reasons*.)

(*Describe any procedures for orderly termination*.)

(*Describe procedures that will be followed when participants withdraw from the research, including partial withdrawal from procedures with continued data collection*.)

# Risks to Participants:

(*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, describe the probability, magnitude, duration, and reversibility of the risks. Consider physical, psychological, social, legal, and economic risks*.)

(*If applicable, indicate which procedures may have risks to the participants that are currently unforeseeable*.)

(*If applicable, indicate which procedures may have risks to an embryo or fetus should the participant be or become pregnant*.)

(*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:

(*Describe the potential benefits that individual participants may experience from taking part in the research. Include as necessary the probability, magnitude, and duration of the potential benefits*.)

(*Indicate if there is no direct benefit. Do not include benefits to society or others*.)

# Vulnerable Populations:

(*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 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.)*

# Sharing of Results with Participants:

(*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 it will be shared*.)

# Setting:

* *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.*
* *Describe the composition and involvement of any community advisory board.*
* *For research conducted outside of the institution and its affiliates describe:*
* *Site-specific regulations or customs affecting the research for research outside the institution.*
* *Local scientific and ethical review structure outside the institution.*

# Resources Available:

* *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. You do not need to list individual names of your staff in this protocol.*
* *Describe other 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.*
* *Describe the time that you will devote to conducting and completing the research. (Note: This description is intended to provide the IRB with information relative to conduct of the study as relevant for the protection of research participants, not for effort reporting.)*
* *Describe your facilities. (Note: This description is intended to provide the IRB with information relative to conduct of the study as relevant for the protection of research participants, not for Facilities and Administration considerations.)*
* *Describe the availability of medical or psychological resources that participants 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.*

# Prior Approvals:

(*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*.)

# Confidentiality:

(*If this is a multicenter study, describe the local procedures for maintenance of confidentiality*.

* *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?)*

# Provisions to Protect the Privacy Interests of Participants:

(*Describe the steps that will be taken to protect participants’ privacy interests. “Privacy interest” refers to a person’s desire to place limits on with whom they interact or to whom they provide personal information*.)

(*Describe what steps you will take to make the participants 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 participant might experience in response to questions, examinations, and procedures*.)

(*Indicate how the research team is permitted to access any sources of information about the participants. (e.g., what permission does the research staff have to access medical records or other sensitive information?*)

# Compensation for Research-Related Injury:

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

# Economic Burden to Participants:

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

# Recruitment Methods:

(*Describe when, where, and how potential participants will be recruited*.)

(*Describe the source of participants*.)

(*Describe the methods that will be used to identify potential participants*.)

(*Describe materials that will be used to recruit participants. (Upload copies of these documents in iRIS). For advertisements, upload the final copy of printed advertisements*.) *(When advertisements are taped for broadcast you may submit the wording of the advertisement prior to taping to preclude re-taping because of inappropriate wording, after the wording is approved you will provide the final version of the audio/video file to the IRB*.)

(*Describe the amount, timing, and method of any payments to participants. (e.g., gift card, ClinCard, check*.)

# Study-Wide Recruitment Methods:

(*If this is a multi-center study for which you are the lead investigator 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 for non-multicenter research 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.)*

# Consent Process:

(*Indicate if you will be obtaining consent; and if so, the person consenting participants to the research may be the principal investigator or an individual authorized by the principal investigator and approved by the IRB to obtain consent for the specific protocol, such as a co-investigator, or team member. Regardless of who is obtaining consent, the Principal Investigator is responsible to ensure the correct procedures are carried out.*)

(*Describe*:

* Where the consent process will take place.
* Any waiting period available between informing the prospective participant and obtaining the consent.
* Any process to ensure ongoing consent.
* 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 participants’ understanding.)

*(****For 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 participants’ preferred language. Indicate the language that will be used by those obtaining consent and by those communicating any relevant future research information*.)

***Waiver or Alteration of Consent Process***:

*You must review the “CHECKLIST: Waiver or Alteration of Consent Process (HRP-410)” to ensure you have provided sufficient information for the IRB to approve an alternation or waiver.*

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

*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.*
* *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 participation.*

*Describe the process for assent of the children. Indicate whether:*

* *Assent will be required of all, some, or none of the children. If some, indicated, which children will be required to assent and which will not.*
* *If assent will not be obtained from some or all children, an explanation of why not.*
* *Describe whether assent of the children will be documented and the process to document assent.*

*For research conducted outside of the state, provide information that describes which persons have not attained the legal age for consent procedures involved the research, under the applicable law of the jurisdiction in which research will be conducted. See the definition of “children” in “SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013).”*

***Cognitively Impaired Adults***

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

* *Indicate whether assent will be required of some, all or none of the participants. If some, indicate which participant will be required to assent and explain your decision.*
* *Indicate if you will be documenting assent and explain your decision.*

***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, 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 participant to their participation in the procedure(s) involved in this research. One method of obtaining this information is to have the Office of General Counsel review your protocol.*

# Process to Document Consent in Writing:

D*escribe how consent of the participant will be documented in writing*.

(*Upload a consent document in iRIS).*

***Waiver of Documentation of Consent:***

*If your study is no more than minimal risk and you want to request a waiver, you must review the CHECKLIST: Waiver of Written Documentation of Consent (HRP-411) to ensure you have provided sufficient information for the IRB to approve a waiver. Upload a consent script in iRIS.*

# Drugs or Devices:

(*If the research involves drugs or devices or any supplement, substance, contraption or material used as a test article with one or more humans, 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 drug is investigational (has an IND) or the device has an IDE or a claim of an abbreviated IDE (non-significant risk device), include the following information*:

* Identify the holder of the IND
* Identify the holder of the IDE/Abbreviated IDE.
* Explain procedures followed to comply with FDA and any sponsor requirements for the following:

|  |  |
| --- | --- |
|  | Applicable to: |
| USFDA 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 |  |

# Waiver of IND or IDE

*If your test article meets the criteria for a waiver of IND or IDE please describe below.*

*See WORKSHEET: Drugs (HRP-306) or WORKSHEET: Devices (HRP-307) for guidance.*

# Multi-Site Research:

(*If this is a multi-site study where you are the lead investigator,* . See HRP-830 - WORKSHEET - Communication and Responsibilities, *Describe the processes to ensure communication among sites, such as*:

* *All sites have the most current version of the protocol, consent document, and HIPAA authorization.*
* *All required approvals 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 as required by local information security policies.*
* *All local site investigators conduct the study appropriately.*
* *All non-compliance with the study protocol or applicable requirements will be reported in accordance with local policy.*

(*Describe the method for communicating to participating sites that are engaged*. See HRP-830 - WORKSHEET - Communication and Responsibilities.

* Problems.
* Interim results.
* The closure of a study.