**INSTRUCTIONS:**

* When you write a protocol, keep an electronic, clean (all changes accepted, all comments deleted) copy. You will need to modify this copy when making changes.
* All referenced checklists, templates, policies, and manuals can be found in the system Library.
* As you are writing the protocol, **remove all instructions in italics so that they are not contained in the final version of your protocol.** Depending on the nature of your study, some sections may not be applicable to your research. If so, mark as “N/A”. **Do not delete** the section numbers.

**PROTOCOL TITLE:**

*Include the full protocol title. This title should match section 1 of the Basic Study Information page in the BullsIRB application.*

**PRINCIPAL INVESTIGATOR:**

*Name*

*Department*

*Telephone Number*

*Email Address*

**VERSION NUMBER/DATE:**

*Include the version number and date of this protocol.*

*\*The version number should remain unchanged during pre-review until initial approval. The version date can be updated to reflect changes that are made.*

**REVISION HISTORY**

**\*This table should only be used during submission of a Modification application to the IRB.**

|  |  |  |  |
| --- | --- | --- | --- |
| **Revision #** | **Version Date** | **Summary of Changes** | **Consent Change?** |
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# Study Summary

1.1 *Please provide a brief summary of the study in the table below. A complete description of the study with detailed information should be provided in the body of the protocol. For sections not applicable to the study, mark them as N/A.*

|  |  |
| --- | --- |
| **Study Title** |  |
| **Study Design** |  |
| **Primary Objective/Purpose** |  |
| **Secondary Objective(s)/Purpose** |  |
| **Research Intervention(s)/ Investigational Agent(s)** |  |
| **IND/IDE #** |  |
| **ClinicalTrials.gov NCT#** |  |
| **Study Population** |  |
| **Sample Size** |  |
| **Study Duration for individual subjects** |  |
| **Study Specific Abbreviations/ Definitions** |  |

# Objectives

2.1 Describe the purpose, specific aims, or objectives. (There should be one or two primary objectives with additional objectives listed as secondary.)

2.2 State the hypotheses to be tested.

# Background

3.1 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. Include research references in section 24.0 of this template. Note: this section should be limited to only information directly related to the research questions and objectives. Do not include your full dissertation proposal.

3.2 Describe any relevant preliminary data (e.g. pilot data).

# Safety Endpoints

4.1 Describe any primary or secondary safety endpoints.

# Study Interventions, Investigational Agents, and FDA-Regulated Products *(as applicable)*

5.1 *Describe the study intervention that is being evaluated.*

5.2 Drug/Device Handling: If the research involves drugs or devices, select the applicable options in the table below.

|  |  |
| --- | --- |
| **Devices** | **Drugs/Biologics** |
| FDA Approved Device – Approved Use | FDA Approved Drug/Biologic – Approved Use |
| FDA Approved Device – Unapproved Use | FDA Approved Drug/Biologic – Unapproved Use |
| Investigational Device – Non-Significant Risk | Investigational Drug/Biologics |
| Investigational Device – Significant Risk | Placebo |
| Humanitarian Use Device Exemption | Other Drugs/Biologics |
| Other Devices |  |

* 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 and attach as an appendix at the end of the protocol.

5.3 Investigational or Unapproved Use of Drugs, Biologics, Devices, and HUDs: 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.

* If approved but being used for unapproved use, describe how the use differs from the approved use. For approved drugs/biologics being used for unapproved use, indicate whether you have received an IND for the use of the drug in this study or justify why the drug meets the requirements for an IND exemption (refer to HRP-306 - WORKSHEET - Drugs and Biologics for exemption criteria). For approved devices being used for unapproved use, indicate whether the device has an IDE or qualifies for an abbreviated IDE or IDE exemption (refer to HRP-307 - WORKSHEET - Devices for IDE requirements).
* Provide justification for selecting ‘Non-Significant Risk Device’ in the table above (refer to HRP-418 - CHECKLIST - Non-Significant Risk Device for criteria).

5.4 FDA Approved Drugs/Biologics/Devices: Describe the purpose of any approved drugs, biologics, and/or devices to be used in this study.

5.5 If anyone on the study team is acting as the investigator-sponsor for this clinical investigation, indicate who serves as the manufacturer of the test article and the quality controls that are in place. Indicate where the test article will be stored, who will be responsible for dispensation and documentation of same, and for drugs, whether it requires reconstitution or mixture with another agent, etc. If you are manufacturing the test article, attach the Good Manufacturing Practice (GMP) plan as an appendix at the end of the protocol.

# Procedures Involved

6.1 Describe and explain the study design.

6.2 Please select the methods that will be employed in this study (select all that apply):

|  |  |
| --- | --- |
| Audio/Video Recording | Physical Exam |
| Blinding | Radiation or Radiation-Producing Machines (e.g. X-ray, CT, etc.) |
| Control Group | Radioactive Materials (e.g. Radiopharmaceuticals) |
| Deception | Randomization |
| Focus Groups | Record, Chart, or Dataset Review |
| Follow-Up Call | Specimen Analysis |
| Interviews | Specimen Collection |
| New Innovative Practice/Therapy | Surveys and/or Questionnaires |
| New Investigational Procedure (e.g. a new surgical procedure) | Other Biomedical Procedures |

* Provide a description of all research procedures being performed and when they are performed. (Upload all surveys, scripts, and data collection forms on the Local Site Documents page in the IRB application.)

6.3 Describe which procedures will be conducted per standard of care and which procedures will be conducted solely for research purposes. If the study will involve radiation above standard of care, provide justification in this section.

6.4 Describe the procedures performed to lessen the probability or magnitude of risks of items selected in 6.2.

6.5 If accessing or collecting existing data, describe:

* The data that will be collected during the study (e.g. demographics, medical history, etc.). Attach the data capture sheet(s) on the Local Site Documents page in the IRB application.
* How the data will be obtained, including how you have the authority to access the data.
* The source or location of the data (e.g., USF Epic, TGH Epic, Hillsborough County School records, CANVAS records, publicly available databases, etc.).

6.6 If collecting and/or analyzing biological specimens, describe:

* How the biological specimens will be or have been collected.
* How the biological specimens will be stored.
* How long the biological specimens will be stored.
* How the biological specimens will be used.
* The laboratories that will be used.
* Whether the collected biological specimens will undergo genetic testing. If so, indicate if this study is part of a Genome Wide Association Study (GWAS) and whether the data will be forwarded to the NIH dbGaP.

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

6.8 For Humanitarian Use Device (HUD) uses, provide a description of the device, a summary of how you propose to use the device, including a description of any screening procedures, the HUD procedure, and any patient follow-up visits, tests or procedures. Specify whether the HUD will be used for the HDE-approved indications only or if it will/could be used for other indications as well.

# Data and Specimen Storage for Future Research

7.1 If data or specimens will be banked for **future** **research studies**, describe where the data or specimens will be stored, how long it/they will be stored, how the data or specimens will be labelled and how it/ they will be accessed, and who will have access to the data or specimens. Describe whether the collected biological specimens will undergo genetic testing. If so, indicate if this study is part of a Genome Wide Association Study (GWAS), whether the data will be forwarded to the NIH dbGaP, and attach the NIH-approved Genomic Data Sharing Plan as an appendix to the protocol.

7.2 Once this project has ended, list the data to be stored or associated with each specimen for use in future research.

7.3 Once the project has ended, describe the procedures to release data or specimens, for future research studies 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

8.1 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, indicate whether the lab is CLIA certified, describe under what circumstances results will be shared and how.

# Study Timelines

9.1 *Describe the time commitment of the subjects (i.e. number of study visits, length of visit, length of participation in months or years, etc.).*

# Inclusion and Exclusion Criteria

10.1 Describe how individuals will be screened for eligibility.

10.2 Describe the criteria that define who will be included in your study.

10.3 Describe the criteria that define who will be excluded from your study.

10.4 Describe the circumstances that would make the subject ineligible to continue on the study once included.

10.5 Indicate specifically whether you will include or exclude each of the following special populations: (You may not target members of the populations listed below as subjects in your research unless you indicate this in your inclusion criteria.)

* Students
* Employees
* Socially and/or economically disadvantaged
* Wards of the state

# Vulnerable Populations

11.1 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, review 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.

# Local Number of Subjects

12.1 Indicate the total number of subjects to be accrued locally. Account for screen fails, withdrawals, and drops.

12.2 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.)

# Recruitment Methods

13.1 Describe when, where, and how potential subjects will be recruited.

|  |  |
| --- | --- |
| Email | Online/Social Media Advertisement |
| Flyer | Record Review |
| Letter | Research Match (must upload HRP-500 template) |
| News Advertisement | Other |

13.2 Select and describe the methods that will be used to identify potential subjects, including the plan to review medical records.

* Upload copies of the documents selected above on the Local Site Documents page in the IRB application. For advertisements, upload the final copy of printed advertisements. When advertisements are taped for broadcast, attach the final audio/video recording. You may submit the transcript of the advertisement prior to recording to preclude re-recording because of inappropriate wording, provided the IRB reviews the final audio/video recording. See Question 31 of the Investigator Manual for required language.

13.3 Describe how you will minimize undue influence and coercion during recruitment of special populations as defined in section 10.5 of the protocol and of vulnerable populations as described in section 11 of the protocol.

# Withdrawal of Subjects

14.1 Describe anticipated circumstances under which subjects will be withdrawn from the research without their consent.

14.2 Describe any procedures for orderly termination.

14.3 Describe procedures that will be followed when subjects withdraw from the research, including partial withdrawal from procedures with continued data collection.

# Risks to Subjects

15.1 List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the subjects related the subjects’ 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, and economic risks as well as risks to privacy and/or confidentiality.

15.2 If applicable, indicate which procedures may have risks to an embryo or fetus should the subject be or become pregnant.

15.3 If applicable, describe risks to others who are not subjects.

# Potential Benefits to Subjects or Others

16.1 Describe the potential benefits that individual subjects 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. Note: incentives/compensation for participation are not considered benefits.

16.2 Describe benefits to society or others, if any.

# Data Management and Confidentiality

17.1 Describe the data analysis plan, including any statistical procedures or power analyses.

17.2 Describe the physical and electronic location where the data, including the informed consent document, will be stored and 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.

17.3 Describe any procedures that will be used to ensure the accuracy and quality of collected data.

17.4 Describe how data will be handled study-wide:

* What identifiable information will be included in the data or associated with the specimens (e.g. names, MRNs, dates, zip codes, accession number, etc.)?
* How long the data will be stored? Please refer to the Investigator Manual for data retention requirements.
* How the data will ultimately be destroyed?
* If you plan to share confidential data with anyone outside of the research group (e.g. those not described in the consent), describe:
* With whom you will share the confidential data, under what circumstances this will occur and explain how/whether subjects will be informed.

17.5 If you will review/access and/or collect/obtain Protected Health Information (PHI) during recruitment or the main study, select all that apply:

|  |  |
| --- | --- |
| Obtaining Signed Authorization | Waiver of HIPAA Authorization for Recruitment/Screening Purposes Only |
| Obtaining Online or Verbal Authorization (Alteration of HIPAA Authorization) | Data Use Agreement |
| Waiver of HIPAA Authorization for Entire Study | Business Associate Agreement |

* Describe the PHI that will be disclosed to or received from individuals outside of the research group (e.g. those not described in the consent), and your plan to maintain an accounting of disclosures.
* If you have selected an alteration or waiver in the table above, describe:
  + - The inclusion criteria you will utilize to identify the records (e.g. diagnosis codes (ICD 10), treatments received, etc.).
    - The time interval of the charts/records involved, if applicable.
    - The plan to protect identifiers collected under the waiver or alteration from improper use and/or disclosure.
    - The plan to destroy the identifiers collected under the waiver or alteration at the earliest opportunity consistent with the conduct of the research.
    - Provide written assurance that the PHI will not be reused/disclosed to any other person or entity except as required by law, for authorized oversight of the research project, or for other research which use/disclosure of PHI would be permitted by the HIPAA privacy regulations.
    - Why it is not practicable to obtain signed HIPAA Authorizations from the subjects before using or disclosing their PHI in your study.
    - Why your study cannot be conducted without access to and use of subjects’ PHI.

17.6 NIH Data Sharing Plan

* If this is a NIH funded study, copy and paste the data sharing plan accepted by the NIH sponsored grant. The IRB needs to consider if the plan to share individual subject data is appropriate with regards to the sensitivity of the data collected and the vulnerability of the subject (i.e., if the population being studied is re-identifiable using modern technology, the IRB may restrict sharing certain data points. They may also mandate the data are not shared in an open database system.)

# Provisions to Monitor the Data to Ensure the Safety of Subjects

18.1 If you are using surveys/questionnaires/focus groups and any portion thereof could be upsetting to subjects, describe the nature of the questions and how you will refer subjects for counseling or other assistance. Include a plan for the study team developing criteria for which answers indicate distress, reviewing the answers before the subject leaves the study visit, and a plan for treatment or referral.

18.2 This section is required when research involves **more than minimal risk** to subjects. Describe:

* The plan to periodically (e.g., every 6 months or every nth subject) evaluate the data collected regarding both harms and benefits to determine whether subjects 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 will be 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 subjects).
* The frequency of data monitoring, including when safety data collection starts and how often the data monitoring committee will meet.
* Who will review the data (e.g. a blinded independent monitor, the sponsor, the PI, coordinating center). For investigator-initiated trials, include the names and credentials of the data monitoring committee. If the study is funded by the Department of Defense, provide the name of and contact information for the independent medical monitor, their duties, authorities, and responsibilities.
* The statistical tests for analyzing the safety data to determine whether harm is occurring.
* How it will be decided whether an individual subject should be withdrawn from the study (that is, the study no longer provides the prospect of a potential benefit or the benefits are outweighed by the risks to that subject).
* Any conditions that trigger an immediate suspension and/or termination of the research because the potential benefits of the study are outweighed by the risks to subjects.

# Provisions to Protect the Privacy Interests of Subjects

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

19.2 Indicate how the research team is permitted to access any sources of information about the subjects.

# Compensation for Research-Related Injury

20.1 If the research involves more than minimal risk to subjects, describe the available compensation in the event of research related injury.

# Subject Costs and Compensation

21.1 Describe any costs that subjects will incur because of participation (e.g. travel costs, parking fees, purchase of special materials, etc.) that are over and above the costs that would be incurred from standard care or services, were they not in this study. Indicate whether these costs will be reimbursed. In addition, describe any support that may be available to help defray costs to subjects.

21.2 Describe the amount and timing of any payments/incentives to subjects.

# Consent Process

22.1 Select the consent options you will use during the course of the study. Each selection below must have a description in the subsequent section(s). Choose all that apply:

|  |  |
| --- | --- |
| Obtaining Signed Consent (Subject or Legally Authorized Representative) | Obtaining Consent Online (Waiver of Written Documentation of Consent) |
| Obtaining Signed Parental Permission | Obtaining Verbal Consent (Waiver of Written Documentation of Consent) |
| Obtaining Signed Assent for Children or Adults Unable to Consent | Waiving Consent and/or Parental Permission (Waiver of Consent Process) |
| Obtaining Verbal Assent for Children or Adults Unable to Consent | Waiving Assent/Assent is Not Appropriate |
| ObtainingeConsent Signatures (Subject or Legally Authorized Representative) | ObtainingeConsent Parental Permission |
| Obtaining eConsent Assent for Children |  |

22.2 If you will be obtaining signed consent or electronic consent (eConsent) from the subject or legally authorized individual (LAR), or will be obtaining signed parental permission, describe:

* *Where the consent process will take place.*
* *Specify the platform used for eConsent, if applicable. Refer to Question #32 of the Investigator Manual for regulatory requirements.*
* *Any waiting period available between informing the prospective subject, subject’s LAR, or subject’s parent about the study and obtaining the consent/parental permission.*
* *The process to ensure ongoing consent.*
* *Describe:*
  + The role of the individuals listed in the application as being involved in the consent process. (Do not include names of the individuals.)
  + 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.

22.3 If you will be obtaining consent online or verbally (no signature), review the HRP-411 - CHECKLIST - Waiver of Written Documentation of Consent and provide justification for the requested waiver. Also, please describe:

* Where and/or how the consent process will take place
* Any waiting period available between informing the prospective subject and obtaining the verbal or online consent.
* The process to ensure ongoing consent (if applicable; e.g. for studies involving multiple visits).
* The role of the individuals listed in the application as being involved in the consent process. (Do not include names of the individuals.)
* 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.

22.4 If you will not obtain consent/parental permission for any part of the study, review the HRP-410 - CHECKLIST - Waiver or Alteration of Consent Process and provide justification for the requested waiver.

22.5 If you will obtain consent from non-English speaking subjects, indicate the different language(s) of the prospective subjects and describe the process to ensure that the oral and written information provided to those subjects will be in their primary/native language, including who will act as translator. Refer to Question #20 in the Investigator Manual for requirements.

22.6 If you will enroll individuals who have not attained the legal age for consent (children) or individuals who are unable to provide legal consent (e.g. cognitively impaired individuals or individuals requiring a LAR), describe:

* The criteria that will be used to determine whether a prospective subject has not attained the legal age for consent or is unable to provide legal 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, review HRP-013 - SOP - Legally Authorized Representatives, 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 or cannot provide legal consent to treatments or procedures involved the research, under the applicable law of the jurisdiction in which research will be conducted.
* Whether parental permission will be obtained from:
  + 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.
  + 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. Signatures from both parents are required for studies that are greater than minimal risk with no prospect of direct benefit.
* Whether permission will be obtained from individuals other than parents, and if so, how you will determine that the individual providing consent has the authority to do so.
* For subjects with a LAR, 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.)
* The process for obtaining assent from the subjects. Indicate whether:
  + Assent will be required of all, some, or none of the subjects. If some, indicate 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.
  + Assent of the subjects will be documented and the process to document assent.

22.7 For HUD uses, provide a description of how the patient will be informed of the potential risks and benefits of the HUD and any procedures associated with its use.

# Setting

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

* Identify where research procedures will be performed.
* For research conducted outside of the organization and its affiliates, including research conducted internationally, describe:
  + Site-specific regulations or customs affecting the research for research outside the organization.
  + Local scientific and ethical review structure outside the organization.
  + The composition and involvement of any community advisory board.
  + Upload a letter of support/other committee approval/host country approval on the Local Documents page of the IRB application.

# References

24.1 Provide your references.