**INSTRUCTIONS:**

* Use “TEMPLATE PROTOCOL” to prepare a document with the information from following sections.
* Depending on the nature of your study, some sections may not be applicable to your research. If so mark as “NA”. For example, research involving a retrospective chart review may have many sections with “NA.” For subsections, like 1.x or 8.x, you can delete it if it’s not applicable.
* When you write a protocol, keep an electronic copy. You will need to modify this copy when making changes.
* As you are writing the protocol, remove all instructions in italics so that they are not contained in the final version of your protocol.
* Omit starred (\*) items if this is the activation of a protocol at a new site or sites that will be overseen by a principal investigator who will take separate and full responsibility for that site or those sites. Complete by describing information specific to the site(s). Do not repeat information in the approved protocol that applies to all site(s).

**PROTOCOL TITLE:**

*Include the full protocol title.*

**PRINCIPAL INVESTIGATOR:**

*Name*

*Department*

*Telephone Number*

*Email Address*

**VERSION NUMBER/DATE:**

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

**REVISION HISTORY**

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

|  |  |
| --- | --- |
| **Study Title** |  |
| **Study Design** |  |
| **Primary Objective** |  |
| **Secondary Objective(s)** |  |
| **Research Intervention(s)/ Investigational Agent(s)** |  |
| **IND/IDE #** |  |
| **Study Population** |  |
| **Study Duration for individual participants** |  |
| **Study Specific Abbreviations/ Definitions** |  |

# Objectives\*

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

# Background\*

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

# Study Endpoints\*

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

# 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 subjects for safety or minimize risks.
  3. 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 that will be used to collect data about subjects. (Attach all surveys, scripts, and data collection forms.)
  4. What data will be collected during the study and how that data will be obtained.
  5. If there are plans for long-term follow-up (once all research related procedures are complete), what data will be collected during this period.

# Study Timelines\*

* 1. Describe:
     + The duration anticipated to enroll all study subjects.
     + The estimated date for the investigators to complete this study (complete primary analyses)

# Inclusion and Exclusion Criteria\*

* 1. Describe how individuals will be screened for eligibility.
  2. Describe the criteria that define who will be included or excluded in your final study sample.
  3. Indicate specifically whether you will include or exclude each of the following special populations: (You may not include members of the above populations as subjects in your research unless you indicate this in your inclusion criteria.)
     + Individuals who are not yet adults (infants, children, teenagers)
     + Prisoners

# Risks to Subjects\*

* 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.
  2. If applicable, indicate which procedures may have risks to the subjects that are currently unforeseeable.
  3. If applicable, indicate which procedures may have risks to an embryo or fetus should the subject be or become pregnant.
  4. If applicable, describe risks to others who are not subjects.

# Potential Benefits to Subjects\*

* 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.
  2. Indicate if there is no direct benefit.

# Data Management\* and Confidentiality

* 1. Describe the data analysis plan, including any statistical procedures or power analysis.
  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. Children’s Business Intelligence requires the following data storage elements for every study that uses CHOA data. Please include this language in each protocol: “Data will be stored on each users secure servers and not downloaded to external devices, including laptops. The information, even if de-identified, will be destroyed at the expiration of the project.”

# Consent Process

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

* For waiver of consent:
  + Explain how the research involves no more than minimal risk
  + Explain why the waiver or alteration will not adversely affect the rights and welfare of the participants.
  + Explain why the research could not practicably be carried out without the waiver or alteration.

# HIPAA Applicability

* 1. *Describe the use of PHI in the study.*
  2. *If PHI is being used, indicate whether there will be Written Authorization, a Partial Waiver, Full Waiver, or Alteration of HIPAA Authorization.*
  3. *If requesting a waiver of HIPAA authorization (partial, full, or alteration) please include the following:*
     + *Describe the plan to protect identifiers from disclosure or improper use.*
     + *Describe an adequate plan to destroy the identifiers at the earliest possible opportunity consistent with the conduct of research.*
     + *Describe written assurances that the identifiers will not be re-used or disclosed to any other person or entity (except as required by law, for authorized oversight of the research, or for other research for which the use of disclosure of PHI would be permitted by HIPAA)*
     + *Certify and describe why the research cannot practicably be conducted without access to and use of PHI.*
     + *Describe why the waiver will not adversely affect the rights or welfare of the research subject.*
     + *Note: If accessing psychotherapy notes (notes recorded by a health care provider who is a mental health professional documenting or analyzing the contents of conversation during a private counseling session or a group, joint, or family counseling session and that are separated from the rest of the of the individual’s medical record), the study is not eligible for a HIPAA waiver.*

# 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 subjects.
     + Identify where research procedures will be performed.
     + 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.