Protocol TEMPLATE: Observational Study

This template can be modified to accommodate a variety of observational study designs. “Observational” research studies are those in which individuals are observed, researchers collect information from participants, and/or assess and measure certain outcomes. No intervention is introduced that could impact the outcome.

1. Please note all instructions are in BLUE and all examples are in BLACK.
2. Sections that are not applicable to this protocol may be deleted.
3. You may add other sections if you feel they are necessary.
4. For any section that is addressed in both the SmartForm and attached protocol, the content must be consistent.

Investigators are advised to review this document before drafting a protocol to ensure familiarity with the details that are required.

|  |  |
| --- | --- |
| Title: | **Complete Title** |
| Principal Investigator: |  |
| Protocol Number: |  |
| Protocol Date: |  |
| Amendment 1 - Date: |  |
| Amendment 2 - Date: |  |
| Amendment 3 – Date: |  |
| Amendment 4 – Date: |  |
|  |  |

Abbreviations and Definitions of Terms

Define any abbreviated terms

Example:

|  |  |
| --- | --- |
| °C | Degrees Centigrade |
| AE | Adverse Event |
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Protocol Synopsis

The synopsis should provide a rapid overview of the study that is accessible to individuals without a medical background

* Keep the synopsis BRIEF.
* Use bullet points.
* Use lay language as much as possible and avoid overly technical terms.

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| --- | --- |
| Study Title | Title |
| Funder | Grant agency or departmental funds |
| Study Rationale | No more than ½ page |
| Study Objective | Primary   * To determine (obtain, evaluate, verify, etc.…)   Secondary   * To determine (obtain, evaluate, verify, etc.…) |
| Study Design | Overview of observational study design.  *Explain the basic design such as cohort study, case-control study, or cross-sectional. Specify image collection and/or other primary data points that will be collected and analyzed.* |
| Participant Population | **Inclusion criteria**   1. Participants age X – XX 2. Include main criteria, but does not need to be complete, etc.   **Exclusion Criteria**   1. Participants with X or Y, etc. |
| Number of Participants | Total Number of Participants   * Total number at BCH * Total number at all Sites if multicenter study |
| Study Duration |  |
| Duration of each participant’s participation |  |
| Study Phases | Usually, observational studies have at least 2 phases:   1. Screening: Screening for eligibility and obtaining HIPAA authorization/consent (if applicable) 2. Observation Period: Measurements made for monitoring participants once (Cross-sectional) or over time (cohort) |
| Statistical and Analytical Plan | Limit to discussion of analysis to primary endpoint and possibly main secondary endpoint |
| Data and Safety Monitoring Plan (DSMP) | Describe who is responsible for data quality management and ongoing assessment of safety: PI, internal safety committee, or Data Safety Monitoring Board (DSMB) |

Example – Table 1: Schedule of Study Procedures

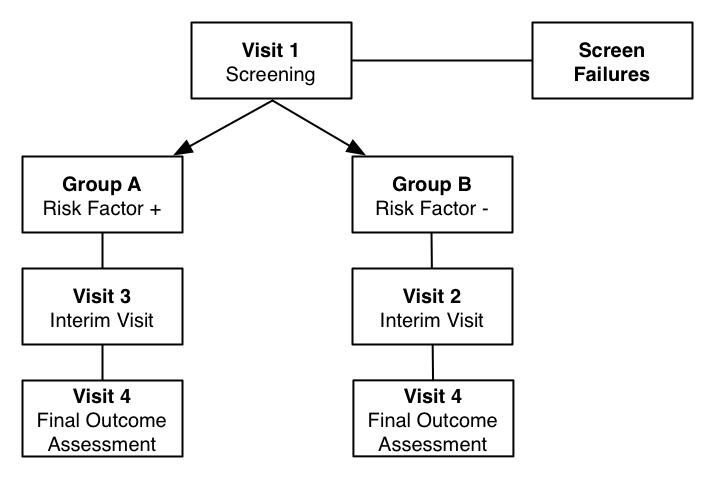
This table is an example of a schedule of procedures. The Investigator should construct a table based on the procedures in the protocol. If the study involves more than 1or 2 visits, a table should be include in the Consent Form or as an Appendix to the Consent Form. This type of table may also be moved near section 4.

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| --- | --- | --- | --- | --- | --- | --- |
| **Study Phase** | Screening | Observation Study Visits | | | Follow-up | |
| **Visit Number** |  | 1 | 2 | 3 | 4 | 5 |
| **Study Days** |  |  |  |  |  |  |
| Informed Consent/Assent |  |  |  |  |  |  |
| Review Inclusion/ Exclusion Criteria |  |  |  |  |  |  |
| Demographics/ Medical History |  |  |  |  |  |  |
| Physical Examination |  |  |  |  |  |  |
| Vital Signs  BP, HR, RR |  |  |  |  |  |  |
| Height & Weight |  |  |  |  |  |  |
| Pregnancy Test |  |  |  |  |  |  |
| Prior & Concomitant Medications |  |  |  |  |  |  |
| Abdominal Ultrasound |  |  |  |  |  |  |
| Brain MRI |  |  |  |  |  |  |
| DEXA Scan |  |  |  |  |  |  |
| Questionnaires |  |  |  |  |  |  |
| Adverse Event Assessment |  |  |  |  |  |  |

# Example – Figure 1: Study Diagram

A flow diagram of the study may be relevant to explain the flow of participants in the trial. Whenever possible do not copy the detailed table form the manual of operations and rather format this as a simplified flow diagram. This type of table may also be moved near section 3.

Example: Prospective cohort study



**1. Introduction**

**1.1 Study Rationale**

**Describe the setting and rationale for the study**.

* Include background information for the following (this information should be linked to the study rationale as relevant):
  + a description of the disease, including the mechanism
  + the burden and epidemiology of the disease
  + the population(s) and demographics of the populations affected
  + If there are subgroups, describe and address any variability in safety/efficacy/etc. by subgroup
  + unmet medical needs or specific requirements of the population and/or subgroup
  + available drugs and/or intervention(s) for treatment, including treatments by subgroup, if applicable
* Address whether the population that you are enrolling has similar demographics to the disease population for whom the intervention is intended

**1.2 Relevant Literature and Data**

**Include an overview of the literature and data relevant to the trial and provide background for the trial, and relevant literature establishing the validity for scales, evaluation tools, etc.**

2. Study Objectives and Design

* A study objective is a statement of purpose (e.g., to assess, to determine, to compare, to evaluate) and include the general purpose and/or specific purpose.
* Do not include hypotheses in this section. If there are hypotheses, they belong in the Analysis section.

**2.1 Primary Objective (or Aim)**

**State the primary objective of this study.**

This is the most important objective which generally drives the statistical planning (e.g., calculation of sample size to provide appropriate power for statistical planning).

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| Examples:   * The primary objective of this study is to determine the whether the X intervention reduces … * The purpose of the study is to determine [efficacy, pharmacokinetics, safety etc.] of … |

**2.2 Secondary Objectives (or Aim)**

**State the secondary objective(s).**

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| Examples:   * Determine if there is a relationship between X to Y. * Additional secondary objectives as applicable |

3. Investigational Plan

**3.1 General Schema of Study Design**

Section 3.1 is intended to be a brief overview of the study design. Please note, Section 4 is where the study details and procedures belong.

**Provide a general description of the study design**, which should include (as applicable):

* Indicate if single-site or multi-site
* Type of trial: e.g., retrospective or prospective cohort studies, cross sectional studies, case control studies, descriptive studies.
* Description of each study groups

**3.2 Study Duration, Enrollment, and Number of Sites**

*3.2.a* **Duration of Study Participation for each Participant**

**Describe the duration of participant’s participation, not the duration of study.**

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| Example:  The study duration per participant will be up to #days, with up to #days for screening, up to #days for Phase 1, up to #days for Phase 2, and #days for follow-up. |

*3.2.b* **Total Number of Study Sites/Total Number of Projected Participants**

This information is also included in the CHeRP SmartForms, so please ensure it is consistent with the information in the SmartForm.

**Specify the total number of**:

* Study Sites
* Planned Enrolled participants (those who consent to participate)
* Projected Evaluable participants (enrolled participants whose data is used in final analysis). This number may be lower than the number of enrolled participants if it is expected that some participants will withdraw.

*\* Please note that the evaluable goal cannot be larger than the enrolled goal*

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| Examples:   * The study will be conducted at approximately X sites in the United States and will enroll XX participants. * It is expected that approximately X participants will need to be enrolled to produce XX evaluable participants. |

**3.3 Study Population and Recruitment**

**Define the study population using inclusion and exclusion criteria, regardless of study design.**

For each participant group, there needs to be separate inclusion/exclusion criteria. For example, the control population may have different selection criteria than the population with the disease or condition of interest.

*3.3.a* **Inclusion/Exclusion Criteria for each participant group.**

Consider the following:

* Exclusion must be scientifically, medically, and ethically justified.
* If there are subpopulation, inclusion criteria may need adjusted for laboratory and other differences by subgroup
* As appropriate, accessibility efforts and provisions for populations such as individuals:
* with disabilities
* whose preferred language is other than English (or the preferred language of the region)
* who are transgender or non-binary. Note that in data collection:
  + Sex and gender should be reported as different variables.
  + Consider when and how sex and gender will be collected and reported.

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| Examples:  **Index/Case Participant Inclusion Criteria**   1. Individuals age X to XX years 2. Diagnosis of XX 3. Individuals able to give birth ≥ 11 years of age must have a negative pregnancy test.   *Consider referencing “Individuals able to give birth” and “their partners,” rather than specifying any sex or gender.*  *“Able to give birth” is defined as the individual is in puberty as defined by Tanner stage or menarche.*   1. Parental/guardian permission (informed consent) and if appropriate, child assent.   **Index/Case Participant Exclusion Criteria**   1. Laboratory abnormalities that indicate clinically significant renal disease  |  |  | | --- | --- | | AST/SGOT | > 2.0 times the upper limit of normal | | Total bilirubin | > 2.0 times the upper limit of normal | | Hemoglobin | < 9 gm/dL | | White blood cell count | < 3,000/ mm3 |  1. Pregnant or lactating individuals 2. Parents/guardians or participants who in the opinion of the Investigator may not be complaint with study schedules or procedures   **Control Participant Inclusion Criteria**   1. Individuals age X to XX years 2. Additional inclusion criteria as applicable   **Control Participant Exclusion Criteria**   1. Exclusion criterion 1. 2. Additional inclusion criteria as applicable |

*3.3.b* **Recruitment Strategy**

This information is also included in the CHeRP SmartForms, so please ensure it is consistent with the information in the SmartForm.

* **Describe the approach to recruiting participants**, including:
* how you are ensuring that the study cohort is representative of the population with the disease/disorder under study.
* efforts of inclusion and accessibility.
* *If considered*, **provide details about how culturally and linguistically appropriate recruitment methods and materials will be used and their development** (e.g. working with a community advisory board, working with Boston Children’s Hospital’s Office of Health Equity, and Inclusion (OHEI), etc.).
* **Detail where and how potential participants will be recruited by providing the following information**:

1. Where will participants come from?
2. How will the investigator identify prospective participants?
3. Will the participants come from the investigator’s patient pool, or will they be patients of other care providers?
   1. If the prospective participants are not patients of the investigator, who will first approach the participants and by what method (e.g. in person, via mail, via telephone contact)?
4. Will advertising be used?
   1. All recruitment materials, visual and auditory that will be presented to potential participants must receive prior review and approval from the IRB before being utilized in participant recruitment.

* **Describe if eligibility screening requires collection of data about prospective participants** (via medical record review, direct query or other procedures), and if this screening will take place before participants consent to participation in the main study.

4. Study Procedures

This section should list the procedures, observations, measures, etc., including history, examination, or other monitoring procedures and measurements. This is usually included as a simple bullet list of all the procedures that will take place at each visit. Items to note:

* Section 4 lists what will be done.
* Section 5 describes how it will be done.
* For complicated studies with several visits, it is recommended that the investigator create a Table of Procedures.

The study should consider efforts that enable ease of participant accessibility. Examples could include, but are not limited to doing virtual visits, night and weekend hours, using local labs, and/or home health care for visits. If possible, include provisions or efforts to accommodate individuals who may have challenges with transportation, employment, or childcare. Visit frequency should be minimized to the extent possible, while still aligning with the objectives of the study.

**4.1 Screening Visit**

**Create a simple list of the timing and all the procedures to be performed at the screening visit. Indicate NA if screening is conducted solely through medical chart review.**

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| Example:   * Informed Consent/Assent/HIPAA authorization [See the IRB’s webpage on Recruitment vs Screening for more information on whether consent is required for screening) * Physical Exam * Abdominal Ultrasound * Brain MRI * DEXA Scan * Electrocardiogram (ECG) * Laboratory Tests * Questionnaires * Medical Record Review |

**4.2 Observational Period**

**Provide a general overview of this phase**. This can be a simple bullet list of all the study procedures that will take place. If possible, all study procedures for a visit will be performed on the same day. The study coordinator should be able to quickly review the list of procedures at each visit to correctly execute the study.

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| Example:  Participants will be seen three time during the first 6 months. |

*4.2.a* **Visit 1 (Baseline)**

**List all procedures to be performed during this study visit**

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| Example:  **Visit 1**   * Physical Exam * Vital Signs * Abdominal Ultrasound * DEXA Scan * Questionnaires * Laboratory Tests |

*4.2.b* **Study Visits**

**List all study visits. For each visit, indicate time frame and list the procedure to be performed during specific visit.**

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| Example:  **Visit 2** (3 months)   * Physical Exam * Abdominal Ultrasound * DEXA Scan * Questionnaires   **Visit 3** (6 months)   * Physical Exam * Vital Signs * Questionnaires |

**4.3 Follow-up Phase and End of Study Visit**

**Provide a general overview of this phase***, if applicable*.

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| Example:  After visit 3, participants will be contacted by phone every six months for a total of three years.  Visits 4 – 9 (phone call @ 12, 18, 24, 30, 36 and 42 months):   * Questionnaire 1 and 2   Visit 10 (48 months – Final study visit)   * Physical Exam * Abdominal Ultrasound * DEXA Scan * Questionnaires |

**4.4 Unscheduled Visits.**

**Describe how unscheduled visits will be handled.**

**4.5 Participation Completion/Withdrawal**

**Describe the withdrawal process of participants and plans for provision of care after withdrawal.**

* Participants may withdraw from the study at any time without prejudice to their care. They may also be discontinued from the study at the discretion of the Investigator for lack of adherence to study treatment or visit schedules, Adverse Events (AEs), or due to [REASON] (i.e., provide list).
* The Investigator or the Sponsor may also withdraw participants who violate the study plan, or to protect the participant for reasons of safety or for administrative reasons. It will be documented whether or not each participant completes the clinical study. If the Investigator becomes aware of any serious, related adverse events after the participant completes or withdraws from the study, they will be recorded in the source documents and on the CRF.

Consideration*: Track sociodemographic characteristics of withdrawal and early terminations to* monitor for patterns/impact on certain groups.

*4.5.a* **Early Termination Study Visits**

**List the procedures that will be performed for each participant that withdraws prior to completing the study.**

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| Example:  Participants who withdraw from the study will have all procedures enumerated for Visit XXX as the early termination visit. |

5. Study Procedures

**For each monitoring procedure and measurement listed in Section 4, describe exactly how the measurement will be made.**

* Each evaluation, BP, QOL questionnaire, etc. should be listed with a description here.
* A copy of any non-standard and non-validated instrument should be attached as an appendix. Standard validated tests and test instruments do not have to be included.
* Inclusion of data collection forms or case report forms are not required.

**5.1 Screening and Monitoring Evaluation and Measurements**

*5.1.a* **Medical Record Review**

**Include a listing of the variables that will be abstracted from the medical chart (paper or electronic).**

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| Example:   * Date of birth * Weight * Additional data points as applicable |

### *5.1.b* Physical Examination

**Describe the baseline evaluations including the medical history, physical examination, demographic characteristics (e.g. age, gender, race), and other information that will be collected.**

*5.1.c* **Vital Signs**

**Describe which measures will be taken and how they will be made.**

Possible descriptions to provide:

* Will BP be measured with an automated device or with an aneroid sphygmomanometer?
* Which arm will be used? Sitting or lying down?
* Will more than one BP measurement be made and averaged?

*5.1.d* **Laboratory Evaluations for Research Purposes**

**Only list evaluations performed for research, not performed as part of clinical care**.

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| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Example:  ***Clinical Laboratory Tests – Validated tests performed in a CLIA/CAP lab***   |  |  | | --- | --- | | **Category** | **Tests** | | Hematology | RBC, hemoglobin, hematocrit, platelet count, WBC w/differential | | Liver function tests | SGOT/AST, SGPT/ALT, total Bilirubin | | Renal function tests | BUN, creatinine | |

*5.1.e* **Research Laboratory Tests – Non-validated tests performed in a research lab**

**Only list evaluations performed for research, not performed as part of clinical care.**

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| Example: Exploratory Biomarkers |

*5.1.f* **Pregnancy Testing**

*If applicable*: Remember that pregnancy testing in adolescents and decisionally impaired adults requires accepting responsibility for communication of positive results to the adolescent in a fashion that respects their privacy

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| Example:  A urine pregnancy test will be performed for all individuals capable of becoming pregnant ≥ 11 years of age and those <11 years who have had a menstrual period. |

**5.2 Brain MRI**

### Describe the MRI, address whether contrast or sedation will be used and whether all MRI sequences are FDA-approved, etc, *if applicable.*

**5.3 Questionnaires, Surveys, Psychological Assessment Tools**

**Describe the questionnaires, surveys, psychological assessment tools that will be used, including validation information, age range for which the measures are validated, etc. Copies of questionnaires should be attached in the smart forms.**

**5.4 Other Evaluations, Measures**

Describe other rating scales, psychological tools, laboratory evaluations, etc. These should be attached in the smartforms.

6. Statistical Considerations

This section should provide sufficient detail to permit assurance that the sample size is justified and the statistical methods sufficient and appropriate for the research question(s). The statistical analysis plan should include whether and how subgroup population differences will be evaluated and reported.

If there are hypotheses, in this section those can be outline with a description of the analyses that address the hypotheses.

**6.1 Primary Endpoint**

**Describe the primary endpoint**.

The primary endpoint is the variable that relates back to the primary objective and serves as the basis for the justification for the sample size.

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| Example:  The primary endpoint will be based on timeline or certain clinical parameters |

**6.2 Secondary Endpoints**

**List the secondary endpoint(s)**.

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| Examples:   * Survival   Improvement/deterioration of QOL   * Improvement or exacerbation of symptoms * Measurements and evaluations |

**6.3 Control of Bias and Confounding**

Participants in observational studies are not assigned by a process of randomization and are therefore subject to bias.

**Describe the measures to be taken to avoid bias (details can be given in Section 4).**

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| Examples:   * Radiographic studies might be read by a radiologist blinded to the diagnosis, psychological measurements can be made by an individual blinded to the participants group assignment or outcome, charts can be reviewed without knowledge of outcome. * Cases might be included only if the initial presentation was within the study window; otherwise complex cases or recurrent disease might be over-represented in the sample because both old and new cases would be captured. |

**6.4 Statistical Methods and Analysis**

*6.4.a* **Baseline Data**

**Describe how baseline and demographic characteristics will be summarized by standard descriptive summaries** (e.g. means and standard deviations for continuous variables such as age and percentages for categorical variables such as gender).

*6.4.b* **Special considerations**

* **Selection bias, subgroup exclusion, and loss to follow-up**

Examining screen failure rates and data are important to determine if there is selection bias and whether the resulting data is representative. It is important to assess whether certain subgroups are disproportionately impacted by the screening process. This section of the protocol should address how screen failures will be reviewed to identify potential disparity in subgroup exclusion. Investigators may consider scheduled study participant reviews during the study to evaluate if sample stratification is occurring and if recruitment efforts are not reaching certain groups (i.e. marginalized patients historically underrepresented in research or those primarily affected by the diagnosis). These scheduled reviews give the PI time to review recruitment strategies and potentially further recruitment efforts to assure equitable access and inclusion.

The protocol application should provide a plan to review participant loss-to-follow-up, considering both demographic and non-demographic factors. Examining discontinuation/withdrawal rates and associated data are important to identify any patterns that may emerge. Further, it is important to assess whether there is selection bias that could potentially impact the generalizability of the study results.

The statistical analysis plan should include whether and how subgroup population differences will be evaluated and reported.

* **Considerations of Race/ethnicity in the Interpretation of Results and Impact**: Studies that focus on differences by certain subgroups, such as race/ethnicity have the potential to perpetuate theories of biological inferiority and discriminatory behavior. The study team should be mindful of how they interpret the results so as not to draw conclusions that individuals who have been historically underrepresented in research, from marginalized populations, and/or medically underserved populations are more likely to have negative outcomes (i.e., surgical complications) through some fault of their own – rather than considering potential structural factors. While the study team cannot influence how others interpret their work, the study team could help ensure their work is not used to perpetuate biases by carefully considering and focusing on how they describe and discuss their results, the language used in the title, and presentations and manuscripts that present study findings.
* **Guidance**: [AAMC](https://www.ama-assn.org/system/files/ama-aamc-equity-guide.pdf) and [CDC Health Equity Style Guides](https://www.cdc.gov/healthcommunication/Resources.html).

**6.5 Sample Size Power**

**Include sample size justification and power analysis**, *if applicable.*

All studies must include a justification for the chosen sample size even if a power analysis isn’t appropriate (i.e. a PK study). The basis for how the size was chosen should be explained. Any assumptions made (mean and SD), clinically important differences, and the details of the calculation should be included. Make sure there is adequate power to consider subgroups (e.g., race/ethnicity) if that is part of the purpose of the study.

**7. Adverse Events and Serious Adverse Events**

**7.1 Definitions**

*7.1.a* **Definition of an Adverse Event**

An adverse event is any untoward medical occurrence in a participant who has received an intervention (drug, biologic, or other intervention). The occurrence does not necessarily have to have a causal relationship with the treatment. Therefore, an AE can be any unfavorable or unintended sign (i.e. including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product.

**Provide the definition of an AE being used for the study.**

*7.1.b* **Definition of a Serious Adverse Event (SAE)**

An SAE is any adverse drug experience occurring at any dose that results in any of the following outcomes:

* death,
* a life-threatening event (at risk of death at the time of the event),
* requires inpatient hospitalization or prolongation of existing hospitalization,
* a persistent or significant disability/incapacity, or
* a congenital anomaly/birth defect in the offspring of a participant.

Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered a serious adverse drug event when based upon appropriate medical judgment – events may jeopardize the participant and may require medical or surgical intervention to prevent one of the outcomes listed in this definition.

**Provide the definition of a SAE being used for the study.**

**7.2 Identification and Classification of AEs and SAEs**

The Investigator is responsible for recording all AEs and SAEs related to research that occur during and after study treatment. For each AE and SAE, with a full description of the event, including the following:

* 1. Expectedness
  2. Severity of the event
  3. Relationship to study intervention
  4. Duration and Frequency: date and time of onset
  5. Outcome of the event

*7.2.a* **Severity of Event**

**Describe method of grading severity and intensity of event** (e.g., Mild, Moderate, Severe)

*7.2.b* **Time Period and Frequency for Event Assessment and Follow-up**

**Describe how AEs and SAEs will be identified and followed until resolved or considered stable. Specify timeframes and procedures for recording and follow-up of AEs and SAEs**

**7.3 Reporting AEs, SAEs and other Unanticipated Events**

Unanticipated problems related to the research involving risk to subjects or others that occur during the course of this study (Including SARS) are required to be reported to the IRB in accordance with BCH IRB policy Reportable Events unanticipated problems and Adverse Effects Involving Risks to Research Subjects and Others Policy /Procedure **Describe the reporting procedures for the IRB, Sponsor and regulatory agencies as applicable, including timeframes.** Further details could be included or described through:

* Manual of Operations
* Standard Operating Procedures (SOPs)
* Description and a flow chart of when events are reported to various oversight and regulatory groups, and what study staff are responsible for completing and signing off on the reports, and who will receive notification of reports .

**7.4 Medical Emergencies**

**Describe any plans or procedures for taking care of medical emergencies that might develop during the study***, if applicable:*

**7.5 Multisite Safety Monitoring**

**If this is a multi-site study, describe plans for completion of safety monitoring. Describe the process for communication among sites concerning information relevant to the protection of participants such as serious adverse events, unanticipated problems, interim results and protocol modifications. If this is not a multisite study, state that .**

**8. Study Administration**

**8.1 Data Collection and Management and Confidentiality**

This information is also included in the CHeRP SmartForms, so please ensure it is consistent with the information in the SmartForm.

* **Describe the system for maintaining primary records (source documents), case report forms, screening data (both for participants who are eligible and enrolled in the main study and for individuals who are screening failures, when applicable), and for entering the data into any computerized systems.**
* Address how the confidentiality of the data be ensured, from abstraction though analysis. Provide a specific plan for removing identifiers that meets the needs of the study and potential future uses of the data.
* Include a statement that all data and records generated during this study will be kept confidential in accordance with institutional policies, HIPAA on participant privacy, and that the Investigator and other site personnel will not use such data and records for any purpose other than conducting the study or describe how the data may be shared.
* Describe the safeguards to maintain participant confidentiality.

**8.2 Data and Safety Monitoring Plan**

This information is also included in the CHeRP SmartForms, so please ensure it is consistent with the information in the SmartForm.

* **Describe the data safety and monitoring plan (DSMP**).
* Include the processes and safeguards that will be in place to identify risks to research participants and to protect participants during the execution of the trial. The plan should be tailored to the risks of the study intervention, the nature of the disease process, and should provide oversight for the emerging safety information could include one or more of the following:
* Principal Investigator
* Medical Monitor associated with the sponsor or the study
* Independent Safety Officer
* Internal Steering Committee or Internal Data Monitoring Committee made up of representatives of the sponsor and study investigators
* Data Safety Monitoring Board (DSMB) or Data Monitoring Committee (DMC) made up of representatives who are independent of the study sponsor and investigators.
* Certain studies may be required to include an independent Data and Safety Monitoring Board (DSMB) that will be in place to monitor the safety events associated with the study. If a DSMB will be employed, the full details of the composition of the DSMB, how it will operate, and how the interim analyses are to be performed should be provided.

**8.3 Risk Assessment**

This information is also included in the CHeRP SmartForms, so please ensure it is consistent with the information in the SmartForm.

* **Describe the risks of each research intervention or procedure in terms of magnitude and probability of harm.** Risks categories are:
* not greater than minimal
* a minor increase above minimal
* greater than minimal.
* Consider all physical, psychological, economic, or societal harms that might accrue to participants or others. Possible descriptions to include:
* Do certain subpopulations face greater risk or potential benefit than others? If so, how, and why?
* What measures are the study taking to minimize burden and risk, and ensure protections for those most vulnerable, understudied, or underrepresented?
* Does the study have the potential to influence health equity or disparities among individuals, communities, or other groups?
* As applicable, include potential risk by demographic subgroups.
* In addition, factors relating to social determinants of health (SDOH) may need to be listed with potential mitigation strategies for risk reduction.
* Distinguish between risks associated with routine clinical care from those that will occur as a result of research.
* Summarize the overall anticipated risks from the study intervention and study-related procedures.
* Address how the study design and execution will minimize the risks of harm.

**8.4 Potential Benefits of Trial Participation**

This information is also included in the CHeRP SmartForms, so please ensure it is consistent with the information in the SmartForm.

**Summarize all potential benefits**, as applicable. Benefits should be broken down into direct benefits (i.e. accrue to the study participant as a result of participation) and indirect benefits (i.e. benefits that accrue to the individual or society in the future).

**8.5 Risk-Benefit Assessment**

This information is also included in the CHeRP SmartForms, so please ensure it is consistent with the information in the SmartForm.

**Include the justification for the Risk-Benefit for proceeding with the trial based on the balance between risks and benefits.**

**9. Informed Consent**

This information is also included in the CHeRP SmartForms, so please ensure it is consistent with the information in the SmartForm.

**9.1 Informed Consent/Assent and HIPAA Authorization**

**Describe the procedures that will be used to obtain informed consent/HIPAA Authorization and assent.** Include:

* who will obtain consent and assent
* where will consent/assent process take place
* how privacy will be assured

*e.g., the consent conference will occur in a private exam room*

* how much time will subjects be permitted to make a decision
* how the investigators will assure that subjects comprehend the nature of the study the study procedures and the risks and benefits of participation
* steps that will be taken to avoid coercion and documentation of consent.

**If the study includes several populations or scenarios for obtaining consent, create subsections to address them** (e.g. for those who provide consent/assent/HIPAA authorization in person, those who provide consent/assent/HIPAA authorization over the phone, etc.).

**9.2 Consent/HIPAA Authorization Plan for Subjects Who Reach Age of Majority**

**Describe the consent/HIPAA authorization process for individuals who become legal adults while enrolled in the study.**

* If subjects will provide verbal consent/HIPAA authorization for their continued participation (e.g. if they are contacted over the phone), make sure the CHeRP SmartForm request a waiver of documentation of consent (to obtain verbal authorization), and that a verbal consent/HIPAA authorization form is provided.
* If no subjects will reach the age of majority while enrolled, delete this section

**9.3 Individuals with Limited English Proficiency**

**Describe the consent/assent/HIPAA authorization process for individuals with limited English proficiency.**

* If subjects will be enrolled over the phone, outline the role of the interpreter in the phone conversation (i.e. will they be physically present with the investigator or conferenced into the call, how will interpreters/witnesses document their role in the consent process, etc.).

**9.4 Adults with Impaired Decision-Making Capacity**

**Describe the process to determine whether an individual is capable of consent and who will make this assessment.** This process should reflect the complexity and risk level of the study.

**Describe the consent process for individuals with impaired decision-making capacity who are capable of consent.**

**10. Publication**

This information is also included in the CHeRP SmartForms, so please ensure it is consistent with the information in the SmartForm.

**Describe the plans for publication.**

Include plans for dissemination of research findings to participants/community.

**11. References**

**Include all references in this section.**

**12. Appendix**

**Append relevant information.**