**NOTE:**

This is a template.

Please adjust to suit research project.

**Template Version: April 22, 2020**

**Protocol Template: Qualitative Study**

**PREFACE**

Remove this **Preface** before finalizing and distributing the Qualitative Research Study protocol. This protocol template should be used for investigators conducting qualitative studies such as Grounded Theory, Phenomenology, Ethnography, Narrative Research, and Case Study\*.

**\*NOTE:** A **case study** as a qualitative research methodology enables the exploration of a complex real-life and space-bound (a case) phenomenon through multiple data sources (allowing for multiple facets of the phenomenon to be discovered and understood). The observed case is a real situation such as exploring registered nurses’ engagement with electronic health records. Whereas a **clinical case study** is a type academic publication / report where medical practitioners share patient cases that are unique or unreported (i.e., complication of a known disease, adverse response to a treatment).

The goal of this template is to assist you in writing a comprehensive Qualitative Research Protocol*.* Its use will help you think through the scientific basis of your assumptions, minimize uncertainty in the interpretation of outcomes, and prevent loss of data.

**INSTRUCTIONS ON HOW TO USE THIS TEMPLATE**

The template includes the framework for organizing your protocol, as well as instructions and example text.

*Italics:* **Instruction / Explanatory Text** is indicated by *italics.* This text provides information on the content that should be included; these instructions should be deleted once you complete a section. Footnotes to instructional text should also be deleted. The instructions also note if a section should be left blank.

[Regular font]: **Example Text** is indicated in [regular font]. Within example text, the need to insert specific information is notated by <angle brackets>. Example text is included to further aid in protocol writing and should either be modified to suit the study, objectives and / or design. If not applicable for your study, delete the example text.

You will find it helpful to consider all sections, however, depending on your research focus and design, not all sections will be applicable to your study and you should delete sections (including the section heading) that do not apply.

If sections are deleted, ensure that any text that refers to another section is updated as needed. The section headers include formatting to generate a table of contents, once the protocol is written, ensure the table of contents is updated (right click on the table of contents and select ‘Update Field’) to reflect any changes.

Version control is important to track protocol development, revisions, and amendments. It is also necessary to ensure that the correct version of a protocol is used by all staff conducting the study. With each revision, the version date located in the header of each page should be updated.

**RESOURCES**

Remove **Resources** before finalizing and distributing the prospective / observational protocol.

* SickKids Clinical Research Services
* [SPRINT: Streamlined Pathway for Research Initiation](about:blank)
* [**Consent for Non-Interventional/Observational Studies - Parent**](about:blank)(v.Nov 2019)

**<tITLE OF THE PROTOCOL>**

|  |  |
| --- | --- |
| **Principal Investigator:** | *Insert the Name of the Investigator*  *Insert Department Name*  *Insert Address*  *Insert Email Address*  *Insert Phone Number* |
| **Additional Investigators:**  *[PI at additional sites, etc. as applicable]* | *Insert the Name of the Investigator*  *Insert Department Name*  *Insert Address*  *Insert Email Address*  *Insert Phone Number* |
| **Sponsor:** | *Insert Sponsor* |
| **Funded by:** *[If applicable]* | *Insert Funding Source (e.g., CIHR, Heart and Stroke Foundation, MOHLTC, etc.)* |
| **Version Date [Day, Month, Year]** | *All versions must have a date. Version date must be updated with each amendment. Use the international date format (day month year) and write out the month (e.g., 24 May 2020).* |

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*Be sure to update the table of contents when you are finished creating your protocol. You can do this in Microsoft Word by going to the References tab and clicking on “Update Table” in the Table of Contents section.*

**List of Abbreviations**

*Add all disease or study-specific abbreviations / acronyms in this section. Modify this list as needed for your particular study and remove abbreviations that are not used in the document.*

|  |  |
| --- | --- |
| PHI | Personal Health Information |
| PI | Principal Investigator |
| PHIPA | Personal Health Information Protection Act |
| REB | Research Ethics Board |
| TP | Treating Physician |

# 1 PROTOCOL SUMMARY

## 1.1 Synopsis

|  |  |
| --- | --- |
| Title | *Full title of protocol.* |
| Short Title | *Shortened title, if one is typically used by you or your Center / Dept.* |
| Study Description | *Provide a short overview of the protocol, study design, sample, sampling method, sample size as well as data collection and analysis procedures.*  *This summary should be only a few sentences in length.* |
| Objectives | *Include the primary and secondary objectives. These objectives should be the same as the objectives contained in the body of the protocol.* |
| Study Design | *Include an overview of the qualitative research design.* |
| Participant Population, Selection Criteria | *Include the inclusion and exclusion criteria.* |
| Planned Sample Size (if applicable) | *Insert a list of participating sites. If greater than 3 sites, indicate number of sites.* |
| Participant Duration | *Time it will take for each individual participant to complete all participant observation(s).* |
| Data Collection Procedures | *Evaluation measurements that will be used to assess the primary and secondary objectives.* |
| Statistical Analysis | *A very brief description of the main elements of the statistical methodology to be used in the study. Limit this section to discussion of the analysis of the primary objectives and perhaps the main secondary objectives.* |
| Data and Safety Monitoring Plan | *Describe who is responsible (i.e., Principal Investigator) for data quality management and ongoing assessment of the study conduct.* |

## 1.2 Role of Study Sponsor or Funder

*Aim: To clarify the potential influence of sponsor and funders over the study.*

*The sponsor can be defined as the company, institution, or organization assuming overall responsibility for the initiation and management of the study and is not necessarily the main funder. Identification of the study sponsor provides transparency and accountability.*

*The protocol should explicitly outline the roles and responsibilities of the sponsor(s) and any funder(s) in the study design, study conduct, data analysis and interpretation, manuscript writing, and dissemination of results. It is also important to state whether the sponsor(s) or funder(s) control the final decision regarding any of these aspects of the study.*

## 1.3 Roles and Responsibilities of Study Management Committees, Groups and / or Persons

***Study Steering Groups***

*Aim: To outline any committees or groups involved in study coordination and conduct.*

*For each committee / group, the protocol should state their roles and responsibilities and degree of independence from Sponsor and Investigators. If not included in the document, the protocol should state where the information on the committee / group can be found.*

***Patient & Public Involvement Group***

*Public involvement plays an important role in study design and planning and may also help reduce delays in approvals. Public involvement in study design and study documentation may help with the acceptability of a study to the public, which in turn may assist with study set-up and recruitment. Ongoing involvement of the public may help understand blockages to recruitment and the acceptability and relevance of study findings.*

# Introduction, Background Information and Scientific Rationale

## Background Information and Relevant Literature

<Insert Text>

*Aim: To identify the phenomenon under investigation and position the study in the context of available empirical evidence. The background should be supported by appropriate references to published literature on the area of interest:*

* *A thorough literature review of relevant studies and analysis, new research should build on formal review of prior evidence.*
* *A brief description of the proposed study.*
* *A description of the population to be studied.*

*It should be written so it is easy to read and understand by an individual with a basic sense of the topic who may not necessarily be an expert in the area. Some explanation of terms and concepts is likely to be beneficial.*

## Rationale

<Insert Text>

*Aim: To explain why the research question(s) / aim(s) being addressed are important and why closely related questions are not being covered.*

*This should include:*

* *A clear explanation of the research question(s) / aim(s) and the justification of the study (i.e. why the question is worth asking and, through consultation with public and patient groups, why this is worthwhile to participants or wider service delivery).*
* *A contextual framing of the research question / aim(s) in relation to relevant policy and historical and / or literature bases.*
* *Discuss the significance of the study.*

## Research Question(s)

*Aim: To define the primary research question / aim(s).*

*The objectives may be phrased using neutral wording (e.g. “to explore renal patients’ perceptions of their first dialysis session”) rather than in terms of a particular direction of effect.*

# Objectives and Purpose

<Insert Text>

*Provide a detailed description of the primary objective(s) and any secondary objective(s) of the study. An objective is the reason for performing the study in terms of the scientific question to be answered. The primary objective is the main question.*

## Primary Objective

<Insert Text>

*Specify the primary outcome measures of this study.*

## Secondary Objectives (if applicable)

<Insert Text>

*Specify any secondary outcome measures of this study.*

# METHODS

## STUDY DESIGN

<Insert Text>

*Aim: To describe the study design. A suitable design should be chosen to reflect the aim(s) of the study and the chosen theoretical framework. A suitable design might include ethnography, phenomenology, grounded theory, and narrative research.*

## THEORETICAL FRAMEWORK

*Aim: To describe the theoretical framework for the study.*

* *A clear explanation of the proposed approach and why it is suitable to address the gaps outlined in the BACKGROUND section.*
* *Briefly outline a system of concepts, from published literature, that frames your study.*
* *Can be presented either visually or textually.*

## STUDY SETTING

*Aim: To state where the data will be collected, explain what activities will take place in that site, and justify the choice of site and any special requirements. The protocol should address:*

* *Where and how you are accessing your participants?*
* *How the research setting is appropriate to address the research question / aim(s)?*
* *If it is a multi-site or single site study.*
* *If there are any site-specific requirements to run the study.*
* *Outline if there are different ‘types’ of activities being undertaken at each site (e.g. identifying or recruiting) and what the specific requirements are for each.*

# Sample and Recruitment

*The following subsections should include a description of the study population, participant recruitment strategies, and issues related to participant withdrawal. The study population should be appropriate for the stage of the study.*

*Use the following guidelines when developing participant eligibility criteria to be listed in Sections 5.1 Participant Inclusion Criteria, and 5.2 Participant Exclusion Criteria:*

* *The eligibility criteria should provide a definition of participant characteristics required for study entry / enrollment.*
* *If participants require screening, distinguish between screening participants vs. enrolling participants. Determine if screening procedures will be performed under a separate screening consent form.*
* *The same criterion should not be listed as both an inclusion and exclusion criterion (e.g., do not state age >18 years old as an inclusion criterion and age ≤18 years as an exclusion criterion).*

## 5.1 Participant Inclusion Criteria

Inclusion criteria are characteristics that define the population under study, e.g., those criteria that every potential participant must satisfy, to qualify for study entry. Provide a statement that individuals must meet all of the inclusion criteria in order to be eligible to participate in the study and then list each criterion.

*Create a numbered list of criteria that a potential participant must meet to be eligible to take part in the study. Some criteria to consider for inclusion are provision of appropriate consent and assent, willingness and ability to participate in study procedures, age range, gender, health status, diagnosis or symptoms, background medical treatment, and laboratory ranges. Additional criteria should be included as appropriate for the study design and risk.*

*{Begin sample text}*

In order to be eligible to participate in this study, an individual must meet all of the following criteria:

1. Consent provided
2. Aged <specify range>
3. In good general health as evidenced by medical history OR Diagnosed with <specify condition/disease> OR Exhibiting <specify clinical signs or symptoms or physical/oral examination findings>
4. <Specify laboratory test> results between <specify range>]

*{End sample text}*

## Participant Exclusion Criteria

Exclusion criteria are characteristics that make a person ineligible for study participation. Provide a statement that all persons meeting any of the exclusion criteria at baseline will be excluded from study participation and then list each criterion. Limited English proficiency cannot be an exclusion criterion.

*Create a numbered list of criteria that would exclude a person from study enrollment. Some criteria to consider for exclusion are pre-existing conditions or concurrent diagnoses, concomitant use of medication(s) or devices, other factors that would cause harm or increased risk to the participant or close contacts or preclude the participant’s full adherence with or completion of the study. Additional criteria should be included as appropriate for the study design and risk.*

*{Begin sample text}*

An individual who meets any of the following criteria will be excluded from participation in this study:

<Insert Text>

*{End sample text}*

* 1. **Sampling**

*Aim: To clearly explain and justify the detail of sampling in terms of volume and technique.*

* 1. **Sample Size**

*Aim: to explain the rationale behind the size of the sample.*

*It may not always be possible to estimate the size of a sample in qualitative research. This section should describe and justify how your sampling strategy answers your research question / aim(s). Below are recommendations regarding sample size for qualitative research according to Creswell (2013):*

*a) Case Study: no more than 4-5 cases*

*b) Ethnography: a single culture sharing group*

*c) Grounded Theory methodology: 20 to 30 cases*

*d) Narrative Inquiry: 1-2 cases observed unless developing a collective story*

*e) Phenomenology: 3-10 cases, with observed sample sizes ranging from 1-325*

* 1. ***Sampling Technique***

*Aim: To describe the type of nonprobability sampling that will be used to recruit potential participants.*

*This section should detail the methods of selection used for example:*

* + *Snowball, convenience, purposive, and / or quota sampling?*
  + *Where has the sample been derived from?*
  + *What is the rationale for this sampling strategy? The rationale should reflect the methodological and theoretical framework for the study.*

## Strategies for Recruitment and Retention

<Insert Text>

*Identify strategies for participant recruitment and retention,* *e.g. from investigator or sub-investigator clinical practices, referring physicians, advertisement, etc.*

*Include details as to whether or not the recruitment plan proposes to use any SickKids media services (communications, marketing, etc.) and social media (e.g., Facebook, Twitter, etc.). Note: All recruitment materials which will be seen by potential participants need to be approved by the REB.*

*Describe how participants will be identified and recruited for the study. The identification of participants must protect participants’ privacy. Privacy refers to persons and their interest in controlling the access of others to themselves. Include the following:*

* *The time and place where informed consent will take place.*
* *The nature of the information participants will be asked to give about themselves.*
* *Who receives and can use the information?*

*For example, persons might not want to be seen entering a place that might stigmatize them, such as a pregnancy-counseling center that is clearly identified as such by signs on the front of the building.*

*If the study requires long-term participation, describe procedures that will be used to enhance participant retention (e.g., multiple methods for contacting participants, reminders, incentives for visit attendance).*

*If you are using EPIC information for recruitment purposes, discuss:*

* *How the data will be gathered from EPIC.*
* *How the data will be used (be specific regarding the purpose e.g. participant identification, informing participants, initial discussion of participant eligibility, etc.)?*
* *All data points and Personal Health Information (PHI) that will be used for the search.*
* *When the data will be discarded after use and how the data will be discarded.*
* *Parameters (how many times the study team will search EPIC over the course of the study and / or how often queries regarding eligible participants will run during the course of the study).*
* *The method used to notify the treating physician (if any, and if no explain why)?*
* *A description of how the potential participant will be contacted (email, phone, text, mailed letters etc.).*

*In addition, consider inclusion of the following information:*

* *Target sample size (should be consistent with information contained in Section 5.4, Sample Size Determination);*
* *Anticipated accrual rate;*
* *Source of participants (e.g., inpatient hospital setting, outpatient clinics, student health service, or general public);*
* *Recruitment venues;*
* *How potential participants will be identified and approached;*
* *Types of advertisements planned (e.g. national newspaper, local flyers; specific names are not needed), and a statement that any advertisements must be approved by the REB for the site.*
* *If participants will be compensated for study participation, describe amount and schedule of payments.*
* *If the study requires long-term participation, describe procedures that will be used to enhance retention (e.g., multiple methods for contacting participants, visit reminders, incentives for visit attendance, etc.*
* *Describe the plans to minimize loss to follow-up and missing data. The description should include when a participant will be considered lost to follow-up (e.g., if he or she fails to attend a focus group and is unable to be contacted by the study site staff) and whether the study design will accommodate replacing lost / withdrawn participants.*

## Participant Withdrawal or Termination

### Reasons for Withdrawal or Termination

<Insert Text>

*Provide a list of reasons participation may be terminated (e.g. safety reasons, emotional and / or psychological distress, social risk, failure of participant to adhere to protocol requirements, participant consent withdrawal, disease progression, etc.). Also note that participants may withdraw voluntarily from the study at any time.*

*{Begin sample text}*

Participants are free to withdraw from taking part in the study at any point in time throughout the duration of the study upon request. An investigator may terminate participation in the study if:

* Any medical condition, experience of psychological and / or emotional distress or situation occurs such that continued participation in the study would not be in the best interest of the participant.
* The participant meets an exclusion criterion (either newly developed or not previously recognized) that precludes further study participation.

*{End sample text}*

### Handling of Participant Withdrawals or Termination

<Insert Text>

*Describe efforts that will be made to continue follow-up of withdrawn or terminated participants, if applicable. Also specify the methods that should be used before a participant is considered lost to follow-up (e.g. number of phone calls to participant, phone calls to next-of-kin if possible, letters, etc.).*

### Premature Termination or Suspension of Study

<Insert Text>

*List possible reasons for termination or temporary suspension of the study (e.g., study closure based on PI decision or funder decision). For any study that is prematurely terminated or temporarily suspended, the PI will promptly inform the REB and provide the reason(s) for the termination or temporary suspension. State what criteria or review will be done to determine if study can resume.*

*{Begin sample text}*

This study may be temporarily suspended or prematurely terminated if there is sufficient reasonable cause. Written notification, documenting the reason for study suspension or termination, will be provided by the suspending or terminating party to <investigator and funding agency>. If the study is prematurely terminated or suspended, the PI will promptly inform the REB and will provide the reason(s) for the termination or suspension.

The study may resume once concerns about safety, protocol compliance, and data quality are addressed and satisfy the REB.

*{End sample text}*

# 6 Data Collection Procedures

*The following section should describe, in detail, the following:*

1. *Data collection methods (i.e., physiological or biological measurement, observational methods, interview and / or questionnaires, and records of available data). For example,* 
   * ***Observation****- What will be observed? What resources or equipment will be used if recording observation? Who will be observing?*
   * ***In-Depth Interviews****- How will the prompt guide or interview schedule be developed? Who is conducting the interviews?*
   * ***Focus Groups****- Who is leading the focus group? How are the focus groups being recorded?*

*b) Procedures for recording data during data collection (i.e., audio-recorded, video-recorded etc.)*

*c) Procedures for preparing transcripts and field notes for analysis.*

# 7 Data Analysis Procedures

*The following section should describe the data analysis procedures. Specifically, the type of analysis (i.e., inductive, deductive, narrative, discourse, or constant comparative analysis), steps for transcribing and coding information (if appropriate), and procedures to maintain trustworthiness of the analysis (specifically related to credibility, dependability, conformability and transferability).*

# Study Administration

## 8.1 Data Collection and Management and Data Confidentiality

*This section will describe protections for maintaining confidentiality of participant data, including, but not limited to forms, records and samples. Include procedures for maintaining participant confidentiality, any special data security requirements, and record retention. Describe who would have access to records, including the PI and other study staff, the clinical monitor, funding institutions, and representatives from the REB. In addition, consider inclusion of the following information:*

Address the following:

***Confidentiality of Data.*** *How will you ensure the confidentiality of the data, from the beginning of the abstraction process though analysis? Include procedures for maintaining participant confidentiality, any special data security requirements, and record retention. Describe who would have access to records (i.e., transcripts, audio and / or video recordings), including the PI and other study staff, the clinical monitor, funding institutions, and representatives from the REB. In addition, consider inclusion of the following information:*

* *Describe whether identifiers will be attached to data / samples, or whether data will be coded or unlinked.*
* *If unlinked or coded, and additional information (e.g., age, ethnicity, sex, diagnosis) is available, discuss whether this might make specific persons or families identifiable.*
* *If research data will be coded, describe how access to the “key” for the code will be limited. Include description of security measures (password-protected database, locked drawer, other).*
* *List names or positions of persons with access to the key.*
* *Include a discussion of the circumstances in which data or samples will be shared with other researchers.*
* *Include a discussion of plans to publish pedigrees, with a description of measures to minimize the chance of identifying specific persons and / or families.*
* *Describe any situation in which personally identifiable information will be released to third parties.*
* *State who has access to records, data, and samples. Consider if monitors or auditors outside of study investigators will need access.*
* *Discuss any additional features to protect confidentiality (e.g., use of a certificate of confidentiality).*

*{Begin required text}*

Information about study participants will be kept confidential and managed according to the requirements of PHIPA). Those regulations require a signed participant authorization informing the participant of the following:

* What protected health information (PHI) will be collected from participants in this study?
* Who will have access to that information and why?
* Who will use or disclose that information?
* The rights of a research participant to revoke their authorization for use of their PHI.

In the event that a participant revokes authorization to collect or use PHI, the PI, by regulation, retains the ability to use all information collected prior to the revocation of participant authorization. For participants that have revoked authorization to collect or use PHI, attempts should be made to obtain permission to collect at least vital status (i.e. that the participant is alive) at the end of their scheduled study period.

*{End required text}*

*{Begin suggested text}*

Participant confidentiality is strictly held in trust by the participating investigators, their staff, and the sponsor(s) and their agents. The study protocol, documentation, data, and all other information generated will be held in strict confidence. No information concerning the study, or the data will be released to any unauthorized third party without prior written approval of the sponsor.

The study monitor, other authorized representatives of the sponsor, or representatives of SickKids may inspect all documents and records required to be maintained by the investigator, including but not limited to, medical (office, clinic, or hospital) records and data collected (i.e., transcripts, audio and / or video recordings) for the participants in this study. The clinical study site will permit access to such records.

The study participant’s contact information will be securely stored at each clinical site for internal use during the study and kept separate from the data. At the end of the study, all records will continue to be kept in a secure location for as long a period as dictated by the Hospital for Sick Children.

Study participant research data, which is for purposes of statistical analysis and scientific reporting, will be transmitted to and stored at the <specify name of Coordinating Center>. This will not include the participant’s contact or identifying information. Rather, individual participants and their research data will be identified by a unique study identification number. The study data entry and study management systems used by clinical sites and by <specify name of Coordinating Center> research staff will be secured, and password protected. At the end of the study, all study databases will be de-identified and archived at the <specify name of Coordinating Center>.

*{End suggested text}*

***Security.*** *Have a plan for backing up or otherwise recovering data. This can be as simple as a copy of the password-protected file on your office computer, with the original in one of the Hospital’s secure servers, REDCap database, etc.*

***Anonymization, de-identification or destruction.*** *Have a specific plan, for example, “The identifiers and other data will be destroyed 6 years after study completion.”*

# Regulatory and Ethical Considerations

## Ethical Standard

<Insert Text>

*Include in this section the guiding ethical principles being followed by the study.*

## Research Ethics Board

<Insert Text>

*Each participating institution must provide for the review and approval of this protocol, the associated informed consent documents and recruitment material by the REB. Any amendments to the protocol or consent materials must also be approved by the REB before they are placed into use.*

*{Begin sample text}*

The protocol, informed consent form(s), recruitment materials, and all participant materials will be submitted to the REB for review and approval. Any amendment to the protocol will require review and approval by the REB before the changes are implemented to the study.

*{End sample text}*

## 9.3 Informed Consent Procedures and Documentation

*Describe how informed consent will be administered. Describe who will obtain consent (using roles, note names) and how the process of informed consent will be structured to be conducive to rational and thoughtful decision making by the participant / participant’s legally authorized representative. Include information such as:*

* *Where the consent process will take place?*
* *How participant privacy will be assured?*
* *Whether participants will be permitted to provide consent at the time of the consent discussion or whether they will be required to come back to provide written informed consent?*
* *How the PI will ensure that participants comprehend the nature of the study?*
* *What steps that will be taken to avoid coercion?*

*For long-term studies, if assent was originally obtained from participants, a regular re-assessment of capacity should be completed as the child matures and consent will be obtained as soon as the child reaches capacity to consent for their own participation (if applicable).*

*If the protocol involves multiple consenting sessions, or multiple informed consent forms, describe this information and the associated procedures in detail. If a copy of the informed consent form is provided in an appendix to the protocol, state so here.*

*Describe any proposed waivers or alterations to informed consent. Describe any special circumstances regarding obtaining consent. Describe plans for obtaining consent from speakers of language other than English.*

*If not all participants will have the capacity to give informed consent, describe how capacity will be assessed. Describe the anticipated degree of impairment relative to their ability to consent to participate in research. Research with persons who have diminished capacity is allowed only for minimal risk or direct benefit studies.* *Clearly document that the PI has an adequate plan in place to assure an acceptable level of comprehension before consent is obtained. If children will be participants, include a specific plan to assess comprehension during assent (the participant’s agreement).*

*The PI is responsible for ensuring that valid consent is obtained and documented for all participants. Specifically describe how consent will be documented and how / where documentation will be stored.*

*{Begin sample text}*

Informed consent is a process that is initiated prior to an individual agreeing to participate in the study and continues throughout the individual’s study participation. Extensive discussion of risks and possible benefits of participation will be provided to the participants and their families. Consent forms will be REB approved and the potential participant will be asked to read and review the document. The PI will explain the research study to the potential participant and answer any questions that may arise. All potential participants will receive a verbal explanation in terms suited to their comprehension of the purposes, procedures, and potential risks of the study and of their rights as research participants. Potential participants will have the opportunity to carefully review the written consent form and ask questions prior to signing. The potential participants should have the opportunity to discuss the study with their surrogates or think about it prior to agreeing to participate. The potential participant will sign the informed consent document prior to any procedures being done specifically for the study. The participants may withdraw consent at any time throughout the course of the study. A copy of the signed informed consent document will be provided to participants for their records. The rights and welfare of the participants will be protected by emphasizing to them that the quality of their medical care will not be adversely affected if they decline to participate in this study.

A copy of the signed informed consent document will be stored in the participant’s research record. The consent process, including the name of the individual obtaining consent, will be thoroughly documented in the participant’s research record and kept separate from the data collected. Any alteration to the standard consent process (e.g. use of a translator, consent from a legally authorized representative, consent document presented orally, etc.) and the justification for such alteration will likewise be documented.

*{End sample text}*

### Consent / Assent and Other Informational Documents Provided to Participants

<Insert Text>

*This section should demonstrate that the consent form contains all required elements. List all consent documents and materials submitted with this protocol. Include consent and / or assent forms, printed or web-based materials, phone scripts and any other related material.*

*If needed, describe special documents or materials (e.g., Braille, another language, audio recording).*

*If assent was originally obtained from participants, a regular re-assessment of capacity should be completed as the child matures and consent will be obtained as soon as the child reaches capacity to consent for their own participation (if applicable).*

*{Begin sample text}*

Consent forms describing in detail the study intervention, study procedures, and risks are given to the participant and written documentation of informed consent is required prior to starting intervention. The following consent materials are submitted with this protocol <insert list>.

*{End sample text}*

## Study Records Retention

<Insert Text>

*Specify the length of time for the PI to maintain all records pertaining to this study. The PI should use the most conservative rule for document retention – i.e., retention should follow the rule that has the longest period.*

## Potential Benefits of Research Participation

Summarize all potential benefits, if any, from participation in the study. Benefits should be broken down into direct benefits (accrue to the study participant as a result of participation; unlikely for these types of studies) and indirect benefits (benefits that accrue to the individual or society in the future).

## Risk-Benefit Assessment

The Risk-Benefit assessment should include justification for proceeding with the study based on the balance between risks and benefits.

## 9.7 Protocol Compliance

<Insert Text>

*Aim: to demonstrate how protocol compliance will be managed.*

*Protocol deviations, non-compliances, or breaches are departures from the approved protocol.*

*The protocol should state that:*

* *Accidental protocol deviations can happen at any time. They must be adequately documented on the relevant forms and reported to the Chief Investigator and Sponsor immediately.*
* *Deviations from the protocol which are found to frequently recur are not acceptable, will require immediate action and could potentially be classified as a serious breach.*

## Publication and Data Sharing Policy

<Insert Text>

*The publication and authorship policies should be established and clearly outlined in this section. For example, for a study with multiple investigators, this section might state that an Executive Committee will be responsible for developing publication procedures and resolving authorship issues.*

# 

# References

*This is the bibliography section for any information cited in the protocol. It should be organized as any standard bibliography.*

1. Author, Title of work, periodical and associated information.
2. Author, Title of work, periodical and associated information.