******

***Study Title***

**PROTOCOL**

Version Date: Version X.X, YYYY/MM/DD

Principal Investigator:

Co-Investigator(s):

**Investigator Agreement Page**

I, , Investigator, agree to conduct the study according to this protocol and to comply with its requirements, subject to ethical and safety considerations.

I acknowledge that I am responsible for overall study conduct. I agree to personally conduct or supervise the described clinical study.

I agree to ensure that all associates, colleagues and employees assisting in the conduct of the study are informed about their obligations. Mechanisms are in place to ensure that site staff receives the appropriate information throughout the study.

|  |  |
| --- | --- |
| Investigator Signature: |  |
| Date: |  |

Contents

[**1.0** **List of Abbreviations** 4](#_Toc30067489)

[**2.0** **Study Synopsis:** 5](#_Toc30067490)

[**3.0** **Overview** 6](#_Toc30067491)

[**4.0** **Background Information** 6](#_Toc30067492)

[**5.0** **Study Objectives** 6](#_Toc30067493)

[**6.0** **Study Hypotheses** 6](#_Toc30067494)

[**7.0** **Study Design** 6](#_Toc30067495)

[**8.0** **Study Population** 7](#_Toc30067496)

[**9.0** **Study Procedures** 7](#_Toc30067497)

[**10.0** **Data Management** 7](#_Toc30067498)

[**11.0** **Study Measurements** 8](#_Toc30067499)

[**12.0** **Statistical Considerations** 8](#_Toc30067500)

[**13.0** **Ethical and Regulatory Considerations** 8](#_Toc30067501)

# **1.0 List of Abbreviations**

|  |  |
| --- | --- |
| **Abbreviation** | **Definition** |
|  |  |

# **2.0 Study Synopsis:**

|  |  |
| --- | --- |
| Investigators: | **Principal Investigators:**  **Co-Investigators:**  **Student Research Assistants:** |
| Study Objectives | Primary:  Secondary: |
| Study Design | Prospective/Retrospective, etc. |
| Study Population | E.g. A brief description such as health status (e.g. healthy volunteers; HIV-positive; breast cancer patients stage II-III; etc) |
| Outcomes | *Primary Outcome:*  *Secondary Outcomes:* |
| Sample Size | E.g. # of participants |
| Eligibility Criteria |  |
| Duration of Study Period | E.g. Start Date - End Date (total duration of the study including follow-up period, or period of dates to access charts) |
| Study procedure(s) |  |
| Research Ethics Board | Participating sites will require REB approval prior to any study procedures. |
| Informed Consent | E.g. Written informed consent must be obtained from each participant or their proxy. |

# **3.0 Overview**

# **4.0 Background** **Information**

E.g., a summary of findings from previous studies, references to literature and data that are relevant to the study and that provide background for the study and/or rationale of this study.

*Rationale for the study:*

E.g., importance for the conduct of the research study, what gaps in the literature will you address.

# **5.0 Study Objectives**

*Objectives:*

Primary:

1. E.g., a detailed description of the objective/purpose of the study

Secondary:

1. E.g., if applicable, add the secondary objective/purpose of the study

# **6.0 Study Hypotheses**

*Primary:*

1. E.g., what you anticipate to find from the objective(s)

*Secondary:*

# **7.0 Study Design**

*Type of study:*

E.g., prospective/retrospective, observational/interventional/survey/registry, single-centred/multi-centred, etc.

*Expected number of subjects:* E.g., how many participants/charts do you intend to enroll in the study

*Potential Risks:* What is the potential risk to participants, community or institution, if any?

*Potential Benefits:* What are the potential benefits to participants, community/public, and literature?

*Method of screening and enrolment:* How will you recruit or enroll your participants (i.e., patients who are seen by a physician in the Emergency Department).

*Duration of the study period for each subject:* How long will each participant remain in the study, or what is the date range of requested charts (for retrospective studies).

# **8.0 Study Population**

*Inclusion criteria*

* E.g., Characteristics of patients (e.g. gender, age, etc.), disease/treatment (e.g., disease being investigated, current medication, etc.), environmental factors (e.g., geographical location, occupation, etc.), results of an examination (e.g., physical exams, lab results, etc.).

*Exclusion criteria*

* E.g., see above examples

# **9.0 Study Procedures**

*Screening:* E.g., how will you determine who is eligible for the study or not (i.e., review charts to determine eligibility, review referrals to determine eligibility, etc.).

*Informed Consent:* E.g., how will consent be obtained (written, waived, over the phone), and who will obtain consent (research assistant/volunteer).

*Participant Identification:* E.g., how will participants in the study be identified (de-identified by using participant ID numbers).

*Baseline Visit:* E.g., what will happen at the first visit?

*Follow-up Visits:* If applicable, e.g., what will happen at any follow up visits?

*Identifiable data:* What identifiable will you need to collect, if any? (this should reflect what is in the master linking log e.g., name, MRN, etc.).

# **10.0 Data Management**

*Data collection:* What data points will you collect? List all points that will be captured from patient’s charts (this should reflect what is in the data collection form, if applicable).

*Administration of Instruments / Surveys*

* List the name of Instruments / Surveys that will be used (if any)
* Describe how you will administer them (i.e., in person, online survey)
* Describe when you will administer them (i.e., at each visit, before and after their surgery)

# **11.0 Study Measurements**

E.g., describe any measurements that will be used. For example, questionnaires, interviews, focus groups, etc.

# **12.0 Statistical Considerations**

*Sample size calculation:*

E.g., Reason for choice of sample size, including reflections on (or calculations of) the power of the trial/ study and clinical justification.

*Data analysis:*

* What approach will be used (i.e., statistical, thematic approach, etc.)
* How will you analyze your data (i.e., reviewers, SAS, SPSS, Excel, etc.)
* What are the procedure for accounting for missing, unused, and spurious data?
* What is your statistical plan? Describe this in detail, for example, paired t-tests will be used to determine if there are statistical significant differences between XXX before and after the intervention. Or, themes will be created until the data has reached saturation.

# **13.0 Ethical and Regulatory Considerations**

The procedures set out in this protocol, pertaining to the conduct, evaluation, and documentation of this study, are designed to ensure that the investigator abides by the guiding principles detailed in the Declaration of Helsinki. The study will also be carried out in keeping with applicable local law(s) and regulation(s). Documented approval from appropriate research ethics boards (REB) will be obtained before the start of the study. When necessary, an extension, amendment or renewal of the REB approval must be obtained.

Strict adherence to all specifications laid down in this protocol is required for all aspects of study conduct; the investigator may not modify or alter the procedures described in this protocol.

Informed consent

[Please use the following language if consent is being obtained]

It is the responsibility of the Investigator to obtain written informed consent in compliance with national requirements from each subject. The informed consent document used by the Investigator for obtaining subject’s informed consent must be reviewed and approved by the REB.

Each participant / legal representative or proxy consenter will have ample time and opportunity to ask questions and will be informed about the right to withdraw from the study at any time without any disadvantage and without having to provide reasons for this decision.

Only if the participant / legal representative or proxy consenter voluntarily agrees to sign the informed consent form and has done so, may s/he enter the study. Additionally, the investigator and other information provider (if any) will personally sign and date the form. The participant / legal representative or proxy consenter will receive a copy of the signed and dated form.

The signed informed consent statement is to remain in the investigator site file or, if locally required, in the participant’s note/file of the medical institution. Any other handling and storage of the signed informed consent statement will be detailed in the informed consent form.

[Please use the following language if the REB has granted a waiver of consent]

The REB has granted permission to conduct research without consent, in accordance with TCPS2 Chapter 3, TCPS2 Articles 5.5 and/or 12.3, and PHIPA 44, 3c, 3d. The REB has granted this permission because a) potentially identifiable information is essential to the research; b) the use of potentially identifiable information without the participants’ consent is unlikely to adversely affect the welfare of individuals; c) the researchers will take appropriate measures to protect the privacy of individuals, and to safeguard the potentially identifiable information; d) the researchers will comply with any known preferences previously expressed by individuals about any use of their information; e) it is impossible or impracticable to seek consent from individuals to whom the information relates; and f) the researchers have obtained any other necessary permission for secondary use of information for research purposes.

Ethics review committee

The protocol will be submitted to the William Osler Health System Research Ethics Board. Any amendments made to this protocol will be submitted to the REB for review prior to implementation.

Confidentiality

Confidentiality of participant data will be maintained at William Osler Health System. Research personnel will store any paper copies of CRFs in locked cabinets. Electronic files of CRFs will be stored on a high-security computer system that has password protection. All study personnel will ensure no participant identifiers are present on any files transmitted to any committee or clinical center.

Record retention by investigating centres

The Investigator will retain study records, patient files and other source data at least { seven (7) years for non-Sponsored/Health Canada registered studies; twenty-five (25) years for Sponsored/Health Canada studies} after the completion of the study.

**14.0 References**