**Template Version Date: November 2022**

**PROTOCOL TEMPLATE – GENERAL RESEARCH (non-clinical trials)**

Please do not include this page when finalizing your protocol.

This protocol template is intended for general observational research studies. If your study involves the use of secondary use of data/samples, please refer to the Secondary Use of Data or Samples/Retrospective Chart Reviews WCH Protocol Template. If your study is a clinical trial, please refer to the Clinical Trials WCH Protocol Template.

The purpose of this document is to provide a template for WCH investigators to design their research studies in a compliant and standardized method. It is intended to assist investigators in describing the clinical/scientific value of their hypotheses, minimize uncertainty in the interpretation of outcomes, and maximize generalizability of results. This protocol template was created to meet regulatory and institutional standards, and it has been adapted from the CAMH General Research Protocol Template (Version Date: 28-Jun-2022).

For queries related to the use of this template, contact the Research Ethics Office at ethics@wchospital.ca.

**INSTRUCTIONS ON USING THIS TEMPLATE**

It is important to include all applicable sections of the template into your protocol. Do not change the order of sections. For sections that are *not* applicable to your research study, please include the heading but enter “*Not applicable*” under it.

***Instructional text:*** This text provides context and guidance on what should be included within the section and **should be deleted/replaced** prior to finalization of your protocol. *This text will be presented in italics throughout this document. Notes for consideration by the study team will also be highlighted in red.*

**Recommended text:** This text includes suggested wording to be used within your protocol, although it can be modified by you to fit your protocol. This text will be presented in turquoise highlight throughout this document.

Version control is important to track protocol development, revisions and amendments. Please ensure that the protocol version date is tracked in the lower left hand corner of the document.

**<Protocol Title>**

**Principal Investigator:** ***<Principal Investigator>***

**Version Number: *<x.x>***

**Version Date: *<dd-Mmm-yyyy>***

*Any amendments should include amendment numbers and version dates*

*Note: this table should list key members (PIs, Co-Is) of the research team. An entire list of all persons who will have access to study information, why their access is necessary, their roles in relation to the research, and their related qualifications, should be maintained in a separate delegation log for each study team.*

|  |  |
| --- | --- |
| **Principal Investigator:** | ***List PI’s name, position, affiliation*** |
| **Co-Investigators:** | ***List investigator’s name, position, affiliation*** |
| **Study Site(s):** | ***List all sites involved in study (e.g., include sites conducting study activities, providing data storage or analysis, or sites data/samples are being shipped to or from)*** |
| **Funded By:** | ***Insert Funding source (e.g., CIHR, PSI, etc.)***  |

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*Please note: 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.*

# STATEMENT OF COMPLIANCE

*A statement confirming the research study will be conducted in compliance with the protocol, ICH GCP, applicable regulatory agencies and institutional requirements must be included here.*

*For multi-site research studies: A statement of compliance should also be included for each site, with the site Principal Investigator’s (PI) signature.*

This research study will be carried out in accordance with the following:

* Tri-Council Policy Statement 2018 (TCPS 2)
* International Conference on Harmonisation – Good Clinical Practice (GCP)*, if the study involves clinical investigations that may have an impact on the safety and well-being of human participants*
* Personal Health Information Protection Act (PHIPA), 2004; Chapter 3 Schedule A (PHIPA) and applicable regulations
* U.S. Federal Policy for the Protection of Human Subjects (Common Rule)
* Institutional and REB policies and procedures

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Signature of PI Date

*or*

Signature of site PI *(multi-centre research studies)*

# LIST OF ABBREVIATIONS

Include a list of abbreviations used within the research protocol. A sample list is included below:

*AE Adverse Event*

*CRF Case report form(s)*

*GCP Good Clinical Practice*

*ICF Informed consent form*

*PHI Personal Health Information*

*PHIPA Personal Health Information Protection Act*

*PI Principal Investigator*

*TCPS 2 Tri-Council Policy Statement*

# RESEARCH STUDY SUMMARY

|  |  |
| --- | --- |
| **Title** | *Full title of research study.* |
| **Short Title** | *Shortened title, if applicable.* |
| **Methodology** | *Research study design: cohort, case-control, cross-sectional, chart review, etc.* |
| **Research study Duration** | *Estimated time (in months) from when the research study opens for enrollment until closure with the REB.* |
| **Participating site(s)** | *Description and number of participating sites enrolling participants.*  |
| **Objectives** | *Brief statement of primary research objectives.* |
| **Number of Participants/Sample size** | *Number of participants/sample size/charts anticipated for the entire research study.* |
| **Statistical Methodology** | *A brief description of the main elements of the statistical methodology to be used in the research study.*  |

# INTRODUCTION

*The following subsections should include relevant background information and rationale on the research study. This should be an overview (e.g. approximately 1-3 pages). Only include sections that are relevant to the research study.*

## Background

*Provide a brief paragraph to describe the setting and rationale for the study. Include an overview of the literature and data relevant to the study. Include relevant literature establishing the validity for scales, evaluation tools, etc. if/where applicable.*

## Risks/Benefits

*Summarize all reasonably foreseeable benefits and risks or harms, if any from study participation. Benefits should be broken down into direct benefits (i.e., to the participant as a result of participation) and indirect benefits (i.e., benefits to the individual or society in the future), if/where applicable. If potential harms are described, a plan should be provided detailing how researchers intend to address them.*

*Note: If risks of participation are currently unknown, this should be described as well.*

# RESEARCH STUDY OBJECTIVES

*Note: if your team intends to use information collected through this study to establish a resource for future research, this must be reflected in the study’s objectives.*

Describe the overall objectives and purpose of the research study. Include specific research questions or hypotheses in this section. Describe primary, secondary, tertiary, or exploratory objectives, as applicable.

## Primary Objective

An objective is the purpose for conducting the research study in terms of the scientific question to be answered. Express each objective as a statement of purpose (e.g., to determine, to compare, to evaluate) and include the general purpose.

## Secondary Objective

Describe the secondary objective of the research study if applicable.

# STUDY DESIGN

## Overall Design

Include:

* The type/design of the research study (e.g., non-interventional, observational, interview/focus groups, surveys, etc.);
* Expected duration of each participant’s involvement in the research study and date range for collection of prospective data/samples;
* Total expected duration of the research study (while active);
* A description of the sequence and duration of all study visits including follow-up, if applicable; and
* Include any known foreseeable factors that can compromise the outcome of the study or interpretation of results (e.g., factors include participant characteristics, concomitant medication, and participant-related factors such as age, gender or lifestyle). Provide rationale on how these factors could be addressed (i.e., through participant selection, project design, stratified randomization, statistical analysis, etc.).

## Primary Endpoints/Outcome Variables

An endpoint/outcome variable is a specific measurement that relates back to the primary object of the study. Endpoints/outcome variables should be clinically/scientifically relevant and should correspond to the project objectives and hypotheses being tested. Include rationale for the selection of endpoints if applicable. All studies aim to answer a research question where there are objectives with derived endpoints.

Describe the primary, secondary, tertiary, or exploratory endpoints/outcome variables, as applicable, to be analyzed in the research study (e.g., specific laboratory tests, clinical assessments of disease status, assessments of psychological characteristics, patient reported outcomes, behaviours or health outcomes).

## Secondary Endpoints/Outcome Variables

*Describe any secondary endpoints/outcome variables to be analyzed in the research study.*

# 4.0 PARTICIPANT SELECTION AND WITHDRAWAL

## 4.1 Target Population

*This section should summarize the target recruitment population (or population from which medical charts will be accessed) to answer the research question.*

*If applicable, provide justification for the enrollment of vulnerable participants (e.g. pregnant women, children, those with impaired decisions making abilities, etc.).*

## Participant Recruitment and Screening

*Describe general strategies for participant recruitment and screening. Include the following information below, as applicable:*

* *Target study sample size;*
* *Anticipated accrual rate;*
* Anticipated number of sites and participants to be enrolled;
* *Source of participants. Examples include:*
	+ *WCH clinics*
	+ *External healthcare providers or community partners*
	+ *General public*
* *Types of recruitment strategies planned. Examples include:*
	+ *Advertisements including brochures, flyers, posters, videos, and/or social media or other web-based recruitment tools*
	+ *Introduction from community partners*
	+ *Referrals from clinicians/circle of care or other healthcare providers*
	+ *Survey panels*
	+ *Snowball sampling*
	+ *Listserv*
* *Pre-screening procedures, if applicable;*
* *How potential participants will be identified and approached; and*
* *If participants will be compensated or reimbursed for study participation, describe amount, form/type (e.g. cash, e-gift cards), timing, to whom it will be provided (e.g. participant, substitute decision-maker (SDM)) and any limitations (e.g. provision of receipts, maximum amounts) of such compensation in relation to study activities (include financial and non-financial compensation).*

## Equity, Diversity and Inclusion Considerations

*Equity, Diversity and Inclusion (EDI) considerations are important to factor in research study design to ensure ethically sound and rigorous research results are obtained, and these results are impactful and relevant to the diversity of the Canadian population. Research studies that do not consider EDI principles in their design can lead to inaccuracies and misinterpretations of the results.*

*Specifically, CIHR indicates the use of “Gender-based analysis plus (GBA+)”.*

*GBA+ is an analytical process used to systematically examine how differences in identity factors such as sex, gender, race, ethnicity, religion, age and mental or physical disability, affect the outcomes of research and the impacts of research findings.*

*Examples of EDI questions to consider when designing your research study:*

* + *Are sex (biological) considerations taken into account in the research design, methods, analysis and interpretation, and/or dissemination of research findings?*
	+ *Are gender (sociocultural) considerations taken into account in the research design, methods, analysis and interpretation, and/or dissemination of research findings?*
	+ *Are race and ethnicity considerations taken into account in the research design, methods, analysis and interpretation, and/or dissemination of research findings?*
	+ *If the research is using population/sample data, can that data be disaggregated by identity factors to determine differences between groups?*
	+ *Is there diversity in the work that is referenced in supporting/secondary research?*
	+ *Are other identity factors taken into account in the research design, methods, analysis and interpretation, and/or dissemination of research findings?*
	+ *Does the research engage or involve Indigenous Peoples using best practices and established guidelines?*

*If you answered "Yes" to any of these questions: Describe how identity factors will be considered in your research protocol.*

*If you answered "No" for one or more questions: Explain why identity factors are not applicable in your research protocol.*

## Eligibility Criteria

### Inclusion Criteria

Create a numbered list of criteria participants must meet to be eligible for study enrollment/chart mining (e.g., age, gender, target illness, etc.).

*Recommended text:*

The participant must meet all of the inclusion criteria to eligible for this research study:

1. Must sign and date the informed consent form;
2. Stated willingness to comply with all study procedures;

### Exclusion Criteria

*Create a numbered list of criteria that would exclude a participant from study enrollment/ chart mining.*

*If specific populations are excluded (e.g. elderly, pediatric, women or other vulnerable or underrepresented populations), provide a clear and compelling rationale and justification, to establish that inclusion is inappropriate with respect to the health of the participants or the purpose of the research study.*

Recommended text:

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

1. Current use of <specify disallowed concomitant medications*>*;
2. Presence of <specific devices (e.g., cardiac pacemaker)>;
3. Currently smoking or using tobacco *<*specify timeframe*>*; or

## Screen Failures

*Screen failures are defined as participants who consent to participate in the research study but do not meet one or more eligibility criteria required for participation. A minimal set of screen failure information is required to ensure transparent reporting of screen failure participants. Minimal information includes demography, screen failure details, and eligibility criteria.*

## Participant Withdrawal Criteria

### When and How to Withdraw Participants

Describe the scenarios under which a research participant may be withdrawn from the research study prior to the expected completion date (e.g. failure of participant to adhere to protocol requirements, participant consent withdrawal, etc.), as well as whether these participants will be replaced, and how they will be replaced.

Recommended text:

Participants are free to withdraw from participation in the research study at any time.

An investigator may discontinue or withdraw a participant from the research study for the following reasons:

* Significant study non-compliance; or
* If the participant meets an exclusion criterion (either newly developed or not previously recognized) that precludes further study participation.
* It is unsafe for the participant to continue (e.g. the participant is experiencing stress/re-traumatization/negative mental health effects)

The reason for participant discontinuation or withdrawal from the study will be recorded within the participant’s research record.

### Withdrawn Participants

*Include a brief description on any restrictions to withdraw data and/or biological specimens for participants who have withdrawn from the study, if applicable.*

*Recommended text:*

If a participant withdraws consent, they can also request the withdrawal of their data and/or biological specimens subject to any research-specific restrictions <include any regulatory requirements, if applicable>.

Once withdrawn from the research study, no further research procedures or evaluations will be performed, or additional research-specific data collected on the participant. Reason for withdrawal will be recorded within the participant’s research record.

### Participants who are Lost to Follow-up

Note what methods should be used before one can state the participant is truly lost to follow-up (e.g. number of phone calls to the participant, phone calls to next-of-kin if possible, certified letters, etc.).

*Recommended text:*

A participant will be considered lost to follow-up if they fail to return for <specify number of visits> scheduled visits and is unable to be contacted by the research team.

The following actions will be taken if a participant fails to attend a required study visit:

* The research team will attempt to contact the participant and reschedule the missed visit <specify time frame>, counsel the participant on the importance of maintaining the assigned visit schedule, and reconfirm whether the participant wishes to and/or should continue in the research study.
* Before a participant is deemed lost to follow-up, the research team will make every effort to regain contact with the participant (where possible, three telephone calls and, if necessary, a certified letter to the participant’s last known mailing address or local equivalent methods). These contact attempts should be documented in the participant’s research record.
* Should the participant continue to be unreachable, they will be considered to have withdrawn from the research study with a primary reason of lost to follow-up.
1.

# 5.0 RESEARCH PROCEDURES

## 5.1 Research Visits/Activities

In this section, describe all specific procedures (e.g. administration of surveys) required at each research visit. Include which research personnel will be performing study-related procedures.

Recommended text:

* Pre-Screening Visit / Screening Visit
	+ Informed consent
	+ Review of eligibility criteria
	+ Review of medical history and demographics
	+ Etc.
* Baseline Visit
	+ Administration of questionnaires or other instruments*: List all questionnaires and instruments to be completed during this visit*
	+ Procedures that will be completed during the research study as part of standard clinical care (specify)
	+ Etc.
* Study Visit *X*
	+ Administration of questionnaires or other instruments: *List all questionnaires and instruments to be completed during this visit*
	+ Procedures that will be completed during the research study as part of standard clinical care (specify)
	+ Interview/Focus Group
	+ Etc.
* Final Study Visit
	+ Administration of questionnaires or other instruments: *List all questionnaires and instruments to be completed during this visit*
	+ Procedures that will be completed during the research study as part of standard clinical care (specify)
	+ Etc.

## Schedule of Events

Create a study procedures flow chart/table (e.g. schedule of events) that describes the activities and procedures to be followed at each study visit.

Recommended text:

| **Procedures**  | ScreeningDay 1 | BaselineDay 3 | Study Visit 2 Day 7  | Study Visit 3Day 14  | Study Visit 4Day 21 | Study Visit 5Day 28  | Study Visit 6Day 35  | Study Visit 7Day 42 | Study Visit 8Day 49  | Study Visit 9Day 56  | Study Visit 10Day 63  | Study Visit 11Day 70  | Study Visit 12Day 77  | Final Study Visit |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Informed consent | X |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Demographics | X |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Medical history | X |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Focus Group | X | X |  |  | X |  |  | X |  |  | X |  |  |  |
| Self-Report Questionnaire | X | X |  |  | X |  |  | X |  |  | X |  |  | X |
| Complete Case Report Forms (CRFs) | X | X | X | X | X | X | X | X | X | X | X | X | X | X |
|  |

# STATISTICAL PLAN

## Sample Size Determination

*Describe the statistical methods for determining the sample size for the research study, including calculations of the power of the study and clinical justification.*

## Statistical Methods

*Summarize the overall statistical approach for the analysis of the research study. Include:*

* *The level of significance to be used;*
* *Procedures for accounting for missing, unused and spurious data;*
* *Details of an interim analysis if applicable; and*
* *Procedures for reporting any deviations from the original statistical plan.*

*Full details on the statistical plan of this research study can also be captured in a “Full Statistical Analysis Plan” stand-alone document.*

## Control of Bias

*Participants that are not assigned by a process of randomization are subject to bias. Briefly describe the measures to be taken to avoid bias. Examples include: radiographic studies may be read by a radiologist blinded to the diagnosis; psychological measurements may be made by an individual blinded to the participants’ group assignment or outcome; and charts can be reviewed without knowledge of outcome.*

# SAFETY AND ADVERSE EVENTS

*Recommended Text:*

Since the study procedures are not greater than minimal risk, AEs and/or SAEs are not expected. If any unanticipated problems related to the research involving risks to participants or others happen during the course of this study, these will be reported to applicable stakeholders, in alignment with institutional policies. AEs that are not serious but that are notable and could involve risks to participants will documented as per institutional documentation requirements.

## Definitions

*Include definitions applicable to your research protocol, as per ICH GCP and applicable regulatory/granting agencies.*

Recommended text:

Adverse Event

An **adverse event** (AE) is any untoward medical occurrence in a research participant administered an investigational product and which does not necessarily have a causal relationship with this treatment. An adverse event (AE) can therefore be any unfavourable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the investigational product.

**Serious Adverse Event**

A **serious adverse event** (SAE) is any AE that is:

* Fatal;
* Life-threatening;
* Requires or prolongs hospital stay;
* Results in persistent or significant disability or incapacity;
* A congenital anomaly or birth defect; or
* An important medical event (events that may not be life threatening but are of major clinical significance, such as a drug overdose or seizure that did not result in in-patient hospitalization).

Adverse Event Collection Period

Describe the reporting period and follow-up of adverse events for participants.

Recommended text:

The period during which adverse events must be collected is normally defined as the period from the initiation of any research procedures to the final research visit. For this research study, the follow-up period is defined as 30 days following the last research visit.

## Recording of Adverse Events

*Adverse events occurring during the study period should be recorded in accordance with institutional policies and procedures, as applicable. Information on all adverse events should be recorded immediately in the participant’s research record and transcribed into the adverse event log.*

## Reporting of Serious Adverse Events

### Investigator Reporting: Notifying the Sponsor and Applicable Regulatory Agencies

*For studies conducted at or under the auspices of WCH, follow institutional reporting requirements for applicable adverse events or safety incidents.*

*Recommended text:*

The process for notification to the REB for applicable unanticipated problems will be completed as per REB reporting requirements. Copies of each report and documentation of REB notification and REB receipt/acknowledgement must be kept in study team records.

## Safety Management Plan

*As per TCPS 2, investigators must provide the REB with an acceptable plan for monitoring safety, efficacy/effectiveness (where feasible) and validity. Please use this section to describe:*

* *How participant safety will be monitored, and what actions will be taken in the event of a threat to participant safety;*
* *The criteria by which participants may be removed from a research study for safety reasons;*
* *The reporting procedure that will be followed to ensure any information relevant to participant welfare or consent is reported clearly and in a timely fashion to the REB; and*

# RESEARCH STUDY DISCONTINUATION AND CLOSURE

## Research Study Discontinuation

*List possible reasons for termination or temporary suspension of the research study (e.g. closure based on PI decision).*

*For any research study that is prematurely terminated or temporarily suspended, the PI must promptly inform research participants, the REB, and sponsor and provide the reason(s) for the termination or temporary suspension.*

Recommended text:

This research study may be temporarily suspended or prematurely terminated if there is sufficient reasonable cause (i.e. closure based on PI decision). Notification, which includes the reason for study suspension or termination, will be provided by the suspending or terminating party to research participants, the PI, funding agency, and WCH. If the research study is prematurely terminated or suspended, the PI will promptly inform research participants, the REB, and the sponsor, and will provide the reason(s) for the termination or suspension. All communication with participants for this purpose will go through REB review and approval. Research participants will then be contacted, as applicable, and be informed of changes to the study visit schedule.

# DATA HANDLING AND RECORD KEEPING

## Source Documents & Case Report Forms

*Provide general details regarding the type(s) of data capture and any relevant data standards that will be used for the research study. This section should defer to information explained in further detail within the study data management plan, if applicable.*

*Note: Throughout this application, use position titles rather than specific names to minimize protocol modifications due to personnel changes.*

*Recommended text:*

Please reference this study’s Data Management Plan (DMP).

*Recommended text when using REDCap:*

Data for this study will be stored and managed on REDCap. This system is maintained on central WCH servers, and is supported by the WCH REDCap Administrator.

*This study will involve the collection of <describe study data> by <describe relevant study staff> from [insert data source and location (e.g., medical records from EPIC, administrative health data from ICES, direct prospective sample collection, etc.)] in order to <describe how the information will be used>.*

*If the study involves access to medical records/personal health information include the following:*

*The personal health information (PHI) required for this study is described in the [name of data collection form]. PHI is required for this study because [explain why the research cannot reasonable be accomplished without using PHI].*

***Note:*** *Please be sure to submit a template of the* ***data collection form*** *which your team will use to capture this data during the study.*

## Protocol Deviations

*Plans for detecting, reviewing, and reporting deviations from the protocol should be described.*

*Recommended text:*

No deviations from or changes to the protocol will be implemented without prior agreement from the sponsor as required, and approval from the REB, unless to eliminate an immediate hazard to a participant.

## Record Retention

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

*Include detail on how PHI will be disposed of or returned to the health information custodian, as applicable.*

*Note: Although you will destroy the master linking log, WCH requires that the actual data set on which you perform analysis and developed manuscripts, must be kept for a minimum of 7 years.*

# ETHICAL CONSIDERATIONS

*Research study materials (e.g. protocol, ICF, recruitment materials, written information provided to participants, data collection forms for chart reviews. etc.) must be submitted to the research ethics board (REB) for review and approval in accordance with REB requirements. Approval must be obtained prior to initiating any study-specific tasks, and maintained throughout the course of the research study in accordance with REB requirements. Any amendments will require review and approval by the REB before the changes are implemented in the research study, unless to eliminate an immediate hazard to the participant. The REB must be notified of any unanticipated issue or event that may increase the level of risk to participants or that has other ethical implications that may affect participants’ welfare.*

## Research Ethics Board (REB) Approval

*The protocol should describe plans for seeking and maintaining REB review and approval.*

*Recommended text:*

Research Ethics Board (REB) approval will be obtained prior to beginning any research-specific procedures. Following initial ethics approval, ongoing ethical approval will be maintained and the research study will undergo REB review at least annually, in accordance with regulatory and REB requirements. The research study will be conducted in accordance with the REB-approved study documents and the determinations (including any limitations) of the REB, and in compliance with REB requirements.

Whenever new information becomes available that may be relevant to participant consent, a consent form and/or consent for addendum will be presented to the REB for review and approval prior to its use. Any revised written information will receive REB approval prior to use.

## Informed Consent Process & Documentation

*This section should describe how the informed consent process will be completed with research participants, including how the consent discussion will occur (e.g. in person, remotely via video/teleconferencing software or telephone), who will obtain informed consent, how consent will be documented and provision of the fully signed copy of the ICF to participants.*

*Informed consent must be obtained and documented for all research participants in a prospective study. The informed consent process and documentation must comply with applicable institutional and regulatory requirements, as well as adhere to ICH GCP, TCPS 2 and REB requirements. If applicable, describe plans for obtaining consent from speakers of languages other than English; describe procedures for obtaining assent from participants or consent from substitute decision makers (SDM) for those unable to consent on their own behalf.*

*Recommended text for in-person consent:*

Informed consent is a process that is initiated prior to the individual agreeing to take part in the research study and continues throughout their participation.

Informed consent will be obtained from each participant/SDM prior to their participation in this research study. Informed consent will be obtained by <insert description of consent process>.

Each participant/SDM will be provided with a current copy of the REB approved ICF prior to the consent discussion. Research personnel will explain the study to the participant/SDM and answer any questions that may arise. This discussion will include an explanation of the study’s purpose, procedures, potential risks and benefits, confidentiality considerations and participant rights (e.g. participants will not be penalized or lose any benefits regardless of what they decide and they have the right to withdraw from the research study at any time). Participants/SDM may take as much time as they need to make their decision, and may consult with others (e.g. family members, other health care providers, etc.) if they like. Following the consent discussion, and once the participant/SDM has decided to take part, the participant/SDM and the person conducting the consent discussion will personally sign and date the ICF. Each participant/SDM will be provided with a complete (fully signed) copy of the ICF. The original ICF(s) and the informed consent process will be documented in the source documents.

*Recommended text when using Remote Consent Procedures (only use text applicable to your research study):*

Prior to the consent discussion, research personnel will contact participants/SDMs using a verbal consent script. Research personnel will obtain consent to send a copy of the ICF to the participant prior to the consent discussion, which may occur <specify e.g. via REDCap, email, mail or secure file transfer (SFT)> according to participant/SDM preference.

The consent discussion will occur <specify e.g. by telephone or Microsoft Teams/Zoom>, at the participant’s preference. The consent discussion will be conducted by research personnel who are not the PI and do not have a clinical relationship with participants.

Informed consent will be documented in one of three ways, if permissible by the regulatory body that oversees the study, and according to participant/SDM preference:

Verbal Consent (observational studies): Following the consent discussion, the person conducting the consent discussion will orally request confirmation of the participant’s/SDM’s agreement/consent to take part in the study. This confirmation will be recorded by <specify recording device>. Once the

participant/SDM verbally confirms their consent, the person conducting the consent discussion will complete the signature pages of the ICF by writing in the participant/SDM name, the date of the consent discussion, and their own name, signature, and date of signature.

REDCap e-Consent: <Describe REDCap e-Consent process>.

Written Paper Consent: Following the consent discussion, the participant and the person conducting the consent discussion will each personally sign and date the ICF. This will occur by <specify e.g. mailing, emailing or SFT> the ICF to the participant/SDM, the participant/SDM signing the ICF, and the participant <specify e.g. mailing, emailing or faxing> the <specify permitted formats e.g. original, scan or photograph> of the consent back to WCH. The person conducting the consent discussion will also sign the ICF once received. If the ICF is to be sent back by mail, <specify how the cost of postage will be covered e.g. a return postage-paid envelope will be provided or participant will be reimbursed for postage>. No research procedures will begin until after the ICF signed by the participant is received by WCH, and the ICF is signed by the person conducting the consent discussion (i.e. the ICF and documentation has been completed).

After informed consent has been obtained, a complete (fully signed) copy of the ICF will be provided to participants by <specify e.g. email, mail, or SFT> according to their preference.

# 11.0 PRIVACY AND CONFIDENTIALITY

*Include general procedures for maintaining participant confidentiality, privacy protections, and any special data security requirements. Generally, describe who would have access to records, including the PI and other research staff, the sponsor, external auditors, REB, etc. Note that specifics are also recommended to be described in an accompanying Data Management Plan (DMP) that includes detailed information on how data is collected, documented, handled, accessed, protected, and preserved.* *Note: If necessary, submit a template of the master linking log that will be used in this study.*

* + *If the research study involves an app, social media, a wearable device, ‘smart technology, a portal, or other non-WCH-issued technology, identify the tool and who provides it, describe how it works, what data elements it will collect, where data is stored, how data is transferred from the tool to WCH, and whether participants could be identifiable in the tool. Please include an agreement, Terms of Use, and privacy policy with your protocol.*
	+ *If data will be stored in the cloud, please identify the cloud provider, the data elements that will be in the cloud, whether participants could be identifiable in the cloud, where the data is stored, and how the data is secured when it moves in and out of the cloud.*
	+ *If data will be stored in a registry (e.g. consent to contact), a biobank, or a shared database, please identify the system name, who provides it, how it works, what data elements it will collect, where data is stored, whether participants could be identifiable in the system, who has access to data in the system, and how the system is secured. Please include information on the system where available (e.g. a website).*
	+ *If participant PHI will be stored/retained in an identifiable format, please specify for how long and provide a rationale (e.g., if recorded participant interviews will be deleted after transcription or samples will be anonymized after analysis)*
	+ *If data is stored or transmitted outside of Canada, please identify which country, who the recipient is, what data elements are stored or transmitted, how data is protected in transit and at rest outside of Canada.*
	+ *If the research study collects data about individuals outside of Canada, please identify where they are from and what data is collected about them.*
	+ *Note: It is a requirement of the institution and of PHIPA that a complete delegation/information log be kept for each study and for the duration of the study to identify all personnel who have access to the personal health information for research purposes.*

*Recommended text:*

All study-related documents and data will be held in strict confidence and stored at WCH or on WCH servers, and will follow WCH policies and procedures to ensure participant privacy and confidentiality. Data in <app, wearable device, etc. list each one> is limited to <identify data elements or include as attachment to protocol>.

The <app, device, etc.> will be used to <list specific functionality the tool provides for this research study>. The <app, device, etc.> is managed by <technology provider> and participant data is stored in <country>. Data is accessible by <e.g. research team only; the technology provider has access to emails for the purposes of technical support; list all that apply>. Data containing personal health information will be retained in an identifiable form for <specify length of time and rationale>. Data is <encrypted / not encrypted> and data is protected in the tool via <security standard>while traveling in and out of the <app, device, etc.> and while stored in it.

Data will be deleted from the tool <e.g. at the request of the research team at the end of the research study, the participant continues to access the data at the end of the research study>. The participant will have to agree to a <Terms of Use, Privacy Policy> to use the <app, device, etc.> prior to data collection. No information concerning the research study or the data will be released to any unauthorized third party without prior written approval of the sponsor, and the consent of the participant (where applicable).

All research activities will be conducted in as private a setting as possible. Authorized representatives of the sponsor, representatives of the REB, regulatory agencies may inspect all documents and records required to be maintained by the PI, including but not limited to, medical records for the participants in this research study. The participant’s contact information will be securely stored at WCH for internal use during the research study. At the end of this study, all records will continue to be kept in a secure location in accordance with applicable institutional and regulatory requirements.

An information log identifying all persons including non-institutional service providers that will have access to the personal health information now or in the future will be maintained throughout the duration of the study.

#  RESEARCH STUDY FINANCES

##  Funding Source

This section should describe how this research study will be financed, but should not contain specific dollar amounts.

Recommended text:

This study is funded through a grant from the US National Institute of Health.

## Conflict of Interest

*Any investigator who has a conflict of interest (COI) with this research study (patent ownership, royalties, or financial gain greater than the minimum allowable by their institution, etc.) must have the conflict declared and a conflict management plan that has been reviewed and approved by the study sponsor prior to involvement in this study.* *Conflicts should also be disclosed to the WCH REB using section 8 of the TAHSN (Toronto Academic Health Sciences Network) form.*

# PUBLICATION POLICY/DATA SHARING

This section should include the requirements of publication policies at WCH or other participating institutions/entities. In addition, identify who holds the primary responsibility for publication of the results of the research study. Define the need to first obtain approval from the primary responsible party before any information can be used or passed on to a third party.

*The general nature of any applicable data sharing agreements should be described in this section. Please refer to your specific contract, grant, and/or study agreements.*

## Future Secondary Use of Data

*Recommended text:*

*Anonymized/De-identified* data from this project may be used for future research by internal and/or external project collaborators. *De-identified/anonymized* data from this research study will be deposited to *<include repository or database name, details, and location>* for future use by other investigators including those outside the research study. Participant consent to use data collected from this research study for future research will be collected in accordance with WCH REB requirements.

# REFERENCES

*Include a list of relevant literature and citations for all publications referenced in the text of the protocol. Use a consistent, standard, referencing format.*