**PROTOCOL COVER PAGE**

**STUDY TITLE:**

**PRINCIPAL INVESTIGATOR*:***

***Name and title of principal investigator(s) responsible for the trial with address and phone number***

**Co-Investigators*:******Co-Investigators responsible for the trial with addresses***

**Funded by***:* ***Insert funding source (e.g., CIHR, PSI etc )***

**Legend**

**(Delete in final version)**

**BLUE IS DESCRIPTION OF SECTION**

**Black IS Standard template or suggested language**

**Grey IS language to be specified by research team**

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# Background Information and Scientific Rationale

**1.1****Background and rationale**

Briefly summarize prior experience and/or history relevant to the research. Discuss briefly any literature important to the study and include references. Describe the research and provide the rationale or justification for the project and/or the hypothesis and research questions.

# Study Objectives

Describe the overall objectives and purpose of the study. This section should include both primary and any secondary objectives.

# Eligibility Criteria

## Inclusion Criteria

Describe the inclusion criteria.

## Exclusion Criteria

Describe the exclusion criteria.

# Study Design

Describe the study design.

# Expected Duration of Participation

Describe how long participants are expected to participate in the study, sequence of visits, length of time visits will require, including follow up, if any. If the study extends over several visits with multiple procedures, please include a table indicating when the visits will occur, the content, and duration of the visit.

# Study Procedures/Evaluations

Describe all study procedures as outlined in the following sections.

## 5.1 Recruitment Procedures

### 5.1.1 Participant Identification and Initial Contact

Describe the process for identification of participants and initial contact. In accordance with PHIPA, a member of the patient’s circle of care must first obtain the express consent of the patient to share their personal health information (PHI) and personal identifiers for the purposes of recruitment into a research study (e.g., initial approach of patients by researchers for a research study).

If using email for recruitment, only staff who have legitimate access to email addresses of potential participants must send the study invitation.

If **Research Connection Program** ([SharePoint](https://mycheo.sharepoint.com/sites/CI_RI_ResearchConnection/SitePages/Using-the-Program-for-Research(1).aspx?csf=1&web=1&e=UNPG7s&CID=f32126f6-9659-4f70-b8ec-502973395aa2)) will be used to make initial contact with prospective participants, include the following text. *Note: Contact with potential participants identified via pre-screening activities, clinic lists, etc. is outside the scope of the Research Connection Program, and initial contact must be made by a person within the individual’s circle of care.*

Research Connection will be used to make initial contact with potential participants. Procedures will be carried out in accordance with relevant institutional policies and guidelines. All research team members making initial contact through Research Connection have completed all applicable training requirements on use of the program.

|  |  |
| --- | --- |
| Mode(s) of Contact | Phone  MyChart  In Person |

### 5.1.2 Recruitment materials

Specify whether the recruitment plan includes the use of CHEO RI communication services and/or social media platforms (e.g., Facebook, Twitter) to promote the study.

* If the **Research Connection Program** will be used, the Program scripts/templates must be used (as these scripts explain the Program to patients/families) and are available on [SharePoint](https://mycheo.sharepoint.com/sites/CI_RI_ResearchConnection/SitePages/Using-the-Program-for-Research(1).aspx?csf=1&web=1&e=UNPG7s&CID=f32126f6-9659-4f70-b8ec-502973395aa2). These scripts to not require REB review.
* Study-specific recruitment scripts/templates that will be used in conjunction with the Program scripts/templates must be submitted for REB review and approval. A template for study-specific recruitment scripts/templates is available on the [CHEO REB templates page](https://www.cheoresearch.ca/for-researchers-and-partners/research-ethics-board/templates/).
  1. **Consent Process and Documentation**

Describe the consent procedures, including discerning capacity and/or ability to assent; and consent model (e.g., written, electronic, verbal consent) . Outline how consent will be documented.

* 1. **Study Assessments and Procedures**

Describe procedures for collection of all study data including clinical observations, laboratory results, biospecimens, images, and questionnaire responses.

Procedures completed during the study as part of normal standard of clinical care should be identified as such.

If collecting ethnodemographic (ethnic/ethnocultural) or gender identity data:

* It should ideally be voluntary. If *required* for the purposes of the study, provide a justification as it relates to the study objectives.
* Provide the reference for the validation of the set of categories selected (i.e., what is the scientific basis (social science or other) for these categories? Where do they come from? Has this set of categories been validated?).
* Provide information on the analysis/interpretation of this data. The use of such variables in health research requires rigour in conceptualization, terminology, and analysis to, e.g., avoid stigma or harm. It is especially important to explicitly acknowledge that *unsubstantiated conclusions* are not drawn about any specific participant populations.

# Incidental Findings

Incidental findings are defined as findings of potential or actual clinical significance discovered in research participants and unrelated to the purpose of the study. Researchers have an obligation to screen for, identify, and properly address and manage potentially serious implications for a participant’s health, safety, and psychological well-being. Responses that constitute actionable findings require clinical follow-up via a safety management plan to ensure the safety and well-being of participants and researchers must disclose any incidental findings to the study participants within the limits of the participants’ consent.

If there is a reasonable chance that the study will produce incidental findings (e.g., genetic information, abnormal lab results on validated tests, disclosure of suicidality on questionnaire, etc.):

* Describe the safety management plan for clinically actionable findings;
* Specify timelines for detecting this information and feedback to research participants and/or most-responsible physician or health practitioner.

***Example***

In the event that [specify type of incidental finding condition] identified that it is unclear whether the care team or participant have had sufficient evaluation (i.e. appropriate referral/treatment), the primary investigator will communicate directly with the most responsible physician for the participant. On a case-by-case basis, if the [specify incidental finding condition] was deemed to be clinically insignificant no further steps will be taken. Should the research team identify a potentially clinically significant {specify finding} that has not had appropriate follow-up, we will notify the most responsible physician.

If we discover a large number of ‘missed’ findings, we will also discuss these with members from the affected teams [specify affected departments] and develop an appropriate educational strategy for staff.

# Potential Risks & Benefits

# Insert summary of the known and potential risks and benefits to human participants. Discuss why the risks to participants are reasonable in relation to the anticipated benefits and/or knowledge that might reasonably be expected from the results. (See minimal risk study [observational Informed Consent From (ICF) template](https://www.cheoresearch.ca/for-researchers-and-partners/research-ethics-board/templates/) for example of risk/benefit language).

# Statistical Plan

## 8.1 Statistical Analysis Plan

Describe how you will analyze the data to achieve your goals. If you are planning on using the CRU for your statistical analysis, it's beneficial to reach out prior to REB submission.

## Sample Size Justification

Describe the sample and how this will allow you to feasibly meet your objectives.

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# Data Collection and Management

In the sub-sections below, describe data handling and record keeping activities. This includes describing: data sources; types of data; data storage and retention of source documents and study data; data access; data transfer; and if applicable, future uses of data.

If using Research Connection Program for the purpose of this study, ensure the following statement is included:

Eligible Research Participant List obtained for initial contact through Research Connection will be managed in accordance with relevant institutional policy and guidelines.

## Data Sources

Specify all primary and secondary sources of data collected to conduct the study. Data sources may include research participants directly or through data records already in existence. Examples include: Prescribed entity/registry, hospital/medical/pharmacy records, laboratory notes, imaging, video- or audio-recorded transcripts, and participant questionnaires.

***Example for CHEO RI Data Warehouse:*** Data will be extracted from the CHEO RI Data Warehouse to a secure CHEO RI Projects database by the Data Warehouse Clinical Data Analyst.

## Types of data (direct or indirect identifiers)

Provide details regarding the type(s) of data that will be *accessed* and *used* for the study. Provide the rationale for the collection/use of direct identifiers (e.g., email address will be used for future contact).

### 9.3.1 Type of data accessed for the purposes of the study

***Example 1:*** Data accessed for the purposes of the study contains identifiable information.

***Example 2:*** Data accessed for the purposes of the study contains non-identifiable information - all accessed data is anonymous.

***Example 3:*** Data accessed for the purposes of the study contains non-identifiable information - all accessed data is anonymized.

### 9.3.2 Type of data used for the study (i.e., study data that is captured on data collection tools, and used for the purpose of data analysis)

Specify the data collection tools and outline whether the data collected on these tools will include non-identifiable or identifiable information.

***Example 1 (if data accessed by the study team is identifiable):*** Data captured on data collection tools will contain directly identifiable information. The rationale for including [*insert identifiers*] in the dataset is [*insert text*].

* If the study data will also include indirect identifiers, provide the rationale for all identifiers collected.

***Example 2 (if data accessed by the study team is identifiable):*** Data captured on data collection tools will be de-identified and will only contain indirect identifiers. The rationale for including [*insert identifiers*] in the dataset is [*insert text*].

***Example 3 (if data accessed by the study team is identifiable):*** Data captured on data collection tools will be de-identified and will not contain directly or indirectly identifiable information.

***Example 4 (if data accessed by the study team is non-identifiable):*** Data captured on data collection tools will be non-identifiable. All data is *[select as applicable: anonymous/has been anonymized]* at the source.

***Example 5 (if identifiable data is accessed by the Data Warehouse):*** Data captured on data collection tools will be non-identifiable. All data has been anonymized by the Data Warehouse and access given to the study team via active directory credentials.

### 9.3.3 Type of data used for administrative purposes (i.e., identifiable data captured on the master list)

Administrative data is information collected primarily for administrative and not research purposes. A master list is created for the purposes of study administration to separate participant identifiable information and study data. This is done by creating and linking a participant study ID to participant identifiable information on a master list. Study ID should use a non-identifiable code/number and not be based on direct or indirect identifiers (e.g., date of birth, ethnicity, medical record number, residency).

***Example 1(master list)***: For the purposes of study administration, the CHEO research team will maintain a master list with *[direct and/or indirect identifiers]*. These include *[insert identifiers*]. Each participant will be assigned a unique study ID that will be used on all data collection tools (e.g., case report forms, questionnaires).

***Example 2 (no master list):*** There will be no master list maintained for administrative purposes as the study data is *[select as applicable: anonymous/has been anonymized]*. ***Example 3 (master list maintained by Data Warehouse):*** For the purposes of study administration, the CHEO Data Warehouse team will maintain a master list. Each participant will be assigned a unique study ID that will be used on all data collection tools (e.g., case report forms, questionnaires). The master list will not be released to the study team.

***Example 3 (master list maintained by Data Warehouse):*** For the purposes of study administration, the CHEO Data Warehouse team will maintain a master list. The master list will be released to the study team and will include the following participant identifying information *[insert identifiers*]. Each participant will be assigned a unique study ID that will be used on all data collection tools (e.g., case report forms, questionnaires).

## Data Storage and Retention

**Administrative data** (i.e., master list) must be stored on a secure institutional server (i.e., CHEO server/cloud-based server).

As a best practice, electronic **study data** should also be stored on a secure institutional server (i.e., CHEO server/cloud-based server). If this is not possible for the purposes of data analysis, specify two locks of protection for electronic storage of data (e.g., combination of encryption, password-protected document, and/or password-protected computer). Paper study documentation must be stored with two locks of protection (e.g., locked filing cabinet in a locked office).

To maintain data security and participant confidentiality, administrative data and study data must always be stored separately. Administrative data stored in REDCap must be stored in a separate project from the study data, unless there is justification not to do that in exceptional circumstances (i.e., linkage between survey responses).

The use of USB keys is not permitted, unless there is justification in exceptional circumstances.

State a maximum time for retention of data (typically 7-10 years), if applicable. Regulated trials must adhere to Health Canada regulatory requirements (15-year retention).

***Standard template***

The **administrative data** (i.e., master list) will be stored on a secure CHEO server/cloud-based server with access limited to the CHEO research team.

[For regulated trials] It may be viewed by approved authorities for monitoring or auditing purposes via mechanisms approved by CHEO Privacy.

**Study data** will be stored on [data management platform (e.g., CHEO servers, CHEO REDCap, Sickkids REDCap, Infonetica, Survey Monkey]. These servers are located [indicate where (e.g., Canada)].

All data will be stored for [specify years] after [indicate when (e.g., the completion of the study, the last publication)] then destroyed. Data exported onto an external drive for the purposes of analysis will be de-identified and stored with two locks of protection.

***Example 1 (study data stored on CHEO instance of REDCap)***

REDCap (Research Electronic Data Capture) is a secure, web-based application designed exclusively to support data capture for research studies. The application and data are stored on CHEO servers. Local support for REDcap is provided by CHEO’s Clinical Research Unit*.* Study data will be stored for [specify years] after the completion of the study and then destroyed.

***Example 2 (study requires that administrative data is stored with/linked to the study data in REDCap)***

Participants will directly input information into REDCap. [Indicate what linkage is required (e.g., initial survey data and follow-up survey data will be linked)]. Participants will provide [specify identifying information to be collected and stored with the study data, e.g., name, email,] which will be stored with study data in REDCap. These fields will be marked as identifying fields in REDCap and removed from data export unless the identifying information is required for data analysis. Study data will be stored for [specify years] after the completion of the study and then destroyed.

***Example 3 (study data provided by the Data Warehouse)***

The study team will connect to the dataset using analysis software and perform any manipulations or calculations necessary to the data within the software. Aggregated data and partial or incomplete study data are stored on CHEO servers. Study data will be stored for [specify years] after the completion of the study and then destroyed.

## Data access

Describe who will have the right or the opportunity to use or review study documentation, including administrative data and study data.

***Standard template***

Access to all study documentation for CHEO will be limited to members of the CHEO research team and approved authorities (e.g., Study Sponsor, Institution where study is conducted, REB of Record) for the purposes of study-related monitoring, audits and inspections. Source documents may contain identifiable data [and if applicable, will only be transferred externally with prior participant consent.]

Members of the research team outside of CHEO will have access to the study data for analysis purposes

***Standard template for REDCap if using Data Access Groups***

Members of the research team will be granted access to the database, and approved authorities for the purposes of monitoring, auditing and/or inspections. Users will be assigned to “Data Access Groups” (DAG) that will restrict their rights to viewing and entering data. Within the DAG, user privileges will be designated by the study coordinator to ensure research team members have only the minimum required rights to perform their duties.

***Example for Data Warehouse***

Audit logging will be performed on the project by the Data Warehouse team to ensure only appropriate access. Data access will be removed upon completion of the analysis.

## Data transfer

If data is transferred or stored at another institution or linked to data from another institution(s), describe which institutions, how this will be done, and how confidentiality will be protected. If this information is already described in the section on storage, it does not need to be repeated here. Transfer of identifiable data outside of the institution requires participant consent. If data are to be generated in one location and transferred to another group, describe the responsibilities of each party.

## Futures uses of data/ Data Sharing

Describe any plans for making the data available for discovery, reuse/redistribution and/or secondary use. Where possible, participants should be informed about future use of their data, including what data would be stored and made available, the scope of potential future use, as well as any specific limitations.

Secondary use of data refers to the use in research of information (data or biological material) originally collected for a purpose other than the current research purpose. A common example is health survey datasets that are collected for specific research or statistical purposes but then re-used to answer other research questions. Other examples include health care records, school records, biological specimens, vital statistics registries.

Data sharing is the practice of making data available for discovery and reuse. This may be done by depositing the data in a repository for access or through other means of data publication. Data sharing may be subject to conditions and limitations, particularly when data are sensitive, subject to legal or regulatory requirements or when data are proprietary in nature.

***Standard template for future uses of data (extended use)***

Data collected for this research may be used in future related research projects that are either an extension of the original project or in the same general area of research (secondary use of data). Researchers outside of this specific study may request access to the coded data for new research purposes. Participants will not be asked to provide additional informed consent for the use of the coded data for future research.

***Standard template for future uses of data (broad use)***

Data collected for this research may be used in future research within or beyond the general area of research of the current study (futures uses of data). Researchers outside of this specific study may request access to the coded data for new research purposes. Participants will not be asked to provide additional informed consent for the use of their data for future research.

## Protocol Deviations

Protocol deviations will be reported to the REB in a timely manner.

# Budget

If applicable, this section should describe how the study will be funded. An itemized budget can be included in Appendix.

# Dissemination \ Publication Plan

Describe how the results of the study will be disseminated to relevant stakeholders.

# References

Include a list of relevant references.