**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 (for prospective studies)

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.

Include the following:

* Describe the recruitment strategy (identification of participants and approach).

*Note*:

According to 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.

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

* If collecting ethnodemographic (ethnic/ethnocultural) 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 information on the analysis/interpretation of this data.

***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.

# 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.

#  Potential Risks & Benefits

# Insert summary of the known and potential risks and benefits, if any, 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 delegated review ICF template for example of risk/benefit language).

#  Statistical Plan

##  Sample Size Determination

Specify how the sample size for the study was determined and how the analysis will be conducted.

##  Protocol Deviations

Any and all deviations will be reported to the REB in a timely manner.

Note: A privacy breach and/or participant complaints are considered deviations that require reporting to the REB.

#  Data Handling and Record Keeping

## 8.1 Data Collection and Management[[1]](#footnote-1)

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

1. **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.

1. **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).

**Definitions**

**Non-identifiable information**

*Anonymous:* The information never had identifiers associated with it (e.g., anonymous surveys) and the risk of identification of individuals is low or very low.

*Anonymized:* The information is irrevocably stripped of direct identifiers, a code is not kept to allow future re-linkage, and risk of re-identification of individuals from remaining indirect identifiers is low or very low. Data is considered to be anonymized if a health custodian (e.g., Data Warehouse) provides de-identified data and does not release the master list to the study team.

**Identifiable information (personal health information and/or personal information)**

*Directly identifying information:* The information identifies a specific individual through direct identifiers (e.g., name, email, address, social insurance number, personal health number (OHIP)).

*Indirectly identifying information:* The information can reasonably be expected to identify an individual through a combination of indirect identifiers (e.g., date of birth, place of residence or unique personal characteristic, full postal code). Medical record number or pathology number on their own are indirect identifiers.

*De-identified or coded information:* Direct identifiers are removed from the information and replaced with a code. Depending on access to the code, it may be possible to re-identify specific participants, and risk of re-identification of individuals from any remaining indirect identifiers is low or very low (e.g., the principal investigator retains a master list that links the participants’ code with their directly identifying information so data can be re-linked if necessary).

***Example for anonymous data***

All data collected will be anonymous. No direct or indirect identifiers will be accessed or collected for this study.

***Example for Data Warehouse if no identifiable data is transferred to the research team***

Data will be anonymized by the Data Warehouse, and access given to the study team via active directory credentials.

***Example if no direct identifiers in study data***

[Datasets or other data sources] accessed for this study will contain identifiable information and will be de-identified for the purpose of data analysis.

Data captured on data collection tools will include indirect identifiers. These include [e.g., date of birth, partial date of birth, medical record number, pathology number, full postal code].

***Example if direct identifiers in study data***

[Datasets or other data sources] accessed for this study will contain identifiable information and for the purpose of data analysis.

Data captured on data collection tools will include direct and indirect identifiers. These include [e.g., name, email, address, phone number, date of birth, partial date of birth, medical record number, pathology number, full postal code, social insurance number].

The collection of [specify identifiable data point] is required for this study to [describe reason].

***Example for secondary use of information or de-identified/coded data***

Datasets accessed for this study will contain indirect identifiers. These include [e.g., date of birth, partial date of birth, medical record number, pathology number, full postal code]. No direct identifiers will be included in datasets. All data will be de-identified.

1. **Data collection and review of data**

**Administrative data: 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***

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).

**Study data**

Specify the data collection tools. Briefly describe steps taken to ensure that the data collected are accurate, consistent, complete, and reliable.

**D. Data storage and retention**

Administrative data must be stored on a secure server (i.e., CHEO server). As a best practice, electronic study data should also be stored on a secure server (preferably a networked 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.

***Standard template***

The master list (administrative data) will be stored on a secure CHEO 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)]. It 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 for REDCap at CHEO***

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 for a study linking data in REDCap (i.e., that requires that administrative data is stored with study data)***

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 for 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.

1. **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.

1. **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.

1. **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.

#  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.

1. Additional resources

[Glossary of Terms for Sensitive Data used for Research Purposes](https://zenodo.org/record/4088946#.YEWLsLCSlPZ)

[Human Participant Research Data Risk Matrix](https://zenodo.org/record/4088954#.YEWMSrCSlPZ) intended to help researchers determine risk level for research data and make decisions with respect to its management and appropriate access/future use.

[Research Data Management Language for Informed Consent](https://zenodo.org/record/4107178#.YEWM-bCSlPZ) intended to assist researchers working with sensitive data in the development of tailored language for informed consent. [↑](#footnote-ref-1)