**Template Version Date: November 2022**

**PROTOCOL TEMPLATE – SECONDARY USE OF DATA OR SAMPLES / RETROSPECTIVE CHART REVIEWS**

This protocol template is intended for research studies that involve **ONLY** the secondary use of data or samples, **or** consist solely of retrospective chart reviews. Projects which **also** involve the prospective collection of data or samples should use the WCH Observational / General Study Protocol Template or WCH Clinical Trial 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 *SickKids Secondary Use Protocol Template (Version Date: August 29th, 2017).*

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.*

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.

Please do not include this cover page when finalizing your protocol.

# Secondary Use Study Title

Research Team Members

***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.*

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| --- | --- |
| **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.)* |

# Introduction

*The following sections should include relevant background information and rationale on the research study*

# Background

*This section should include a background literature review (with accompanying references) that includes an explanation of the need/justification for the study.*

# Risks/Benefits

*This section should include the anticipated public and/or scientific benefit of the research and the foreseeable harms that may arise from the use of the personal health information and how the researchers intend to address those harms*

# Study Purpose and Objectives

*This section should include purpose and objectives of the research, as well as any research questions/hypotheses that the research seeks to answer. Primary endpoints of the study can also be described here.*

The purpose of this study is to determine the [*outcomes, prevalence, and incidence*] of *[insert protocol specific language*].

***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.*

## Primary Objective

*Describe the primary objective of this study.*

The primary objective of this study is to determine [*include language specific to the primary objectives for your study and outcome measures*].

## Secondary Objective(s) **(if applicable)**

*Describe the secondary objective(s) of the study.*

The secondary objective(s) of this studyare to [*list the secondary objective or objectives that are specific to your research study and outcome measures*].

# Study Design and Methods

## General Study Design

This section is intended to provide a brief overview of the study design. Describe the design for the chart review or secondary use biological sample analysis (e.g., Case Series, Case-Control, Matched Case-Control, and Cohort). Justify how the study design will meet the stated objectives.

This study is a retrospective [*cohort study, descriptive study, case-control study, matched case-control study, case-series, etc.*].

***Note:*** *Do not include all of the details of the study design into this section. The details and procedures will be laid out in more detail in the* ***Study Procedures*** *section below.*

## Total Number of Sites and Participants

*Describe the sample size (number of charts, samples, or individual administrative data sets you will be including in your study) and the justification for this sample size. Consider the size that is required to answer the research question, and the size that is feasible given the data source.*

We expect *[# of participants*] participants to be enrolled at WCH

### 3.2.1 Multi-Site Study

*Multi-site studies are when any part of the study (data analysis, collection, storage, etc.) takes place at more than one location. For multi-site studies, state the overall sample size from all sites as well as the anticipated number of records that will be reviewed at each site.*

Overall, [*total # of participants*] will be enrolled in the study. At WCH, we expect *[# of participants*] participants.

## Inclusion Criteria

*List out the specific criteria for inclusion in this study.*

The inclusion criteria for this study are:

* [*Insert inclusion criteria.]*

## Exclusion Criteria

*List out the specific criteria, for which your team would exclude a potential participant from participating in the study*.

The exclusion criteria for this study are:

* [*Insert exclusion criteria, e.g., list concomitant medications which may exclude participants from the study, medical conditions which may exclude participants from the study, etc.]*

***Note:*** *Consider and include any study specific details of inclusion and exclusion criteria that might be different for cases versus controls if two differing populations are being reviewed retrospectively.*

## Study Procedures

*This section is intended to outline the details of the study. Include a further description of the study details and procedures, augmenting the information provided in the Study Purpose and Objectives section.*

## Date Range and Study Duration

*The REB needs the range of dates during which the study will take place (i.e. study duration) and the date ranges of the data/biospecimens that will be included in the research. If the study has a prospective component, it must be submitted through a prospective application (i.e. this template is not suitable for a prospective study)*. *Collecting data that has not yet been recorded is considered a prospective study.*

*If the study involves access to medical records include the following:*

This study will include charts ranging from [*DD-MM-YYYY*] to [*DD-MM-YYYY*]*.*

*If the study involves access to biospecimens include the following:*

This study will include [name biospecimens] collected from [*DD-MM-YYYY*] to [*DD-MM-YYYY*].

*If the study involves secondary use of data include the following:*

This study will include data from [*describe where the data originates*] collected from [*DD-MM-YYYY*] to [*DD-MM-YYYY*].

The study is anticipated to take [*enter study duration*] to complete.

## Participant Selection

*Provide details on how records will be identified and by whom. This would include querying a data base or providing a list.*

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

***Example:*** *Surgical Information Systems Manager will review charts from the Operating Room Trauma Registry to identify participants.*

## Data Sources

*List all the data sources that will be utilized for study purposes, where they come from and why they are required. If data comes from another WCH study (including biobanks), please provide the REB# of that study.*

This study will use study data from [*insert data source and location (e.g., medical records from EPC, administrative health data from ICES, previously collected tissue samples from a biobank or clinical repository)*] 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 reasonably 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.*

### 4.3.1 If this is a multi-site study:

*If this is a multi-site study, the data sources may be described in a general sense (i.e., Electronic medical records, stored samples from pathology, etc.). Each site may have their own systems and you may not be able to be specific. In the REB application form, you will detail the specific WCH sources.*

#### 4.3.2 If there are multi-database links:

*If more than one database is being used, list the variables which will be used to link the databases and who on the study team will manage the data.**If data will be linked to sources (e.g., ICES), describe why this linkage is necessary and how this will be done.*

## Data Variables

*List and define the study variables (e.g. exposure, outcome, baseline characteristics, covariates). The exposure of interest should be clearly described and used to define the “exposed” group.*

## Statistical Plan

*Even within a minimal risk study, such as a retrospective chart review, a sound scientific design and analysis plan are required. The statistical plan provides clarity to the reviewers that your study hypothesis may be tested. It is also to the investigator’s advantage to have a clear statistical plan in place to ensure that the study data are collected and coded properly so they may be analyzed quickly and efficiently.*

## Primary and Secondary Endpoints

*Summarize the overall statistical approach to the analysis of the study. Include how the study primary and secondary endpoints fit into the statistical analysis plan. The endpoints serve as the specific documentation of what will be evaluated in this research study.*

## Statistical Methods/Data Analysis

*List all the tests, or possible tests, that will be used to analyze the data, including descriptive statistics, frequencies, tests of significance, regression, etc. Be clear on primary as well as any applicable secondary analyses.*

***Note:*** *Adjustments for potential confounding variables and ascertainment biases should be addressed within this section. This is especially important in retrospective studies since they are typically more vulnerable to confounding and ascertainment bias.*

***Example:*** *Baseline and demographic characteristics will be summarized using descriptive statistics (means, standard deviations for continuous variables such as age and percentages for categorical variables such as race and ethnicity. The primary objective of the study is to determine if there is an association between testosterone hormone replacement therapy and risk of heart attacks. We will use a chi-square test to determine if there is a significant relationship between exposure to testosterone hormones and incidence of heart attacks. We will control for age, race and cardiac history in our model.*

## Sample Size and Power

*The sample size should be justified based on the study objectives. While this can be difficult, and less robust, in a retrospective chart review there should still be some description of how the sample size was developed. Estimates of the number of cases can be made by conducting literature reviews or looking at availability of specific diagnosis codes of interest.*

***Note:*** *It is possible that the sample size may simply be one of convenience- meaning all of the available cases. In this case simply state it is a sample size of convenience.*

## Ethical Considerations

*Secondary use studies are not inherently exempt from the requirement to obtain consent for research purposes; however, researchers may request a waiver of the requirement to obtain consent if they can provide justification for doing so in accordance with the TCPS2 article 5.5.*

*This section should include a discussion and justification for a waiver of consent. The justification must be study-specific and provide tangible specific reasons within the context of the study that meet all the requirements set out in TCPS2 article 5.5.*

## Confidentiality of Data

*This section should include a summary of the physical, administrative and technical safeguards in place to protect the data, as well as methods for data storage and destruction.*

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| ***Note****: It is a requirement of the institution and of PHIPA that a complete 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.* |

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.

## Data Management

*Describe the procedure to protect the privacy and confidentiality of participants. Indicate how participants are identified in research records (e.g., unique study identification numbers). If applicable, explain the necessity for collection or maintaining data linked to participants’ identities and how participant’s privacy will be protected. Indicate how long information will be retained in an identifiable form and why.*

***Note:*** *If necessary, submit a template of the master linking log that will be used in this study.*

## Storage

*Describe how data will be stored to safe-guard confidentiality. WCH requires data to be stored behind two physical (i.e., a locked cabinet in a locked office) or two electronic (i.e., an encrypted file on a locked computer) locks. Unless specifically justified, data will be stored on WCH premises and servers.*

## Transfer or Linkages of Data **(if applicable)**

*If data is being transferred or linked to data from another from another institution(s), describe which institutions, how this will be done, and how confidentiality will be protected. Note that identified data cannot be transferred outside of the institution without participant consent.*

## Retention and Destruction

*Describe how long the information will be kept and what the plans are for destroying it once the study is complete. If a waiver of consent is granted, identifiers should be destroyed with no possibility of linking the data with these identifiers as soon as possible. Explain your procedures for this task*. *Indicate whether there is a plan to return any PHI to the health information custodian.*

***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****.*

# Conflict of Interest

*This section should include a description of how the study will manage actual or perceived conflicts of interest.*

# References

*Provide the citations for all resources referenced in the text of this protocol.*