**PROTOCOL INSTRUCTION SHEET**

**USE OF THIS TEMPLATE**

This protocol template is intended for low *or* high risk studies. For all studies regulated by Health Canada, please refer to the [**SPIRIT**](https://www.spirit-statement.org/) protocol for any further guidance.

**

*For Health Canada regulated studies, mandatory sections in this template that are additional are marked with a red maple leaf.*

**HOW TO WRITE YOUR PROTOCOL**

Below are some tips for writing a successful protocol. For any further guidance, or questions, please contact the REB office.

**Links for Reference:**

TCPS2: <https://ethics.gc.ca/eng/policy-politique_tcps2-eptc2_2018.html>

GCP Section 6: <https://database.ich.org/sites/default/files/E6_R2_Addendum.pdf>



Fill out **all** of the sections if they apply to your study.



Remove the **blue** instructional writing and **red** maple leafs prior to submitting.



Write in a lay language (please keep in mind that REB reviewers are not all MD’s, scientists, or

clinicians. Protocols that are not written in lay language will be returned).



 Incorporate Equity, Diversity and Inclusion considerations and language where applicable.



 Do not copy and paste from grant applications, etc.



 Use charts to outline study visits, measures, etc.



 Always spell out acronyms before using them.



 Ensure your protocol encompasses **all** of the components of your study.



 Please do not say “refer to section…”



 Edit your document prior to submitting, including correction of any spelling and grammatical

 errors. Submissions that are poorly written will be returned.

***Study Title***

**Principal/Qualified Investigator:** Click here to enter text.

**Contact Details:** Click here to enter text.

**Study Sponsor:** Click here to enter text.

**Contact Details:** Click here to enter text.

**Study Funder:** Click here to enter text.

**Contact Details:** Click here to enter text.

**Protocol Version:** Click here to enter text.

**Protocol Amendments (if applicable):** Click here to enter text.

**Clinical Trials.gov Identifier:** *required for all interventional studies and clinical trials. Remove if not applicable.*

**TABLE OF CONTENTS**

*(Include all sections)*

**STUDY COLLABORATORS/CO-INVESTIGATORS:**

|  |  |
| --- | --- |
| **Name:** Click here to enter text.**Institution:** Click here to enter text.**Role:** Click here to enter text.**Contact Details:** Click here to enter text.**Name:** Click here to enter text.**Institution:** Click here to enter text.**Role:** Click here to enter text.**Contact Details:** Click here to enter text.**Name:** Click here to enter text.**Institution:** Click here to enter text.**Role:** Click here to enter text.**Contact Details:** Click here to enter text.**Name:** Click here to enter text.**Institution:** Click here to enter text.**Role:** Click here to enter text.**Contact Details:** Click here to enter text. | **Name:** Click here to enter text.**Institution:** Click here to enter text.**Role:** Click here to enter text.**Contact Details:** Click here to enter text.**Name:** Click here to enter text.**Institution:** Click here to enter text.**Role:** Click here to enter text.**Contact Details:** Click here to enter text.**Name:** Click here to enter text.**Institution:** Click here to enter text.**Role:** Click here to enter text.**Contact Details:** Click here to enter text.**Name:** Click here to enter text.**Institution:** Click here to enter text.**Role:** Click here to enter text.**Contact Details:** Click here to enter text. |

***\*It’s advisable to not list study coordinators or staff, unless they are co-investigators.***

**PROTOCOL SIGNATURE PAGE**

I agree to the terms and conditions relating to this study as defined in this protocol. I will conduct this study as outlined and will make a reasonable effort to complete the study within the time designated.

I agree to conduct this study in accordance with the declaration of Helsinki and its amendments, the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS-2), International Council for Harmonisation (ICH) Good Clinical Practice Guidelines (GCP) and applicable regulations and laws. I will obtain the approval of a Research Ethics Board for this protocol prior to its implementation.

*For Clinical Trials, please use the following statement:*

I have read this protocol and agree that it contains all the necessary details for carrying out this study. I will conduct the study as outlined herein and will complete this study within the time designated.

**I will provide copies of the protocol and all pertinent information to all individuals responsible to me who assist in the conduct of this study. I will discuss this material with them to ensure that they are fully informed and trained regarding the study drug, the conduct, and the obligations of confidentiality as per the Canadian Privacy Act, The Personal Information Protection and Electronic Documents Act (“PIPEDA”) and the relevant HealthCare Privacy Legislations.

**I confirm that I will conduct this clinical trial in compliance with the Health Canada Food and Drug Regulations, Part C, Division 5, the International Council for Harmonisation Good Clinical Practice Guideline (ICH-GCP E6), the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS-2), the Protocol as approved, and all applicable local and study specific standard operating procedures (SOPs).

**Site Name and ID:**

**Site Principal Investigator Name (printed):** Click here to enter text.

**Site Principal Investigator Signature:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Date:** Click here to enter a date.

1. **STUDY SUMMARY** *(this section is intended to be brief and succinct, as it summarizes the study)*

|  |  |
| --- | --- |
| **Title:** | Click here to enter text. |
| **Study Design***(RCT, blinding, placebo, etc.)* | Click here to enter text. |
| **Study Duration**  | Click here to enter text. |
| **Study Centre(s)** | Click here to enter text. |
| **Objectives**  | **Primary Objective:** Click here to enter text.**Secondary Objective:** Click here to enter text. |
| **Expected Number of Participants** | Click here to enter text. |
| **Inclusion and Exclusion Criteria** | **Inclusion Criteria:** Click here to enter text.**Exclusion Criteria:** Click here to enter text. |
| **Study Intervention** *(if applicable, include Product/Device, Dose, Route, Regimen, Behavioural, Etc.* | Click here to enter text. |
| **Methodology** | **Primary Endpoint:** Click here to enter text.**Secondary Endpoint(s):** Click here to enter text. |

**1.1 ACRONYMS**

|  |  |
| --- | --- |
| EX | Example |

**1.2 SUMMARY PARAGRAPH/ABSTRACT** *(200-250 words)*

 Click here to enter text.

1. **BACKGROUND AND RATIONALE**

*Be sure to include the following information:*

*Name and description of the IP/device/intervention, if applicable.*

*A summary of findings from non-clinical & clinical studies that potentially have clinical*

 *significance, and from clinical trials that are relevant to the trial.*

*Summary of known and potential risks and benefits to participants.*

*Description of, and justification for, the study measures, and if applicable, include the route of administration, dosage, dosage regimen and treatment period(s).*

*Description of the population to be studied.*

*References to literature and data that are relevant to the trial, and that provide background for the trial.*

 Click here to enter text.

1. **STUDY OBJECTIVES AND PURPOSE**

Click here to enter text.

1. **STUDY DESIGN & METHODOLOGY**

*Include the following if applicable:*

* 1. **Endpoints**

 *(Include a specific statement of the primary endpoints and the secondary endpoints, if any, to be*

 *measured during the study)*

Click here to enter text.

**4.2Study Design**

*(Include a description of the type/design of trial to be conducted (e.g., double-blind, placebo-*

*controlled, parallel design) and a schematic diagram of trial design, procedures and stages. For*

 *non-clinical trials, please include a detailed description of the study design)*

Click here to enter text.

**

**4.3Study Measures**

 *(Include a description of the measures taken to minimize/avoid bias, including randomization*

*and blinding)*

Click here to enter text.

**4.4****Drug/Device Trial Description (for regulated and non-regulated trials)**

 *(Include a detailed description of the trial treatment(s) and the dosage and dosage regimen*

*of the investigational product(s). Also, include a description of the dosage form, packaging, and*

 *labelling of the investigational product(s), drug/device acquisition, intended use, etc.)*

Click here to enter text.

**4.6 Study Duration**

 *(Include the expected duration of the study, and a description of the sequence and duration of*

 *all trial periods, including follow-up, if any.*

 Click here to enter text.

**4.7 Study Stopping Rules/Termination**

*(Include a description of the study stopping rules or criteria for discontinuation for*

 *research participants, including parts of the study, or the entirety of the study)*

 Click here to enter text.

**

**4.8****Drug or Investigational Product Accountability Procedures**

 *(Include accountability procedures for the investigational product(s), including the placebo(s)*

 *and comparator(s), if any.*

Click here to enter text.

**

**4.9****Randomization and Blinding** *(if applicable)*

 *(Include the maintenance of trial treatment randomization codes and procedures for*

 *breaking codes)*

Click here to enter text.

**4.10****Data Records**

 *(Identify any data to be recorded directly on the CRFs (i.e., no prior written or*

 *electronic record of data), and to be considered to be source data)*

Click here to enter text.

1. **SELECTION AND WITHDRAWAL OF PARTICIPANTS**
	1. **Inclusion Criteria** *(numbered list)*

Click here to enter text.

* 1. **Exclusion Criteria** *(numbered list)*

Click here to enter text.

* 1. **Reasons for a Participant Being Withdrawn, or Withdrawing, from the Study**

 *(Please list all the withdrawal criteria, such as, the participant withdraws consent; screening*

 *failure; participant is non-compliant; participant no longer meets the inclusion criteria; lost to*

 *follow-up; protocol violation that requires discontinuation; adverse event occurs and the PI/QI*

 *feels it would be in the best interest to withdraw the participant; participant follow-up;*

 *participant death, etc. Also include whether, and how, participants will be replaced, timing*

 *and method of participants’ being withdrawn)*

 Click here to enter text.

* 1. **Study Stopping/Termination Rules**

*(In consideration of the safety, benefit and futility of the study, the study may result in*

 *suspension or termination prior to reaching its intended completion for the following reasons:*

 *study will not reach its primary endpoint; new risks to participants that are unacceptable;*

 *non-compliance to the study protocol; integrity of the data is compromised or determined to*

 *be incomplete; a new treatment regimen becomes available; due to study results, there is no*

 *longer a justification to continue exposing participants to the risks associated with the study;*

 *infrastructure loss or failure; pandemic restrictions; or for other justifiable reasons the DSMB,*

 *the Sponsor, the REB, or other third parties providing oversight to the study may have)*

Click here to enter text.

1. **STUDY MEASURES AND PARTICIPATION**

**

* 1. **Treatment of Participants for Drug/Device Trials** *(In detail, please describe the study*

*procedures. Include name of the drug/device, the dose, the dosing schedule, the method*

 *of administration, treatment, and follow-up for each investigational product/device*

 *treatment arm. Please include all medications that may or may not be given during the*

 *trial, including rescue medication, along with medication permitted prior to, and*

 *during, the trial)*

 Click here to enter text.

* 1. **Treatment of Participants for all other Studies** *(In detail, please describe the study*

*procedures, including all study measures that will occur during the course of the study, including any restrictions to medications, drugs, certain food/drink, exercise, etc.)*

 Click here to enter text.

 **6.3 Monitoring Participant Compliance** *(Please describe all procedures for monitoring*

 *participant compliance, such as participant diaries, bloodwork, etc.)*

Click here to enter text.

 *\*(For all of the above, please use a chart to indicate a timeline of the screening and consent process*

 *in- person/virtual study visits, all study procedures, including frequency, location, time*

 *commitment, monitoring participant compliance, etc. Please indicate the* ***total time commitment***

 *required by participants)*

1. **ASSESSMENT OF EFFICACY**

 *(Specify efficacy parameters, such as methods and timing used for assessment, recording,*

 *and analysis)*

 Click here to enter text.

1. **POTENTIAL BENEFITS, RISKS AND SAFETY**

**8.1 Potential Benefits**

*(Include any potential benefits, or if there are no benefits to participating in the*

 *study. Please note that receiving compensation or incentives for study participation is not a*

 *benefit, and should not be listed in this section)*

 Click here to enter text.

**8.2 Risks**

*(Please list all the risks involved in this study, even if they are very minor. Risk categories may*

 *include: physical, mental/emotional, short-term or long-term, reproductive,*

 *privacy/confidentiality, etc. Please also include how you will help to mitigate the risks, such as*

 *offering a list of mental health resources, or scheduling a follow-up telephone call/visit, etc.*

 *Please also include how they will be communicated to the research participants, such as the*

 *ICF (mandatory), information pamphlets, etc.)*

 Click here to enter text.

 **8.3 Safety**

*(This section needs to include how you will manage Adverse Events (AE’s), Serious Adverse*

 *Events (SAE’s), and Adverse Drug Reactions (ADR’s). An Adverse Event is defined as any*

 *negative or unintended occurrence in the health or well-being of a research participant who is*

 *administered an investigational product (drug, device, or natural health product), or who*

 *undergoes a research procedure, and the event does not necessarily have a causal relationship*

 *with the investigational product or procedure. A Serious Adverse Event or Adverse Drug Reaction*

 *is defined as any untoward medical occurrence that at any dose: results in death, is life-*

 *threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results*

 *in persistent or significant disability/incapacity, or is a congenital anomaly/birth defect. Please*

 *include details on how you will monitor for AE’s, SAE’s and ADR’s, how they will be documented*

 *in the study files, and who they will be reported to, such as the REB, DSMB, Sponsor, etc. The*

 *timeline for reporting AE’s/SAE’s/ADR’s to the REB is within 5 business days of the QI/PI*

 *becoming aware of the event.*

**

*For all regulated studies, SAE’s/AE’s/ADR’s must be reported via the* ***CIOMS Form*** *as per the*

 *following timeline requirements: a) Where it is neither fatal nor life-threatening, within 15 days*

 *after becoming aware of the information; b) Where it is fatal or life-threatening, within 7 days*

 *after becoming aware of the information; c) Within 8 days after having initially informed Health*

 *Canada of the fatal or life-threatening ADR, submit as complete a report as possible. Please refer*

 *to the following link for more guidance:* [*Health Canada Guidance Document for Clinical Trials*](https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/clinical-trials/clinical-trial-sponsors-applications.html#a2842)

Click here to enter text.

1. **RECRUITMENT**

 *(Include all recruitment activities, such as sample size, method of recruitment: self-referral, email,*

 *telephone or other virtual contact. Please indicate if any hospital departments will be involved,*

 *community sites, social media sites, etc.)*

 Click here to enter text.

1. **CONSENT AND SCREENING**

 *(Include detailed information about screening and informed consent processes, ie: method: in-*

 *person, virtual – Zoom for Healthcare or the paid version of Zoom, telephone, etc; method for giving*

 *participants a copy of the consent form; include all screening activities/measures, time commitment*

 *for participants, where they will occur, etc. If substitute decision makers will be required, please*

 *explain the process, including that either written, verbal, or non-verbal assent will be obtained from*

 *research participants)*

 Click here to enter text.

  **10.1 Ongoing Consent/Assent**

 *(Please provide detailed information on how ongoing consent will be sought. For example, if*

 *you will be asking for verbal consent at the beginning of each study visit/measure, or if you*

 *will be asking for assent from participants who have a substitute decision maker consenting*

 *on their behalf. For participants who are not capable of giving verbal or written consent,*

 *please explain if you’ll be looking for non-verbal cues at the beginning of, and during, each*

 *study procedure.*

 Click here to enter text.

1. **SPECIMEN COLLECTION, STORAGE AND ANALYSIS**

 *(Please indicate where specimen collection will take place, where and for how long it will be stored,*

 *and where analysis will take place. Please include names and full addresses of institutions/clinics.*

 *Please note that the same information must be included in the informed consent form. If genetic*

 *analysis or biobanking of the specimens will occur, please indicate the purpose of the analysis, and*

 *the location of the biobank. You will also be required to submit the* ***Genetic Addendum*** *for REB*

 *review)*

 Click here to enter text.

1. **INCENTIVES AND COMPENSATION**

*(Please include all incentives and compensation that will given to participants for study participation. For compensation, please include all reimbursements for transit, parking, meals/snacks provided, etc., and how the compensation will be offered, such as cash, gift cards, etc. For incentives, please include the dollar amount, if it will be pro-rated, and the method it will be given, such as cash, gift cards, etc. Be sure to include how you will be providing the incentives and compensation, such as in-person, email, etc.)*

Click here to enter text.

**13. INCIDENTAL FINDINGS**

*(Incidental findings are discoveries made in the course of research but that are outside the scope of*

 *the research” (TCPS2 Article 3.4). Please explain the process for handling these, whether*

 *physiological or otherwise. For example, for imaging studies, please explain the Brain Imaging*

 *Centre (BIC) process for reporting, and follow-up with the participant, referral to a physician if*

 *necessary, etc. It’s important to emphasize how and at what stage the participant will be informed.*

 *Please also include how these will be reported to the REB. Please see the* ***Incidental Findings Form***

 *for definitions and reporting timelines. For incidental findings discovered during qualitative studies,*

 *please explain how these will be handled. For example, if there is concern for the participant’s*

 *welfare or safety, or the welfare or safety of someone else, please explain the process for offering*

 *help, support, and/or reporting to the appropriate authorities.)*

Click here to enter text.

1. **PROTOCOL DEVIATIONS**

*(Please explain how you will document and report all noncompliance with the protocol or GCP requirements. Please refer to the* ***Deviation Reporting Form*** *for guidance and timelines on reporting to the REB)*

Click here to enter text.

1. **CONFLICT OF INTEREST**

*(A conflict of interest may be actual, perceived, or potential. All must be declared at the outset, and during, the course of the study. Please include any conflicts of interest, how these will be handled, and disclosed to participants. You will also be required to submit the* ***Conflict of Interest Statement Form*** *to the REB for review.*

Click here to enter text.

1. **PRIVACY AND DATA MANAGEMENT**

*(Please explain privacy/confidentiality procedures, how the study data will be stored, shared and transferred, who will have access to it, how long it will be stored for, and any future use. If you will be transferring or sharing data with another site or institution, please indicate that you will either be seeking a data or materials transfer agreement, or indicate if one is already in place. If you will be asking participants to consent to their data to be used for future research studies, please include a statement to that effect)*

Click here to enter text.

1. **PANDEMIC MEASURES**

 *(Please explain the plan for study continuation or pause during pandemic restrictions)*

 Click here to enter text.

1. **DATA MONITORING**

 *(Please explain the plan for data monitoring, the management of reports, if there will be a data*

 *safety monitoring board (mandatory for all regulated trials unless exempt), etc.*

 Click here to enter text.

1. **DATA ANALYSIS AND PUBLICATION**

 *(Please explain the data analysis process, including any planned interim analysis)*

 Click here to enter text.

1. **STATISTICS**

*(Please provide detailed information for the following applicable sections)*

* 1. **Description of the statistical methods to be employed, including timing of any**

 **planned interim analysis(ses).**

 Click here to enter text.

* 1. **The number of participants planned to be enrolled. In multicentre trials, the numbers**

 **of enrolled participants projected for each trial site should be specified. Reason for**

 **choice of sample size, including reflections on (or calculations of) the power of the**

 **trial and clinical justification.**

 Click here to enter text.

* 1. **The level of significance to be used.**

 Click here to enter text.

* 1. **Criteria for the termination of the trial.**

 Click here to enter text.

* 1. **Procedure for accounting for missing, unused, and spurious data.**

 Click here to enter text.

* 1. **Procedures for reporting any deviation(s) from the original statistical plan (any**

 **deviation(s) from the original statistical plan should be described and justified in**

 **protocol and/or in the final report, as appropriate).**

 Click here to enter text.

* 1. **The selection of participants to be included in the analyses (e.g., all randomized**

 **participants, all dosed participants, all eligible participants, evaluable participants).**

 Click here to enter text.

**21. ACCESS TO SOURCE DATA/DOCUMENTS**

 *(Please include a statement that the investigator(s)/institution(s) will permit trial-related monitoring,*

 *audits, REB review, and regulatory inspection(s), providing direct access to source data/documents)*

Click here to enter text.

**22. REFERENCES**

 *(Please list references used)*

Click here to enter text.