**BRUYÈRE HEALTH RESEARCH ETHICS BOARD –**

**Protocol Template**

**USE OF THIS FORM:**

All Health Canada REB submissions to the Bruyère Health Research Ethics Board must be accompanied by a Protocol. For all other studies that are multi-site, please inquire with the REB office to determine if your submission requires a protocol.

This protocol template is intended to be used for both low risk and greater than minimal risk studies. For Health Canada regulated studies, please refer to the [**SPIRIT**](https://www.spirit-statement.org/) protocol for any further guidance.

For **Health Canada** **regulated studies**, there are additional **mandatory** sections marked with a **red** arrow. For studies that are not regulated, nor clinical trials, there may be sections that are not applicable. Please complete the sections applicable to your study.

**INSTRUCTIONS for writing your Protocol**

Below are some suggestions for writing a successful protocol. Have questions? Please contact the REB Office: REB@bruyere.org

**Reference Links:**

TCPS2: <https://ethics.gc.ca/eng/policy-politique_tcps2-eptc2_2022.html>

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

**Helpful Tips:**



 Complete **all** applicable sections.



 Be mindful of incorporating Equity, Diversity and Inclusion considerations.



 Do not say “Refer to section…” nor refer to sections of the BREB. The protocol must encompass all components

 of your research study.



 Write in concise, lay language. Protocols that are not written in lay language will be returned.



 Use charts and diagrams to explain participant study visits, study measures, timelines, etc.



 Always spell out acronyms before using them.



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

***Study Title***

**Principal/Qualified Investigator:**

**Contact Details:**

**Study Sponsor:**

**Contact Details:**

**Study Funder:**

**Contact Details:**

 **Protocol Version #:** *this is different than the version date.*

**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:** **Title/Position:** **Department/Institution:** **Email Address:** **Name:** **Title/Position:** **Department/Institution:** **Email Address:** **Name:** **Title/Position:** **Department/Institution:** **Email Address:** **Name:** **Title/Position:** **Department/Institution:** **Email Address:** ***\*You do not need to list study coordinator or staff unless they are co-investigators.******ff unless they are co-investigators.*** |  |

**PROTOCOL SIGNATURE PAGE**

I assume full responsibility for the scientific and ethical conduct of the study at my research site as described in this Protocol and supporting documentation (e.g. BREB), and agree to conduct this study in compliance with the Tri-Council Policy Statement 2: Ethical Conduct for Research Involving Humans; the International Conference on Harmonization – Good Clinical Practice: Consolidated Guideline; the provisions of the Personal Health Information Protection Act 2004, and the Food and Drug Act of Health Canada and its applicable regulations, and any other relevant regulations or guidelines endorsed by Bruyère Health, and the Bruyère Health Research Institute. I certify that all researchers and other personnel involved in this study at this institution are appropriately qualified and experienced or will undergo appropriate training and supervision to fulfill their role in this study.

[ ]  By checking here, I certify that I meet the requirements of a “Qualified Investigator” as defined by Health Canada.

*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). **Initial here:**

**Site Name and ID:**

**Site Principal Investigator Name (printed):**

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

**Date:**

1. **STUDY SUMMARY INFORMATION** *(this section is intended to be brief and succinct)*

|  |  |
| --- | --- |
| **Study Title** |  |
| **Study Design *(RCT, blinding, placebo, qualitative, etc.)*** |  |
| **Expected duration of Study** |  |
| **List all study locations/centres** |  |
| **Expected number of participants** |  |
| **Study Objectives** |  |
| **Methodology** | **Primary Endpoint:****Secondary Endpoint:** |
| **Inclusion and Exclusion Criteria** | **Inclusion Criteria:****Exclusion Criteria:** *(please don’t list the opposite of the inclusion criteria)* |
| **Study Intervention***(Investigational product/device or NHP, dose, regimen, behavioural, etc.)* |  |
| **Study Summary or Abstract***(Do not exceed 200 words)* |  |

1. **BACKGROUND AND RATIONALE**

*Be sure to include all of 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 (if applicable) 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.*

1. **STUDY OBJECTIVES AND PURPOSE**
2. **STUDY DESIGN & METHODOLOGY**

*Some of the following sections will apply to regulated and non-regulated clinical trials, as well as studies that are not clinical trials.* ***For Health Canada regulated clinical trials****, please complete all sections.*

* 1. **Endpoints**

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

 *measured during the study)*

**4.2Study Design**

*(****For clinical trials****, 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 all other studies****, please include a detailed description of the study design)*

**4.3 Study Measures**

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

*and blinding)*

**4.4****Drug/Device Trial Description *(for Health Canada regulated and non-regulated clinical***

 ***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.)*

**4.5 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.)*

**4.6 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.)*

**4.7 Drug or Investigational Product Accountability Procedures**

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

 *and comparator(s), if any.)*

**4.8 Randomization and Blinding**

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

 *breaking codes)*

**4.9 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)*

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

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

* 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)*

* 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)*

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)*

* 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.)*

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

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

*\*(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)*

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)*

**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.)*

 **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 Health Canada 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)

1. **RECRUITMENT**

 *(Include all recruitment activities, such as expected 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.)*

1. **CONSENT AND SCREENING**

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

 *person, virtual, 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)*

**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.)*

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)*