University of Guelph

Research Ethics Board (REB)

Supplement V: Clinical Trials

# DIRECTIONS

## How to submit:

* This document can ONLY be submitted as a supplement to the main REB Application form.
* Email the completed form as a Word document along with the rest of the submission package to reb@uoguelph.ca.

## How to answer questions:

* The questions asked are drawn from the
	+ Tri-Council Policy Statement: Ethical Conduct of Research Involving Humans, 2nd Edition ([TCPS2](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/))
	+ [Good Clinical Practices ICH-GCP E6](http://www.ich.org/products/guidelines/efficacy/efficacy-single/article/integrated-addendum-good-clinical-practice.html)
* Not all questions will apply to your research. Feel free to choose the n/a option, or explain in a text box. Do not leave questions unanswered.
* Full functionality of the form will not be available if you edit in Word Online (browser editing on Office 365). Instead, download a copy to your computer and edit in Word.
* This form is ‘unlocked’ to allow the ‘cut and paste’ function and the ‘track changes’ function to be used. You can use CTRL + F to navigate the form or go to ‘View’ and choose “Show Navigation Pane”. Please do not delete questions you think do not apply – just choose n/a.

# SECTION V.A: INTRODUCTION

## V.A.1

Does this research fit the definition of a clinical trial? See Chapter 11 of TCPS2. Must involve a health intervention and a measurement of a health outcome.

[ ]  No

[ ]  Yes

Please describe:

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V.A.1.1

Describe the health intervention

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### V.A.1.2

Describe the measurement of the health outcome:

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## V.A.2

Has this clinical trial been registered?

[ ]  Pending – submit an Amendment with registration is complete

[ ]  Yes

If yes, Name of Registry: *Clinical Trials must be registered in a registry which is compliant with WHO or ICMJE. See TCPS2 for complete discussion*.

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Clinical Trial Registration Number

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# SECTION V.B: Approvals and Attestation

## V.B.1

The Sponsor, or for unfunded or researcher initiated research, the Researcher, will adhere to the following (pick all that apply):

[ ]  TCPS2

[ ]  Protocol as cleared by the REB

[ ]  ICH-GCP E6

[ ]  Food and Drug Act

[ ]  NHPD Regulations

[ ]  Medical Devices Regulations

[ ]  Other

Describe:

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## V.B.2

Does your project involve a **Natural Health Product**?

[ ]  No

[ ]  Yes

If yes, will permission be sought from NHPD?

[ ]  No

Explain why not:

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[ ]  Yes

Include approval from NHPD with your submission.

## V.B.3

Does your project involve the testing of a **Medical Device**?

[ ]  No

[ ]  Yes

If yes, will permission be sought from Health Canada?

[ ]  No

Explain why not:

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[ ]  Yes

Include approval from Health Canada with your submission.

## V.B.4

Does your project involve the testing of a **regulated drug**?

[ ]  No

[ ]  Yes

If yes, will permission be sought from TPD?

[ ]  No

Explain why not:

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[ ]  Yes

Include approval from TPD with your submission.

# SECTION V.C. RISKS

## V.C.1

Discuss risks of research involving participants who are undergoing high-risk therapies. Which risks are attributable to the research (including cumulative risks), and which risks the participants would normally be exposed to in the course of their clinical care?

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## V.C.2

Should the subject's primary physician be informed about the subject's participation in the trial (if the subject has a primary physician and if the subject agrees to the primary physician being informed)?

[ ]  No

[ ]  Yes

If no, state the reasons why this will not be done. Discuss how physician will be kept informed of any information which would be pertinent to the health and well-being of the participant.

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## V.C.3

Describe the plan for monitoring the safety of participant.

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## V.C.4

Discuss the plan for sharing of other new information which may affect the safety of participants to:

* the REB.
* other appropriate regulatory or advisory bodies (describe)
* participants

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# SECTION V.D CONFLICT OF INTEREST

## V.D.1

Do you have a clinical relationship with your participants?

[ ]  No

[ ]  Yes

## V.D.2

Discuss the relationship that each individual involved in the research team may have with individual participants, and how this relationship may impact the participant’s decision to take part in the research. Discuss how you will ensure that the participant fully understands what portion of the project is therapy and what portion is research.

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# SECTION V.E TRIAL DESIGN

## V.E.1

Are you using an **investigative product**?

[ ]  No

[ ]  Yes

**Submit the investigator’s brochure for that product with your application.**

### V.E.1.1

Describe how you will maintain records, including dates, quantities, batch/serial numbers, expiration dates (if applicable), and the unique code numbers assigned to the investigational product(s) and trial subjects:

* of the product's delivery to the trial site
* of the inventory at the site
* of the use by each subject
* the return to the sponsor or alternative disposition of unused product(s)
* that document adequately that the subjects were provided the doses specified by the protocol
* reconcile all investigational product(s) received from the sponsor
* show any change or correction as dated, initialled, and explained (if necessary). Changes should not obscure the original entry (i.e., an audit trail should be maintained); this applies to both written and electronic changes or corrections

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### V.E.1.2

Describe how investigational products in use are manufactured, handled, and stored in accordance with applicable good manufacturing practice (GMP), and will be used in accordance with the approved protocol.

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### V.E.1.3

If not described in the overview, describe how, the treatment(s) to be administered, including the name(s) of all the product(s), the dose(s), the dosing schedule(s), the route/mode(s) of administration, and the treatment period(s), including the follow-up period(s) for subjects for each investigational product treatment/trial treatment group/arm of the trial. Also include a description of the dosage form, packaging, and labeling of the investigational product(s)?

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### V.E.1.4

Describe procedures for monitoring subject compliance.

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### V.E.1.5

Describe the measures taken to minimize or avoid bias, including randomization and blinding.

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### V.E.1.6

If not included in the overview, provide a description of the type/design of the trial to be conducted (e.g. double-blind, placebo controlled, parallel design) and a schematic diagram of trial design, procedures and stages.

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### V.E.1.7

Address the strengths and weaknesses of the selected design. Specifically indicate why a particular design was selected.

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## V.E.2

Is this a **psychotherapy** Trial?

[ ]  No

[ ]  Yes

### V.E.2.1

Does this trial compare the outcomes of two or more patient populations with the same diagnosis but receiving different therapies?

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### V.E.2.2

Describe how investigational products in use are manufactured, handled, and stored in accordance with applicable good manufacturing practice (GMP), and will be used in accordance with the approved protocol.

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### V.E.2.3

Does this trial compare the outcome of those who have received a therapy with those who are on the waiting list for treatment?

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### V.E.2.4

Does this trial compare a behavioural therapy approach with a pharmaceutical treatment approach or some combination or both?

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### V.E.2.5

Describe the training of the principal investigator and/or others on the research team. Is the training sufficient to provide the investigational therapy?

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### V.E.2.6

Could there be a negative impact on mental health?

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## V.E.3

Is this a **medical device** trial?

[ ]  No

[ ]  Yes

### V.E.3.1

Provide information about the device.

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### V.E.3.2

Provide feasibility studies.

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### V.E.3.3

Determine the risk classification.

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### V.E.3.4

Discuss whether or not the use of the device in the trial is appropriate and that the foreseeable risks to participants are justified by the potential benefit.

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## V.E.4

Is this a **surgical** trial?

[ ]  No

[ ]  Yes

### V.E.4.1

Discuss the appropriateness of the technique to the participants.

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### V.E.4.2

Discuss the validation of technique.

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V.E.4.3

Discuss whether the tools required have been approved for use in Canada.

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### V.E.4.4

Discuss the control group size.

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### V.E.4.5

Discuss any sham surgery which will be performed.

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### V.E.4.6

Discuss the experience of the PI *(note: need not be surgeon - could be biomechanical engineer)*

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## V.E.5

Is this project another **health-related intervention**?

[ ]  No

[ ]  Yes

If yes, please describe:

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## V.E.6

is this a **placebo** controlled study?

[ ]  No

[ ]  Yes

### V.E.6.1

Describe the nature of the placebo. Is this the established effective therapy? Please provide references.

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### V.E.6.2

How was the size of the placebo group determined?

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### V.E.6.3

Affirm that any therapy which will be withdrawn or withheld for the purposes of the research and the anticipated consequences of this are fully described in the consent form.

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### V.E.6.4

Affirm that the nature of the placebo is clearly stated on the consent form.

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### V.E.6.5

Justify the choice of placebo control group (vs other options)

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### V.E.6.6

Provide scientific statements regarding how risks should be assessed for each treatment arm and control arm.

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### V.E.6.7

Provide scientific statements regarding how choice of control arm was established.

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# SECTION V.F TRIAL PARTICIPANTS

## V.F.1

Describe the population to be studied.

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## V.F.2

Discuss any medication(s)/treatment(s) permitted (including rescue medication) and not permitted before and/or during the trial.

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## V.F.3

Affirm that any therapy which will be withdrawn or withheld for the purposes of the research and the anticipated consequences of this are fully described in the consent form.

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## V.F.4

Justify the sample size using a sample size calculation.

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## V.F.5

Discuss the expected duration of subject participation, and a description of the sequence and duration of all trial periods, including follow-up, if this information is not included elsewhere in this application.

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## V.F.6

Describe when and how to withdraw subjects from the trial/ investigational product treatment.

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## V.F.7

Will participants who withdraw or are withdrawn from the study be replaced?

[ ]  No

[ ]  Yes

## V.F.8

Describe the follow-up for participants withdrawn from the investigation product treatment/trial treatment.

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## V.F.9

Describe the type and timing of the data to be collected for withdrawing participants.

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# SECTION V.G INFORMATION SECURITY

Discuss the following:

## V.G.1

Specification of the efficacy parameters

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## V.G.2

Methods and timing for assessing, recording, and analysing of efficacy parameters

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## V.G.3

A description of the statistical methods to be employed, including timing of any planned interim analysis(ses)

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## V.G.4

The level of significance to be used

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## V.G.5

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

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## V.G.6

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).

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## V.G.7

The selection of subjects to be included in the analyses (e.g., all randomized subjects, all dosed subjects, all eligible subjects, evaluable subjects).

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## V.G.8

Data storage: Indicate how long data will be stored.

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## V.G.9

Provide draft data collection sheets (**submit with application**) and a description of use which will demonstrate how information will be recorded, handled, and stored.

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# SUPPLEMENT V: OPTIONAL INFORMATION

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