Ottawa Health Science Network Research Ethics Board (OHSN-REB) /
Conseil d'éthique de la recherche du réseau de science de la santé d'Ottawa (CER-RSSO)

Notification of a Planned Protocol Deviation during the COVID-19 Publicly Declared Emergency

If a sponsor or Investigator needs to make the changes in order to eliminate apparent immediate hazards to research participants, these changes can be documented and implemented without REB approval (N2 CAREB SOP 404, Section 5.1.10); **however, if the changes meet the reporting criteria outlined below they must be reported to REB via this form within 7 calendar days**.

- Use this form if you are carrying out temporary changes to approved study procedures as a result of the COVID-19 publicly declared emergency **AND** the changes impose an increase in the risk of harm to participants and/or adversely affect the integrity of the data.

  If you have already reported such changes to the REB, you are not required to re-submit using this form; your previous notification will be held on file. However, for any additional changes or for those not yet reported, please utilize this form.

  - If according to the sponsor or Investigator the temporary changes do **not** impose an increase in the risk of harm to participants and/or adversely affect the integrity of the data, the changes do **not** need to be submitted to the REB but must be well documented in a **note to file** (NTF), as well as in the **next Continuing Review Form to REB.** Examples could include temporary study holds, temporary suspensions in study enrolment, or changes to recruitment and/or initial consenting procedures.

- This form is only for **temporary** planned protocol deviations amid the COVID-19 pandemic. Once the declared emergency is over, study activities must resume as outlined in the Protocol approved by the REB.

  - If the implemented changes are planned to continue past the emergency, an Amendment Form must also be submitted.

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OHSN-REB Planned Protocol Deviation Form for COVID-19 Pandemic

Section 1.0: General Information

1.1 Form Date: Click or tap here to enter text.

1.2 OHSN-REB Protocol Number: Click here to enter text.

1.3 Protocol Title: Click here to enter text.

1.4 Local Principal Investigator: Click here to enter text.

1.5 Sponsor: Click here to enter text.

1.6 Study regulated by:

☐ Health Canada
☐ FDA
☐ Other; *specify*: Click here to enter text.
☐ N/A

Section 2.0: Submission Details

2.1 Select all that apply, indicating the nature of each planned protocol deviation and the impact to participant safety:

☐	**A)** Change to the **location** of the research visit, which may increase the risk of harm to participants and/or adversely affect the integrity of the data
i. Specify the currently approved location: Click here to enter text. ii. Specify the new location: Click here to enter text. iii. Describe the research activities to take place at the visit: Click here to enter text. iv. Describe increase in risk of harm to participants and/or adverse effect to integrity of data: Click here to enter text.	

☐	**B)** Changes to study **intervention** visit activities AND/OR visit cancelled/rescheduled outside of approved window, which may increase the risk of harm to participants and/or adversely affect the integrity of the data.
i. Describe study activities that were planned for the study intervention visit: Click here to enter text. ii. Describe the alterations to the intervention visit activities and/or schedule (i.e. removal of study procedures, timing of rescheduled visits etc.): Click here to enter text. iii. If impact to dispensing study drug/intervention, explain: Click here to enter text. iv. Explain how long dosing window will be extended/compressed by: Click here to enter text. v. Describe how participant safety will be maintained: Click here to enter text.	

vi. Describe increase in risk of harm to participants and/or adverse effect to integrity of data: Click here to enter text.

☐	**C)** Changes to post-intervention **follow up visit activities** OR **visit cancelled/rescheduled** outside of approved window, which may increase the risk of harm to participants and/or adversely affect the integrity of the data.

i. Describe study activities planned for the follow-up visit: Click here to enter text.
ii. Describe the alterations to the follow-up visit activities and/or schedule (i.e. removal of study procedures, timing of rescheduled visits etc.) Click here to enter text.
iii. Describe increase in risk of harm to participants and/or adverse effect to integrity of data: Click here to enter text.

☐	**D)** Change to the **nature of the study visit** (i.e. from in-person visit to telephone visit), which **may increase the risk of harm** to participants and/or adversely affect the integrity of the data.

i. Explain the nature of the change: Click here to enter text.
ii. Describe increase in risk of harm to participants and/or adverse effect to integrity of data: Click here to enter text.
iii. Other impacts (i.e. participant compensation, data analysis, study budget): Click here to enter text.

☐	**E)** Other planned **protocol deviation, which may increase the risk of harm** to participants and/or adversely affect the integrity of the data. *Replicate this table as many times as needed to describe each change.*

i. Explain the planned protocol deviation: Click here to enter text.
ii. Describe increase in risk of harm to participants and/or adverse effect to integrity of data: Click here to enter text.
iii. Other foreseeable impacts (i.e. participant compensation, data analysis, study budget): Click here to enter text.

2.2 Describe the plan for notifying participants of the proposed changes:

☐ In person clinic visit; *describe:* Click or tap here to enter text.
☐ By mail; *describe:* Click or tap here to enter text.
☐ By email; *describe:* Click or tap here to enter text.
☐ Over the phone; *describe:* Click or tap here to enter text.
☐ Other; *describe:* Click or tap here to enter text.
☐ Participants will not be notified; *explain why participants will not be notified:* Click or tap here to enter text.

☐ N/A- no participants recruited to date or study does involve recruitment of participants

2.3 Confirm that notification to participants will align with the REB recommended script (see template provided at the end of this form and note that the final script does not need to be enclosed or approved/acknowledged by REB):

☐ Yes, I confirm

☐ N/A- notification to participants is not required

2.4 Confirm all stakeholders (i.e. Sponsor, Funder etc.) are aware of the planned deviation(s):

☐ Yes

☐ N/A - no other stakeholders

2.5 Confirm deviation plan(s) will only be implemented until the end of the publicly declared emergency:

☐ Yes

If no, an Amendment Form must be submitted in addition.

Section 3.0: Attestation

Reporting Person
Name:
Role:
Date:
Contact Number or Email:

Send the completed form directly to your Research Ethics Coordinator via email or to REBAdministration@toh.ca.

The email must be sent directly from the PI or have the PI cc'd.

Do not submit in hardcopy.

Template Script - Participant Notification of Alteration to Study Procedures due to COVID-19 Publicly Declared Emergency

Hello, am I speaking to [participant name]?

[If no]: Thank you I will try them again at another time [no message].

[If yes]: Hi there, my name is [researcher name] from [site name]. We are contacting you today regarding your participation in [study name]. Due to the recent impact of COVID-19 we are taking certain precautionary steps for the safety of our participants and research staff. As such, we wanted to notify you of some changes to the study.

[describe changes]

[describe impact to them including special instructions, new schedule or timeline, any new risks]

Participation in the study is voluntary and you remain free to withdraw from the study at any time without impact to your or your family's care at [site name].

Do you have any questions?

Do you consent to continue the study with these changes / want to go through the consent form?

[if yes, document consent with date of consent or agreement]

[if no] Thank you and have a nice day