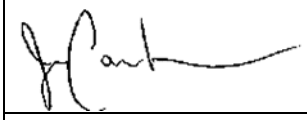
Section 400:	**Review of Research**
Title:	**GREB Protocol Deviation Reporting**
SOP Code:	**411.001**
Effective Date:	**2021JUN30**

Site Approvals

Signature of Responsible Individual:		
Manager, Research Ethics Compliance	 Name: Jennifer Couture	Date: 2021JUN30
Approval Authority:		
Chair, GREB	 Name: Dr. Dean Tripp	Date: 2021JUN30
Approval Authority:		
Director, Research Ethics Compliance	 Name: Dr. Andrew Winterborn	Date: 2021JUN30

1.0 PURPOSE

The purpose of this standard operating procedure (SOP) is to describe the procedure for reporting protocol deviation(s) in ethically cleared research to GREB.

2.0 SCOPE

This SOP pertains to GREB that reviews human participant research in compliance with applicable regulations, guidelines and current and emerging best practices.

3.0 RESPONSIBILITIES

All GREB Members, GREB Office Personnel, and Researchers are responsible for ensuring that the requirements of this SOP are met.

The Researcher is responsible for reporting all unplanned deviations or departures from the GREB ethically cleared research to the GREB, local regulatory authorities and the sponsor as applicable.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURES

A protocol deviation is an unanticipated or unintentional divergence or departure from the expected conduct of an ethically cleared research project. Protocol deviations in general, can be a result of changes necessary to ensure participant safety, be inadvertent in nature, or may be minor logistical/administrative changes. Deviations are different from amendments, as they generally only apply to a single occurrence or participant and are not intended at the time to modify the entire research protocol.

Some general examples are noted below:

- Changes in procedures initiated to eliminate immediate hazards to participants,
- Enrollment of participants that do not meet inclusion/exclusion criteria as defined by the protocol (i.e. randomization of ineligible participant), regardless of sponsor approval,
- Intervention errors for those interventions administered by the research team,
- Inadvertent deviations from the study timing (missed/late study visit) or procedures (missed lab test, etc.,) on part of the research team;
- Deviations with the consent process on part of the research team;

5.1 Reporting Protocol Deviations

5.1.1 Protocol deviations are required to be reported to the GREB through TRAQ using the GREB Protocol Deviation Reporting Form;

5.1.2 The timeline for reporting protocol deviations to the GREB varies depending on the significance of the protocol deviation, as outlined in this SOP.

5.2 Minor Protocol Deviations

5.2.1 Minor protocol deviations are those that do not impact participant safety, compromise the integrity of the data, or affect the participants willingness to participate in the research project;

5.2.2 Minor deviations can be reported to the GREB on a **quarterly basis (every three months**);

5.3 Major, Planned Non-Emergent Deviations

5.3.1 Major non-emergent deviations are planned deviations that evolve throughout the research project and are considered a significant change in the ethically cleared research;

5.3.2 Major, planned, non-emergent deviations should be treated as an amendment (See SOP 405 Amendments to GREB Applications and cleared by the GREB **prior to implementation)**;

5.3.3 If major, non-emergent deviation(s) occurs without prior GREB clearance that was not necessary to eliminate an immediate hazard(s) to participant(s), the GREB may consider such actions as suspension and/or termination of ethics clearance. In addition, such deviations may be considered as non-compliant (see SOP 903 GREB Non-Compliance).

5.4 Major, Unplanned Protocol Deviations

5.4.1 Major unplanned protocol deviations are considered any deviation that has an impact on participant safety, the integrity of the data, or affects the participant's willingness to participate in the research project;

5.4.2 Major unplanned deviations can vary in the degree of seriousness depending on how the changes impact participant safety, the degree of foreknowledge of the event, and the degree of non-compliance with applicable regulations (See SOP 903 GREB Non-Compliance);

5.4.3 The Researcher must submit a Protocol Deviation Report to the GREB within **five days** of becoming aware of any major, unplanned protocol deviation;

5.4.4 Any permanent changes that are necessary as a result of the deviation to the ethically cleared research should be submitted to the GREB in the form of an amendment (See SOP 404 Amendment Reporting).

5.5 Emergency Protocol Deviations

5.5.1 The TCPS2 does allow for Researchers to deviate from the protocol to eliminate immediate hazard(s) to participant(s) without prior GREB clearance;

5.5.2 The Researcher must submit a Protocol Deviation Report to the GREB within **five days** of becoming aware of the deviation;

5.5.3 If the protocol deviation was related to a serious adverse event (SAE) or resulted in an SAE the investigator should submit an SAE report as well to GREB (See SOP 406 Adverse Events Related to GREB Applications);

5.5.4 If the protocol deviation impacts the rights, safety or well-being of research participants or the scientific integrity of the study protocol, the Researcher may also be required to report the protocol deviation to local regulatory authorities, as applicable;

5.5.5 If the protocol deviation has immediate implications for the safety of participants, this may result in the suspension or termination of ethics clearance by GREB (See SOP 410 Suspension or Termination of Ethics Clearance);

5.6 GREB Review of Protocol Deviations

5.6.1 When reviewing a protocol deviation, the GREB should:

- Assess the appropriateness of any proposed corrective or preventative measures by the Researcher and/or sponsor,
- Consider any additional appropriate measures that may or may not have been identified or proposed by the sponsor and/or Researcher,
- Consider whether the affected research still satisfies the requirements for GREB ethics clearance; in particular whether risks to research participants are still minimized and reasonable in relation to the anticipated benefits, if any, to the research participants and the importance of the knowledge that may reasonably be expected to result,
- Consider whether some or all of the research participants should be notified of the events (i.e. if it may affect the participant's willingness to continue participation in the research), and
- Consider whether suspension or termination of the ethics clearance of the research is warranted;

5.4.2 If the event does not raise concerns and does not appear to involve risks to research participants or others, the GREB Chair or designee acknowledges the report, and no further action is required;

5.4.3 If the GREB Chair or designee determines that the event meets the criteria for an SAE, and if immediate action is required to

protect the safety of research participants, ethics clearance may be suspended pending review by the Full Board;

5.4.4 If the event raises concerns or involves risk to research participants such that GREB action may be required, the item is added to the agenda of the next Full Board meeting;

5.4.5 For reportable events reviewed at a Full Board meeting, the GREB determines whether further action is required. Possible actions that could be taken by the GREB include, but are not limited to:

- Placing a hold on the research pending receipt of further information from the Researcher,
- Requesting modifications to the research,
- Requesting modifications to the consent form,
- Providing additional information to past participants,
- Notifying current participants when such information might affect the participants willingness to continue to take part in the research, and requiring that current participants re-consent for ongoing participation,
- Altering the frequency for renewal of ethics clearance,
- Observing the research or the consent process,
- Requiring additional training of the Researcher and research staff,
- Termination or suspension of the research,
- If the GREB determines that the event does not raise concerns about risks to research participants, the GREB may decide that no further action needs to be taken;

5.4.6 If the GREB Chair or designee determines that the event meets the criteria for a SAE, and if immediate action is required to protect the safety of research participants, ethics clearance may be suspended pending review by the Full Board;

5.4.7 The Researcher is responsible for reporting to the GREB and applicable authorities new information generated throughout the course of the research that might affect the rights, safety and well-being of research participants, including reportable events that meet the reporting criteria as outlined in this SOP and/or in the research protocol;

5.4.8 If it becomes known that no action has been taken by the Researcher to fulfil their reporting obligations and to ensure the protection of the rights, safety, and well-being of participants, the GREB Chair or designee may report the incident to the

appropriate institutional officials, and has the authority to notify the sponsor and the appropriate regulatory authorities, as applicable;

5.4.9 GREB may delegate regulatory authority reporting as applicable.

6.0 REFERENCES

See references.

7.0 APPENDICES

None.

8.0 REVISION HISTORY

SOP Title	Version	Updates