

**Section 400:**

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.

- 5.3.2 Major, planned, non-emergent deviations should be treated as an amendment (See SOP 404 Amendment Reporting) and cleared by the HSREB **prior to implementation**;
- 5.3.3 If major, non-emergent deviation(s) occurs without prior HSREB clearance that was not necessary to eliminate an immediate hazard(s) to participant(s), the HSREB may consider such actions as suspension and/or termination of ethics clearance. In addition, such deviations may be considered as

5.5.5 If the protocol deviation has immediate implications for the safety of participants, the HSREB may result in the suspension or termination of ethics clearance (See SOP 407 Suspension or Termination of Ethics Clearance);

**5.6 HSREB Review of Protocol Deviations**

5.6.1 When reviewing a protocol deviation, the HSREB should:

Assess the appropriateness of any proposed corrective or preventative measures by the sponsor and/or Researcher,  
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 HSREB ethics clearance; in particular whether risks to research participants are still minimized and reasonable inr RReviews3.73Sfreffectemn it0 gat3(e)-n s3.7y0 gated

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,

## 7.0 APPENDICES

None.

## 8.0 REVISION HISTORY

SOP Title	Version	Updates
HSREB Protocol Deviation Reporting	v.408.001 2016JAN28	Original: Adoption of standardized SOPs developed by CAREB/N2. Replaces SOP404.0.5 T2TJ2695.38 Tm0 gC