

GUIDANCE NOTE FOR SUBMITTING PROTOCOL DEVIATIONS TO THE UBC BCCA REB

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INTRODUCTION

The purpose of this Guidance Note is to instruct investigators concerning the UBC REB requirements for submitting information concerning a protocol deviation that had not received prior approval by the applicable REB, as required under the [ICH Guidance E6: Good Clinical Practice: Consolidated Guidelines](#) Article 4.5.2 and 4.5.4, because the deviation was necessary in order to ensure subject safety, was of an inadvertent nature, or was administrative in nature.

ARTICLE #1: DEFINITION OF PROTOCOL DEVIATION

A protocol deviation is an unanticipated or unintentional divergence or departure from the expected conduct of an approved study that is not consistent with the current research protocol, consent document or study addenda. Examples of protocol deviations include:

- i) changes in procedures initiated to eliminate immediate hazards to study subjects;
- ii) enrolment of subjects outside protocol inclusion/exclusion criteria, whether agreed to or not by the sponsor;
- iii) medication/intervention errors [i.e. incorrect drug/intervention, incorrect dosage of the drug];
- iv) inadvertent deviation in specific research intervention procedures or timing of the research intervention which could impact upon the safety or efficacy of the study-related intervention or upon the experimental design [n.b. this would not include appointment deviations usually];
- v) breach of confidentiality or privacy whereby confidential information about a subject is revealed in inappropriate settings, or to persons without a need to know, or by data exposure (computer security breach, documents left unsecured), and;
- vi) significant deviation from the consenting process.

[\(Also see Article #3\)](#)

ARTICLE #2: ICH-GCP REQUIREMENTS

2.1 [ICH GCP](#) Article 4.5.4:

“The investigator may implement a deviation from, or a change of, the protocol to eliminate an immediate hazard(s) to trial subjects without prior IRB/IEC approval/favourable opinion. As soon as possible, the implemented deviation or change, the reasons for it, and, if appropriate, the proposed protocol amendment(s) should be submitted:

- (a) to the IRB/IEC for review and approval/favourable opinion,***
- (b) to the sponsor for agreement and, if required,***
- (c) to the regulatory authority (ies).”***

2.2 [ICH GCP Article 4.5.2](#):

This article permits changes which involve only logistical or administrative aspects of the trial (e.g. change in monitor(s), change of telephone number(s) to be implemented prior to obtaining REB approval. It states:

“The investigator should not implement any deviation from, or changes of the protocol without agreement by the sponsor and prior review and documented approval/favourable opinion from the IRB/IEC of an amendment, except where necessary to eliminate an immediate hazard(s) to trial subjects, or when the change(s) involves only logistical or administrative aspects of the trial (e.g. change in monitor(s), change of telephone number(s)).

ARTICLE #3: OBLIGATIONS OF PRINCIPAL INVESTIGATOR

It is the responsibility of the Principal Investigator to notify the applicable UBC REB of all protocol deviations that:

- 1) expose subjects to potential increased risk;
- 2) compromise the integrity of the entire study;
- 3) are repetitive in nature;
- 4) alter subject eligibility, or
- 5) affect the privacy of the subject.

The Principal Investigator, or person designated by the investigator, must complete and sign a report that documents the protocol deviation that occurred and submit it to the applicable UBC using the Request for Acknowledgement form in RISE.

ARTICLE #4: REPORTING REQUIREMENTS FOR NOTICE OF A PROTOCOL DEVIATION

4.1. Time-lines for submission:

4.1.1 A deviation from, or change of, the protocol to eliminate immediate hazards to the study subjects must be reported to the REB within **five days (5)** of its discovery.

4.1.2 All other deviations must be reported to the REB within **fifteen days (15)** of their discovery.

4.2. Simultaneous Amendments: If appropriate, amendments to the protocol must also be submitted to the applicable REB at the time that the protocol deviation report is submitted.

4.3. Notification of protocol deviations will be acknowledged. Depending on the circumstances of the specific deviation, a request for further information may be sent to the investigator by the REB Chair/designate. The UBC REB's do not approve deviations from the protocol that are reported after the fact.

4.4. Content of the Protocol Deviation Report

The protocol deviation report must be completed and signed by the Principal Investigator/designated representative for the study concerned. The report must include the following content:

- i) A description of the deviation that occurred with an explanation of the circumstances that lead to the deviation and the resulting problem;
- ii) An explanation of how the deviation did/did not compromise the scientific integrity of the study;
- iii) An explanation of how the deviation did/did not increase the risk or the possibility of risk for the research subject;

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- iv) A description of steps taken or that will be taken to correct/address the problem resulting from the deviation, and;
 - v) A plan for ensuring that a similar deviation does not occur in the future.