

## **Joint Research Ethics Board Protocol Deviation Guidelines and Report**

### **Guidelines:**

#### **1. Definition of protocol deviation:**

One time unintentional/unanticipated divergence from the approved research protocol or consent document (s), identified after the event occurred.

#### **2. Principal Investigator's (PI) Responsibilities:**

- To complete the Protocol Deviation Report and submit to the JREB.
- If it jeopardizes participant's safety, study efficacy or data integrity, it must be promptly reported to the JREB using the attached protocol deviation form.
- Specific examples of reportable deviations (i.e., if they place participants at greater risk):
  - Implementation of additional procedures for monitoring participants;
  - Suspension of enrollment of new participants;
  - Suspension of research procedures in currently enrolled participants;
  - Informed consent improperly obtained or not obtained;
  - Emergency deviations to the research protocol initiated by the investigator prior to obtaining JREB approval (e.g., to eliminate apparent immediate hazards to participants);
  - Major non-emergent deviations without prior approval;
  - Enrolment of participants outside protocol inclusion/exclusion criteria, whether agreed to or not by the sponsor;
  - Medication / intervention errors (i.e., incorrect study drug/intervention, incorrect dosage of the drug with increased risk of harm to participant);
  - Inadvertent deviation in specific research intervention procedures or timings of the research intervention which could impact upon the safety or efficacy of the study related intervention or upon experimental design;
  - Breach of confidentiality or privacy whereby confidential information about a participant is revealed in inappropriate settings, or to persons without need to know, or by data exposure (computer security breach, documents left unsecured);

#### **3. Reporting Timeline:**

- a) **48 hours:** Protocol deviations that lead to a serious adverse event (SAE) should be reported within 48 hours
- b) **10 days:** if deviation affects patient's safety or the integrity / outcome of the study, must be reported within 10 working days.

**4. JREB office will review the report. If further information is required then the PI will be contacted.**

**5. Possible follow-up actions by the JREB office:**

- a) If there are no concerns, then the report will be filed and no further action will be taken
- b) If the deviation is an unanticipated risk to research participants, or a result of serious or continuing noncompliance then further action is required and it will be on the agenda for the next JREB meeting for discussion.
- c) Immediate action may occur at the JREB Chair's discretion. Justification for this will be documented.

**6. Resources:**

1. OCREB Protocol Deviation Reporting and (SOPs) Ongoing OCREB review activities, v2009Apr27-
2. Office for Human Research Protection (OHRP) Guidance on Reviewing and Reporting Unanticipated problems Involving risks to Participants or Others and Adverse Events  
[www.hhs.gov/ohrp/policy/AdvEvtGuid.htm](http://www.hhs.gov/ohrp/policy/AdvEvtGuid.htm)
3. ICH Good Clinical Practice Guidelines, Section 3.3.7 & Section 4.5.1 – 4.5.5
4. Goldfarb, Norman M. Directory of Protocol Deviation and Violation (PDV) codes: A Lexicon for Understanding & Communicating Protocol Deviations and Violations. First Clinical Research.  
[www.firstclinical.com/resources/codes](http://www.firstclinical.com/resources/codes)
5. Guidance Protocol Deviation & Violation.
6. Health Canada: Summery report of the inspections of clinical trials conducted in 2003 / 2004

## Protocol Deviation Report

1. Project / Study title:

2. JREB #:                      Main Sponsor:                      Sponsor Protocol #:

3. Local Principal Investigator (PI):

Title:	First Name:	Initial:	Last Name:
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4. Date The Protocol Deviation Occurred: (yyyy/Mmm/dd):

5. Have you attached a copy of sponsor's Protocol Deviation Form? YES  NO

6. Was the protocol deviation a planned or and unintentional /unanticipated occurrence?

Planned                       Unintentional/Unanticipated

7. Was the protocol deviation result of an error or an incorrect action by the sponsor, investigator(s), and / or his/her staff? YES  NO

If "YES" what measures/corrective actions have been/will be taken to ensure this, or a similar problem, will not occur again:

8. Was the protocol deviation caused by the study participant(s)? YES  NO

If "YES" what measures/corrective actions have been/will be taken to ensure this, or a similar problem, will not occur again:

9. Describe the kind of protocol deviation being reported:

10. In the opinion of local principal investigator, did the deviation increase the risk or the possibility of risk for the research participant(s)? YES  NO

If "YES" describe the increased risks:

11. In the opinion of local principal investigator, does the deviation compromise the study efficacy or data integrity of the study? YES  NO

If "YES" describe how the deviation will compromise the study efficacy or data integrity of the study:

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**12. Person Completing This Form (if different from principal investigator):**

<b>Title:</b>	<b>First Name:</b>	<b>Last Name:</b>
<b>Telephone (area code):</b>	<b>Extension:</b>	<b>Email:</b>
<b>Signature:</b>		

**13. Signature of Local Principal Investigator (PI):**

<b>Signature:</b>	<b>Date: (yyyy/Mmm/dd)</b>
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