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| | **REB REVIEW OF RESEARCH** | |
| **POLICY: REB-406** | **PROTOCOL DEVIATION** | |
| **This policy pertains to:** | The activities of researchers under the authority of Baycrest and the Research Ethics Board (REB) operating under the authority of Baycrest | |
| **Responsibility for executing this policy:** | Chair, Baycrest REB (or designate) | |
| **Approval authority:** | Chair, Baycrest REB<br>President & Chief Scientist, Baycrest Academy of Research and Education | |
| **Effective date:** | October 5, 2025 | **Supersedes document date:** September 26, 2013 |
| **Approved:** | Chair, Baycrest REB<br>President & Chief Scientist, Baycrest Academy of Research and Education | |

## 1. PURPOSE

This SOP describes the policy for protocol deviation submission and review by the Baycrest REB.

## 2. POLICY

A PI who deviates from the REB-approved protocol either inadvertently or to eliminate an immediate hazard(s) to participants or others without prior REB approval must notify the REB using appropriate procedures.

## 3. SPECIFIC POLICY

### Protocol Deviations

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 currently approved research protocol, consent document or study addenda.

**REFERENCES**

Health Canada Food and Drugs Act, Div 5
ICH GCP 3.3.7 and 4.5.2.

Examples of protocol deviations include:

- Changes in procedures initiated to eliminate immediate hazards to study participants;
- Enrolment of participants outside protocol inclusion/exclusion criteria;
- Medication/intervention errors (i.e., incorrect drug/intervention, incorrect dosage of the drug);
- Inadvertent deviation in specific research intervention procedures or timing of the research intervention;
- Breach of confidentiality or privacy without a need to know, or by data exposure (computer security breach, documents left unsecured), and;
- Deviation from the consenting process.
- Failure to follow REB SOPs

As noted above, the Investigator should not implement any deviation from, or changes of the protocol without prior REB approval, except where

necessary to eliminate an immediate hazard(s) to participants, or when the change(s) involves only logistical or administrative aspects of the research (e.g., change of telephone number(s)).

A PI who deviates from the protocol either inadvertently or to eliminate an immediate hazard(s) to participants without prior REB approval must submit, as soon as reasonably possible thereafter, a report notifying the REB of the implemented deviation or change, the reasons for it, and, if appropriate, an accompanying proposed protocol amendment(s) for review and approval, using the Baycrest REB Protocol Deviation Report Form.

Deviations from or changes to the protocol to eliminate immediate hazards to the study participants must be reported to the REB within 3 (three) days of discovery. All other deviations must be reported to the applicable REB within 7 (seven) days of discovery.

Protocol deviation reports must be completed and signed by the Local PI for the study concerned. The report must include at least the following content:

- A description of the deviation that occurred with an explanation of the circumstances that led to the deviation and the resulting problem;
- An explanation as to whether or not the deviation compromised the scientific integrity of the study;
- An explanation of whether or not the deviation increased the risk or the possibility of risk for the research participant;
- A description of steps taken or that will be taken to correct/address the problem resulting from the deviation, and;
- A plan to mitigate the risk that a similar deviation does not occur in the future.