

Women's College Hospital Research Ethics Board SOP Addendum

The WCH REB has adopted the N2/CAREB REB SOPs. This SOP addendum is to be used in tandem with the N2/CAREB SOP to address any WCH specific process differences.

SOP 404.004 Ongoing REB Review Activities

| SOP Section | Addendum |
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| 5.2 Reportable Events | |
| 5.2.2 Local AEs: The Researcher must report the following to the REB in a timely manner: | <p>Local Adverse Events (AEs) that in the opinion of the Researcher meets the definition of an unanticipated problem must be reported to the REB within:</p> <ul style="list-style-type: none"> • 15 days of the Researcher becoming aware of them <p>Local AEs that in the opinion of the Researcher meets the definition of an unanticipated problem AND that are considered Serious Adverse Events (SAEs) must be reported to the REB within:</p> <ul style="list-style-type: none"> • 7 days of the Researcher becoming aware of them <p>It is the Researchers responsibility to submit subsequent and final Follow-up reports to the REB when there is new relevant information.</p> <p>If the study action recommended requires any changes to the study, the Researcher must submit an Amendment request.</p> |
| 5.2.3 Non-Local (External) Adverse Events: Upon receipt of an external adverse event (EAE) or a periodic safety update or safety summary report, the Researcher must determine if it meets the REB reporting criteria: | <p>Non-local adverse events (AEs) that in the opinion of the Researcher, meet the definition of an unanticipated problem AND meet all of the following criteria must be reported to the REB:</p> <ul style="list-style-type: none"> • Requires a change to the research and/or informed consent form and/or requires immediate notification to the participant for safety reasons. • AND is considered Serious Adverse Events (SAEs) |

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| | <p>The sponsor and/or Researcher shall notify the REB when the reported information is considered to affect the rights and welfare of research participants, and the recommended actions to follow.</p> <p>All previous safety reports concerning similar events and analysis of the significance of the current event in light of the previous reports may be requested by the REB.</p> <p>If the REB receives reports that do not meet the submission criteria, the REB reserves the right to return such reports, without review, to the Researcher.</p> |
| <p>5.2.5 Deviations to Previously Approved Research: The Researcher must report to the REB any deviations that meet the following reporting criteria:</p> | <p>Deviations should be reported to the REB as soon as the Researcher becomes aware of the deviation</p> |

| Revision History | |
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| Effective Date | Summary of Change |
| December 7, 2022 | Original version |
| April 17, 2024 | Revised to update SOP version number |
| This N2/CAREB SOP Addendum has been reviewed and approved for use by: | |
| <p>Alison Williams, PhD Chair, Women's College Hospital Research Ethics Board</p> | |