UNIVERSITY OF SASKATCHEWAN

Research Excellence and Innovation
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University of Saskatchewan Research Ethics Board N2/CAREB REB SOP Addendum

USask REB has adopted the N2/CAREB REB SOPs. However, in order to reflect specific USask REB requirements, this addendum must be used in tandem with the SOP noted below*.

N2/CAREB SOP 404 – *Ongoing REB Review Activities*

<table>
<tr><th>SOP Section</th><th>USask REB Addendum</th></tr>
<tr><td>5.0
Procedure</td><td>
Ongoing REB Review Submission Timeframes
The following timeframes are to be considered a guidance. Reporting outside of these timeframes will require some justification
<table>
<tr><th>Document Type (for reportable events only)</th><th>Reporting Interval (In business days from the date received by the site and/or the date site became aware of event)</th></tr>
<tr><td>Amendments to the Approved Research</td><td>Within 60 days. The amended research may not be implemented prior to the REB review and approval, except when necessary to eliminate immediate hazards to participants.</td></tr>
<tr><td>Local Reportable Serious Adverse Events</td><td>Within 15 days</td></tr>
<tr><td>Non-Local (External) Serious Adverse Events</td><td>within 15 days if it is deemed actionable at the local site. If it is not deemed actionable at the local site, it is not reportable to the REB at this time, but should be included on the SUSAR report</td></tr>
<tr><td>Other Reportable Events</td><td>Within 7 days for urgent safety measures; Within 60 days for reports not containing urgent safety information</td></tr>
<tr><td>Deviations to Previously Approved Research</td><td>Within 15 days; 7 if led to death or life-threatening adverse event</td></tr>
<tr><td>Privacy Breaches</td><td>Within 15 days of the event</td></tr>
<tr><td>Audit or Inspection Findings</td><td>Within 15 days of the exit interview or provision of findings by the auditor(s)</td></tr>
<tr><td>Research Participant Complaint</td><td>Variable dependent on circumstances, ideally within 15 days of complaint</td></tr>
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Revision History	
Date/Version	**Summary of Changes**
November 15, 2021	Original version.