Research Ethics Office
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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 for all studies. 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>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>
</table>
Ongoing REB Review Submission Timeframes
The following timeframes are to be considered a guidance for Biomedical studies. 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>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.</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>
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UNIVERSITY OF SASKATCHEWAN

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Revision History	
Date/Version	**Summary of Changes**
November 3, 2021	Original version.
July 10, 2025	Non-Local (External) Serious Adverse Events – Deletion of “but should be included on the SUSAR report.” Deletion of “Amendment to the Approved Research” row. Split the table into requirements for all studies and requirements for Biomedical-specific studies Header: Deletion of “Research Excellence and Innovation” replaced by ‘Research Ethics Office”