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6 Week Follow-up Case Report Form

A. Details of Follow-up										
1.	<p>Able to contact subject to complete follow-up: <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If no, please specify reason why, and sign and date the form:</p> <p><input type="checkbox"/> Unable to contact subject after multiple attempts – see resource manual for contact procedures</p> <p><input type="checkbox"/> Subject has died (Please complete End of Study, SAE and Death Outcome Event forms)</p> <p><input type="checkbox"/> Subject withdrew consent (Please complete End of Study CRF)</p>									
2.	<p>Date of follow up: <table border="1" style="display: inline-table; vertical-align: middle;"> <tr> <td style="width: 20px; height: 20px;">D</td> <td style="width: 20px; height: 20px;">D</td> <td style="width: 20px; height: 20px;">M</td> <td style="width: 20px; height: 20px;">M</td> <td style="width: 20px; height: 20px;">M</td> <td style="width: 20px; height: 20px;">Y</td> <td style="width: 20px; height: 20px;">Y</td> <td style="width: 20px; height: 20px;">Y</td> <td style="width: 20px; height: 20px;">Y</td> </tr> </table></p>	D	D	M	M	M	Y	Y	Y	Y
D	D	M	M	M	Y	Y	Y	Y		
3.	<p>Type of follow up: <input type="checkbox"/> In person <input type="checkbox"/> Phone call <input type="checkbox"/> Video call</p>									
4.	<p>Study medication: Subject’s booklet collected? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Study medication bottle collected? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Pill count (confirmed by research team member): <table border="1" style="display: inline-table; vertical-align: middle;"> <tr> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> </tr> </table></p> <p>Number of days missed (based on subject’s booklet): <table border="1" style="display: inline-table; vertical-align: middle;"> <tr> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> </tr> </table></p> <p>Number of days NSAIDs taken (based on subject’s booklet): <table border="1" style="display: inline-table; vertical-align: middle;"> <tr> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> </tr> </table></p> <p>Canadian sites only: Which study medication does the subject think they received?</p> <p><input type="checkbox"/> Aspirin <input type="checkbox"/> Placebo <input type="checkbox"/> Unsure <input type="checkbox"/> N/A</p> <p>Canadian sites only: Which study medication does the research coordinator think the subject received?</p> <p><input type="checkbox"/> Aspirin <input type="checkbox"/> Placebo <input type="checkbox"/> Unsure <input type="checkbox"/> N/A</p>									
5.	<p>Concomitant Medication Form reviewed? <input type="checkbox"/> Yes <input type="checkbox"/> No</p>									
6.	<p>Has the subject experienced any adverse events since the last visit? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If yes, please complete Adverse Event or Serious Adverse Event Form.</p>									
7.	<p>Has the subject’s infant experienced any adverse events since the last visit? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If yes, please complete Adverse Event or Serious Adverse Event Form.</p>									
8a.	<p>Is the infant receiving the subject’s breastmilk (e.g. breastfeeding or pumping)? <input type="checkbox"/> Yes <input type="checkbox"/> No</p>									
8b.	<p>If yes, has the infant received the subject’s breastmilk on average 50% or more of the time during the last 6 weeks? <input type="checkbox"/> Yes <input type="checkbox"/> No</p>									
9.	<p>Has the subject been diagnosed with a postpartum wound complication requiring a procedure? <input type="checkbox"/> Yes <input type="checkbox"/> No</p>									
10.	<p>Does the subject have a diagnosed wound separation or dehiscence? <input type="checkbox"/> Yes <input type="checkbox"/> No</p>									
11.	<p>Has the subject been diagnosed with a postpartum wound infection requiring antibiotics? <input type="checkbox"/> Yes <input type="checkbox"/> No</p>									
12.	<p>Has the subject been diagnosed with new high blood pressure requiring medication or new protein in the urine postpartum? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If yes, please complete Postpartum Pre-eclampsia Outcome Form.</p>									

13.	Complete VTE Screening Form for all subjects.	<input type="checkbox"/> Completed		
14.	How long did the subject’s vaginal bleeding (lochia) last for?	<table border="1" style="display: inline-table; vertical-align: middle;"><tr><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td></tr></table> days <input type="checkbox"/> Ongoing		
15.	Has the subject had any bleeding since the last visit? (other than normal vaginal bleeding*) If “No” to any bleeding: probe further to confirm response by asking specifically about black stools, blood in stools, blood in urine, nose bleeds, excessive vaginal bleeding and coughing up blood. If yes, complete Bleeding Screening Form.	<input type="checkbox"/> Yes <input type="checkbox"/> No		
16.	Has the subject experienced a serious bruise (hematoma)?	<input type="checkbox"/> Yes <input type="checkbox"/> No		
17.	Has the subject had any chest symptoms such as shortness of breath or chest pain, or neurological symptoms such as weakness or numbness since the last visit? If yes, complete ATE Screening Form.	<input type="checkbox"/> Yes <input type="checkbox"/> No		

*Defined as vaginal bleeding equivalent or less in volume to subject’s pre-pregnancy menstrual bleeding and blood flow does not soak through one or more sanitary pads or tampons every hour for several consecutive hours. Normal postpartum vaginal bleeding should diminish in volume and be less red in colour each day when compared to the previous day.

Delegate’s Name

Delegate’s Signature

D	D	M	M	M	Y	Y	Y	Y
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Date