

## 6 Week Follow-up Case Report Form

A. Details of Follow-up										
1.	Able to contact subject to complete follow-up: <span style="float: right;"><input type="checkbox"/> Yes <input type="checkbox"/> No</span> If no, please specify and then go to end of form: <input type="checkbox"/> Unable to contact subject after multiple attempts – see resource manual for contact procedures <input type="checkbox"/> Subject has died (Please complete End of Study, SAE and Death Outcome Event forms) <input type="checkbox"/> Subject withdrew consent (Please complete End of Study CRF)									
2.	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>	D	D	M	M	M	Y	Y	Y	Y
D	D	M	M	M	Y	Y	Y	Y		
3.	Type of follow up: <input type="checkbox"/> In person <input type="checkbox"/> Phone call <input type="checkbox"/> Video call									
4.	Study medication: Subject’s booklet collected? <span style="float: right;"><input type="checkbox"/> Yes <input type="checkbox"/> No</span> Study medication bottle collected? <span style="float: right;"><input type="checkbox"/> Yes <input type="checkbox"/> No</span> Number of medication tablets remaining in bottle (confirmed by coordinator): <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> Canadian sites only: Which study medication does the subject think they received? <input type="checkbox"/> Aspirin <input type="checkbox"/> Placebo <input type="checkbox"/> Unsure <input type="checkbox"/> N/A Canadian sites only: Which study medication does the research coordinator think the subject received? <input type="checkbox"/> Aspirin <input type="checkbox"/> Placebo <input type="checkbox"/> Unsure <input type="checkbox"/> N/A									
5.	Were there any changes to medications since the last visit? <span style="float: right;"><input type="checkbox"/> Yes <input type="checkbox"/> No</span> <b>If yes, please complete Concomitant Medication Form.</b>									
6.	Has the subject experienced any adverse events since the last visit? <span style="float: right;"><input type="checkbox"/> Yes <input type="checkbox"/> No</span> <b>If yes, please complete Adverse Event or Serious Adverse Event Form(s).</b>									
7.	Has the subject’s infant experienced any major concerns since birth that has required hospitalization? <span style="float: right;"><input type="checkbox"/> Yes <input type="checkbox"/> No</span> <b>If yes, please complete Serious Adverse Event Form.</b>									
8.	Has the subject been diagnosed with a postpartum wound complication requiring a procedure? <span style="float: right;"><input type="checkbox"/> Yes <input type="checkbox"/> No</span>									
9.	Has the subject experienced a serious bruise (hematoma)? <span style="float: right;"><input type="checkbox"/> Yes <input type="checkbox"/> No</span>									
10.	Does the subject have a diagnosed wound separation or dehiscence? <span style="float: right;"><input type="checkbox"/> Yes <input type="checkbox"/> No</span>									
11.	Has the subject been diagnosed with a postpartum wound infection requiring antibiotics? <span style="float: right;"><input type="checkbox"/> Yes <input type="checkbox"/> No</span>									
12.	Has the subject been diagnosed with new high blood pressure requiring medication or new protein in the urine postpartum? <span style="float: right;"><input type="checkbox"/> Yes <input type="checkbox"/> No</span> <b>If yes, please complete Postpartum Pre-Eclampsia Event Form.</b>									

**13. Screening Forms:**

**A) Complete VTE Screening Form for all subjects**

B) Other than normal vaginal bleeding\*, has the subject had any bleeding since the last visit?  Yes  No

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.**

C) Has the subject had any chest symptoms or neurological symptoms such as weakness or numbness since the last visit?  Yes  No  
**If yes, complete ATE Screening Form.**

\*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