Preliminary Notice to the Minister

To: Canada Vigilance Program
Marketed Health Products Safety and Effectiveness Information Bureau
Marketed Health Products Directorate
Health Products and Food Branch
Health Canada
Postal Locator: 0701E
Ottawa, Ontario K1A 0K9
Telephone (613) 957-0337
Facsimile: (613) 957-0335

From: **Name of Investigating Facility:** _____

[Subject to Blood Regulations section 113, the investigating facility must notify the Minister of the adverse recipient reaction within 24 hours after it learns of the death of a recipient or within 15 days after it learns of the serious or any other unexpected adverse reaction.]

Our facility has reasonable grounds to believe that a serious and/or unexpected reaction adverse reaction has occurred and is related to a Health Canada-regulated activity carried out by our establishment which affected the quality and/or safety of the transfused blood component(s).

Attached is the Saskatchewan Transfusion Adverse Event Report Form with additional information on the adverse reaction. *[Edit the patient identifier so that only the patient's age, gender and date of transfusion/reaction are sent.]* Once our investigation is complete, a final report will be sent to the Minister.

File/Case #:		
Date of Occurrence:	**Time:**	**Facility:**
Date Discovered:	**Time:**	**Facility:**
Date Reported:	**Time:**	**Name of Reporter:**
Description of serious / unexpected adverse reaction:		
Explanation of how the quality and/or safety of the implicated blood may have been compromised:		
Donation Codes of Implicated Blood:		
☐ **Whole Blood**	☐ **Blood Component**	
Name of suspected transmissible disease or disease agent, if known:		
Name of facility to which the implicated blood was distributed to:		**Date/Time:**
Report Prepared By:	**Date:**	