Comparison of Ideal vs. Actual Weight Based Factor Dosing in Hemophilia A
Adverse Event Reporting Form

Site ID: _____ **Subject ID:** _____ **Date Reported:** _____ **Page** _____ **of** _____

Has the participant had any adverse events during this study? ☐ **Yes** ☐ **No**

(If yes, please list all Adverse Events below. Please continue on additional forms and note total number of pages at the top)

Severity	Study Intervention Relationship	Action Taken Regarding Study Intervention	Outcome of AE	Expected	Serious
1 = Mild 2 = Moderate 3 = Severe	1 = Definitely related 2 = Possibly related 3 = Not related	1 = None 2 = Discontinued permanently 3 = Discontinued temporarily 4 = Reduced Dose 5 = Increased Dose 6 = Delayed Dose	1 = Resolved, No Sequel 2 = AE still present- no treatment 3 = AE still present-being treated 4 = Residual effects present-not treated 5 = Residual effects present- treated 6 = Death 7 = Unknown	1 = Yes 2 = No	1 = Yes* 2 = No (If yes, complete SAE form)

Adverse Event	Start Date	Stop Date	Severity	Study Treatment Relationship	Action Taken	Outcome of AE	Expected?	Serious AE?*	Initials
1.							1 2	1 2	
2.							1 2	1 2	
3.							1 2	1 2	

*Serious adverse events (SAEs) are defined as when the patient outcome is either: death, life-threatening, hospitalization (initial or prolonged), disability or permanent damage, congenital anomaly/birth defect, required intervention to prevent permanent impairment or damage, or other serious, important medical events. SAEs **must** be reported to WCBD **within 24 hours** of the patient reporting it to the site.

Form Completed by:

Initials: _____ **Date:** __ __ / __ __ / __ __ __ __ (mm/dd/yyyy)