

**St. Boniface General Hospital  
SERIOUS ADVERSE EVENTS FORM (PAGE 1 OF 4)**

**SERIOUS ADVERSE EVENT REPORT FOR CLINICAL STUDIES**

**I REACTION INFORMATION**

CLINICAL TRIAL IDENTIFICATION				PATIENT TRIAL NO.				REPORT TYPE				
DATE OF THIS REPORT				DAY	MONTH	YEAR	HEIGHT _____ CM	ETHNIC ORIGIN				
				WEIGHT _____ KG					{ } INITIAL			
PATIENT INITIALS		COUNTRY		DATE OF BIRTH			AGE	SEX	REACTION ONSET			
				DAY	MONTH	YEAR	YEARS		DAY	MONTH	YEAR	
INTENSITY OF REACTION				RESOLUTION OF REACTION			DURATION OF REACTION					
{ } MINOR				DAY			MONTH		YEAR		{ } INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION	
{ } MODERATE											{ } INVOLVED PERSISTENCE OF SIGNIFICANT DISABILITY OR INCAPACITY	
{ } SEVERE											{ } LIFE THREATENING	
DESCRIBE REACTION												

**II SUSPECT DRUG INFORMATION (USE REVERSE SIDE FOR MORE DETAILS)**

SUSPECT DRUG(S) (INCLUDE GENERIC NAME(S))						DID REACTION ABATE AFTER STOPPING DRUG?	
						{ } YES	
						{ } NO	
						{ } NA	
DAILY DOSE			ROUTE OF ADMINISTRATION			DID REACTION REAPPEAR AFTER REINTRODUCTION?	
						{ } YES	
						{ } NO	
						{ } NA	
INDICATION(S) FOR USE							
THERAPY DATES (FROM/TO)						THERAPY DURATION	
DAY	MONTH	YEAR	DAY	MONTH	YEAR		

**FOR MORE INFORMATION, PLEASE USE ADDITIONAL COMMENTS SECTION**

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**III CONCOMITANT DRUGS AND HISTORY (USE REVERSE SIDE FOR MORE DETAILS)**

<b>CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (EXCLUDE THOSE USED TO TREAT REACTION)</b>
<b>OTHER RELEVANT HISTORY (E.G., DIAGNOSES, ALLERGIES, PREGNANCY WITH LAST MONTH OF PERIOD, ETC.)</b>

**IV. INITIAL REPORTER**

<b>NAME, ADDRESS AND TELEPHONE NUMBERS OF TREATING HEALTH PROFESSIONAL(S)</b>	<b>DATE OF REPORTING</b>		
	<b>DAY</b>	<b>MONTH</b>	<b>YEAR</b>
<b>SIGNATURE OF REPORTING PERSON:</b> _____			
<b>CAUSALITY ASSESSMENT</b>  <b>PERFORMED BY:</b> _____  <b>SIGNATURE:</b> _____  <b>COMMENTS:</b>	<b>DO YOU CONSIDER THE ADVERSE REACTION TO HAVE A CAUSAL RELATIONSHIP WITH THE SUSPECTED DRUG?</b>  <input type="checkbox"/> DEFINITE <input type="checkbox"/> PROBABLE <input type="checkbox"/> POSSIBLE <input type="checkbox"/> UNLIKELY <input type="checkbox"/> NOT RELATED <input type="checkbox"/> INSUFFICIENT AMOUNT OF DATA FOR ASSESSMENT		

**FOR MORE INFORMATION, PLEASE USE ADDITIONAL COMMENTS SECTION**



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**VIII. OUTCOME**

<input type="checkbox"/> RECOVERY	<input type="checkbox"/> SEQUELAE
<input type="checkbox"/> REACTION RESOLVING	<input type="checkbox"/> DEATH – AUTOPSY PERFORMED <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> UNKNOWN
<input type="checkbox"/> REACTION CONTINUES	<input type="checkbox"/> UNKNOWN

**IX. CAUSALITY ASSESSMENT BY REPORTING PHYSICIAN**

<b>CAUSAL RELATIONSHIP BETWEEN DRUG AND ADVERSE DRUG REACTION:</b>					
<input type="checkbox"/> DEFINITE	<input type="checkbox"/> PROBABLE	<input type="checkbox"/> POSSIBLE	<input type="checkbox"/> UNLIKELY	<input type="checkbox"/> NOT RELATED	<input type="checkbox"/> INSUFFICIENT DATA
<b>IN CASE OF FATAL OUTCOME STATE CAUSAL RELATIONSHIP BETWEEN DRUG AND DEATH:</b>					
<input type="checkbox"/> DEFINITE	<input type="checkbox"/> PROBABLE	<input type="checkbox"/> POSSIBLE	<input type="checkbox"/> UNLIKELY	<input type="checkbox"/> NOT RELATED	<input type="checkbox"/> INSUFFICIENT DATA
PRINT NAME: _____  SIGNATURE: _____  DATE: _____					

**X. ADDITIONAL COMMENTS SECTION**

SIGNATURE: _____
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