Regina Qu'Appelle HEALTH REGION
Research & Performance Support
Regina Qu'Appelle Health Region
2180-23rd Avenue Regina SK S4S 0A5
Phone: (306) 766-5451 Fax: (306) 766-5530

For Administrative Use Only:

Date Received: _____

Research Ethics Board
Serious and Unexpected Adverse Event Report Form

All information requested must be typewritten in the space provided. Do not leave any box blank. Indicate "not applicable" by typing N/A.
Use an individual form for each adverse event reported.

1.PRINCIPAL INVESTIGATOR'S SURNAME, GIVEN NAME(S):	2. RQHR DEPARTMENT	3. PHONE NUMBER:

4. FACILITY IN WHICH THE RESEARCH IS BEING CONDUCTED: ☐ RGH ☐ PH ☐ WRC ☐ ABCC ☐ Other: _____

5. TITLE OF PROJECT:

6. NAME OF DRUG/DEVICE:	7. RQHR REB FILE NUMBER (#) AFFECTED:

8. REPORT DATES:	**9. EVENT:**	**10. REPORT NUMBER(S) AND A BRIEF CLINICAL DESCRIPTION**
	☐ LOCAL ☐ EXTERNAL	
	☐ LOCAL ☐ EXTERNAL	
	☐ LOCAL ☐ EXTERNAL	
	☐ LOCAL ☐ EXTERNAL	
	☐ LOCAL ☐ EXTERNAL	

11. RQHR PRINCIPAL INVESTIGATOR'S ASSESSMENT OF THE SERIOUSNESS AND CAUSALITY OF THE SIDE EFFECTS AND WHETHER IN HIS/HER VIEW, THEY COMPROMISE ON ETHICAL GROUNDS THE CONTINUATION OF THE STUDY. IF A CHANGE TO THE CONSENT FORM IS REQUIRED, PLEASE ATTACH A COPY WITH THE CHANGES UNDERLINED OR IN BOLD TEXT.

SERIOUS AND UNEXPECTED?	☐ YES	
RELATED/POTENTIALLY RELATED TO THE STUDY DRUG/DEVICE?	☐ YES	
SHOULD THE STUDY CONTINUE?	☐ YES	☐ NO
SHOULD THE CONSENT BE REVISED?	☐ YES	☐ NO
IS THIS A FOLLOW-UP REPORT?	☐ YES	☐ NO
IS THIS SAE BEING SUBMITTED AS A REQUIREMENT OF THE SPONSOR'S PROTOCOL ONLY?	☐ YES	

12. SIGNATURE:		13. REVIEW COMPLETED BY:	
_____	_____	_____	_____
PRINCIPAL INVESTIGATOR	DATE	ON BEHALF OF THE RQHR REB	DATE

14. INVESTIGATOR'S COMMENTS: (Please append additional comments as required)

15. CONTACT PERSON FOR CORRESPONDENCE:

NAME: _____ PHONE: _____ EMAIL: _____

16. ATTACHMENTS:

☐ COPIES OF ADVERSE EVENT REPORTS
☐ A COPY OF THE REVISED CONSENT FORM. Please highlight any changes with **BOLD** text or underlining. Include an updated version #/date on the Consent Form AND include a completed 'Request for Amendment' Form.
☐ REQUEST FOR AMENDMENT FORM