Reference Research Ethics Committee Midlands Area and Corporate (Regional Health Area B)
E-mail: REC.B.CorporateMidlands@hse.ie
Webage: www.hse.ie/rrecmidlands/

Safety reporting template

Full title of study	
RRECB application reference (as included in your letter of approval from RREC)	
Date of this report	
NIMS Record Number (if applicable)	

Please select reason for completing this report:	
Serious Adverse Reaction (i.e. Event at least possibly related to the study drug/ intervention/procedures	☐
Suspected Unexpected Serious Adverse Reactions (SUSARs)	☐
Unforeseen event(s) that may have affected the risk/benefits profile of the study (i.e. new and emerging evidence that relates to the safety profile of the study such as a recent publication or safety signal etc.)	☐

Is this the:		
Initial Report	☐	
Follow-up report:	☐	If follow-up, what is the date of the previous report?

Why is this event Serious? Please tick the appropriate option:	
Death	☐
Life Threatening	☐
Hospitalisation or prolongation of existing hospitalisation	☐
Persistent or significant disability or incapacity	☐
Congenital anomaly or birth defect	☐
Medically significant (requires interventions to prevent permanent impairment or damage	☐

Description of the event:

Information about the Event:	
Start date:	Time (if known):
Ongoing: ☐	
Stop date:	Time (if known)

In the opinion of the Principal Investigator the relationship to study:	
Possible	☐
Probable	☐
Definite	☐

Reporter Information		Principal Investigator	
Name:		Name:	
Title:		Title:	
Email:		Email:	
Date:		Date:	
Signature:		Signature:	

Please return the completed report to REC.B.CorporateMidlands@hse.ie