



# UNANTICIPATED PROBLEMS INVOLVING RISKS TO PARTICIPANTS OR OTHERS REPORTING FORM

Unanticipated problem involving risks to participants or others: is defined as any problem, event, or information that was (1) unforeseen and (2) harmed one or more participants or others, or place one or more participants or others at increased risk of harm.

Risk can be defined as the probability of harm or injury (physical, psychological, social or economic) occurring as a result of participation in a research study.

SITE INFORMATION			
Study Code / Name		Site Number	
Investigator Name		Contact Person:	

PARTICIPANT IDENTIFICATION (or N/A <input type="checkbox"/> )			
Participant Number		Participant Initials	
Study Drug or Assignment number:			

EVENT INFORMATION	
Date of Occurrence	____ / ____ / ____ DD MM YYYY
Describe the unanticipated incident/event as succinctly as possible. Include the underlying reason(s) for this Event. Use additional pages if necessary.	
Describe corrective and/or preventative action(s), if applicable: Use additional pages if necessary.	

AUTHORIZED SIGNATURES			
Investigator / Delegate Signature	.....	.....	.....
	Name (print)	Signature	Date (dd/mm/yyyy)
Appropriate Signature (if applicable)	.....	.....	.....
	Name (print)	Signature	Date (dd/mm/yyyy)
Appropriate Signature (if applicable)	.....	.....	.....
	Name (print)	Signature	Date (dd/mm/yyyy)