

NOTIFICATION/RECEIPT OF SERIOUS ADVERSE EVENTS

	Date Forwarded
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	Name of Principal Investigator Address (for ease of return in a window envelope, please complete in the left hand box)
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Study Title			
Ethics Ref No:		Site:	
Protocol No:		Investigator Brochure:	

Reference/Addendum/ MFR #/Safety report no	Date Reported	Event	Study related? Yes/no	Report attached?

Information sheet changes required? Yes/No (If yes, attach new version)

Investigator's Signature: _____ Date: _____

Name:

Investigator Comments: <i>(must be completed)</i>

NOTED by ETHICS COMMITTEE:

Chairperson/Deputy Chairperson: _____ Date: _____

Name:

Ethics Committee Comments: