Adverse event (non-serious) reporting form.

*This form should be used for **non-serious adverse event** reporting only. If the event (a) results in death,(b) is life-threatening, (c) requires hospitalisation or prolongation of existing hospitalisation, (d) results in persistent or significant disability or incapacity, (e) consists of a congenital anomaly or birth defect or (f) is considered a serious adverse event for other reasons then this is a **serious adverse event** and should be reported using **Serious Adverse Event Notification form (Assessment Form 4)**.*

*This form should only be used to report a non-serious **untoward medical occurrence** occurring in relation to the patient. This non serious **untoward medical occurrence** may not be caused by or related to that product but it still needs to be reported. If the event was not an **untoward medical occurrence** then it is an **adverse incident** and needs to be reported using the relevant NHS Trust local reporting policies.*

STUDY/PATIENT DETAILS			
Main REC name	North Staffordshire REC	Main REC reference no.	06/Q2604/109
Sponsor	North Staffordshire Combined Healthcare NHS Trust		
Address	Research and Development Dept, Academic Suite, Harplands Hospital, Hilton Road, Harpfields, Stoke-on-Trent, ST4 6TH		
Telephone	01782 441624	Fax	01782 441624
Email	nschsponsor@northstaffs.nhs.uk		
Patient study number			

EVENT DETAILS						
Date of AE		Where did the AE take place				
Description of event						
Intensity*	Mild		Moderate		Severe	

* The term severity is often used to describe the intensity (severity) of a specific event. This is not the same as 'seriousness', which is based on patient/event outcome or action criteria. The assessment of intensity will be based on the investigator's clinical judgement using the following definitions:
- **Mild:** An event that is easily tolerated by the patient, causing minimal discomfort and not interfering with everyday activities.
- **Moderate:** An event that is sufficiently discomforting and/or interferes with normal everyday activities.
- **Severe:** An event that prevents normal everyday activities and/or is particularly discomforting.

Causality: (relationship to drug/intervention)	Not related		Possible related		Probably related	
	Unlikely to be related		Definitely related			
Expectedness	Expected		Unexpected**			

** i.e. not described in protocol, product information or investigator brochure.

Outcome	Resolved		Currently being resolved		Other (Please specify below)	

REPORTED BY		ROLE IN STUDY		DATE	
Date emailed to Sponsor		Date faxed to Sponsor		Date copy placed in Investigator Site File	

Sponsor email: nschsponsor@northstaffs.nhs.uk Sponsor fax number: 01782 441624

SPONSOR R & D USE ONLY					
DATE RECEIVED		**DATE REVIEWED**		**REVIEWED BY (NAME & POSITION)**	
FURTHER ACTION (if required)					
DATE RELEVANT R & D INFORMED		DATE SAFETY COMMITTEE INFORMED		DATE EVENT ENTERED ONTO REDA	