NCTU SAE Reference:

University Hospitals of Derby and Burton
NHS Foundation Trust

Serious Adverse Event/Reaction Follow Up Reporting Form

Please send a copy of the SAE follow up form to the NCTU by email nctu-sae@nottingham.ac.uk or by fax on 0115 7484091.

All SAE follow ups to be reported to the NCTU within one working day.

1: Study Information			
Study Title:	POSNOC – a randomised trial of armpit (axilla) treatment for women with early stage breast cancer	**DHFT Study Reference:**	**DHRD/2014/043**
Name of individual completing report:		**Date of report:**	DD/MMM/YYYY
Email address of person completing report			
Site name/ number:		**Principal Investigator:**	

2: Participant Information			
Subject ID:		**Date of Birth:**	DD/MMM/YYYY
Initials:		**Gender:**	☐ Male ☐ Female

3: Follow Up Information			
Follow Up Report Number:		**SAE Reference Number:**	
Changes to event detailed in initial SAE report?	☐ No ☐ Yes *(please detail below)*		
Detail any changes to the event since initial report *(include details of concomitant medication, event/reaction, reported signs and symptoms and diagnoses where possible.):*			
Event Outcome:	☐ On-going ☐ Fatal ☐ Recovered/Resolved	Date of death: DD/MMM/YYYY Date of resolution: DD/MMM/YYYY Date of resolution: DD/MMM/YYYY	

	☐ Recovered/Resolved with sequalae ☐ Unknown	
Participant Status:	☐ Continuing	
	☐ Completed	Date of completion: DD/MMM/YYYY
	☐ Withdrawn	Date of withdrawal: DD/MMM/YYYY

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4: PI sign off	
PI name:	
PI signature:	
Date:	DD/MMM/YYYY

5: CI sign off	
CI name:	
CI signature:	
Date:	DD/MMM/YYYY
Further Follow Up required?	☐ Yes ☐ No

6: NCTU sign off (if applicable)			
Date report received:	DD/MMM/YYYY		
Name of receiver:		**Signature of receiver:**	
Comments:			