



### Protocol Deviation & Event Form

*This form must be completed and returned to the BUMPES Coordinating Centre for every protocol deviation that occurs.*

<b>PART 1: To be completed by centre:</b>		
Centre Name		
Deviation / Event Details		
Reason for Deviation / Event		
Date of Event		
Action Taken		
Name:	Signature:	Date:

<b>PART 2: To be completed by BUMPES Coordinating Team:</b>			
Date Received:		Received By:	
Action Taken			
CI Signature:		Date:	



BUMPES Trial, Clinical Trials Unit, UCL, Gower Street,  
 London, WC1E 6BT  
**Telephone:** 0207 679 0939  
**Email:** bumpes@ucl.ac.uk  
[www.institute.forwomenshealth.ucl.ac.uk/bumpes](http://www.institute.forwomenshealth.ucl.ac.uk/bumpes)



**Protocol Deviation & Event Form  
Instructions for Use**

Please complete part 1 of this form for all deviations from the protocol or events that require notification to the BUMPES coordinating centre.

Please complete all sections then fax, email or post a copy of the form to the BUMPES coordinating centre at the details below:

*BUMPES Study, Clinical Trials Unit  
UCL Gower Street, London, WC1E 6BT  
Fax: 0207 679 6761  
Email: [bumpes@ucl.ac.uk](mailto:bumpes@ucl.ac.uk)*

The original form must then be filed in the PI site file.

Once assessed by the coordinating centre, part 2 of the form will be completed and signed off by the relevant members of the BUMPES Coordinating Team (this may or may not include the Chief Investigator). The completed form will be retained by the BUMPES coordinating centre and copy will be returned to the site to be attached to the original form submitted and filed in the PI site file.

If further action is required, the site will be notified.



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