PREGNANCY ON A CLINICAL TRIAL – NOTIFICATION FORM
Pregnancy on a clinical trial *must* be recorded and reported to the Sponsor (Pharmacovigilance monitor) It is desirable to follow up the pregnancy but the mother's consent must be obtained The forms are complementary to reduce duplication. The Follow Up form should be used to complete the event

1 – Trial Information	
1a) Sponsor	
1b) Chief Investigator	
1c) Investigator name (If other site)	
1d) Study site name	
1e) EudraCT number	
1f) R&D number	
1g) Study Title	

2 – Participant Information		
The participant is ***female*** and has become pregnant while taking part in a clinical trial	☐ *Tick applicable*	
The participant is ***male*** whose female partner has become pregnant while ***he*** is on a trial	☐ *Tick applicable*	
Has the mother given consent to follow up the pregnancy?	☐ *Yes*	☐ *No*

3 – Material Information						
Initials	ID No (if applicable)		DOB	Last menses	Expected Delivery Date	
If participant is male	Initials		ID No		DOB	

4 - Contraception					
Method (or none)		Used as instructed	☐ *Yes*	☐ *No*	☐ *Uncertain*

5 – Previous Obstetric History *(continue in section 8 if required)*	
1	
2	
3	
4	
5	

6 – Previous Medical History

7 – Medical Information

7a) Information about the IMP

Drug	Dose	Route	Start Date	Stop date	Week of pregnancy when medication stopped

7b) Concomitant Medication at time of conception

Drug	Indication	Dose	Route	Start Date	Stop Date	Action taken

8 – Additional Information

THIS REPORT MUST BE SIGNED AND DATED BY THE INVESTIGATOR			
• Fill in the form and email an electronic copy to: rde-tr.RandDSafetyReporting@nhs.net • Print two copies of the completed form, sign and date • Send one signed copy to research & Development at the address below • Put one signed copy in your Trial Master File in the Pharmacovigilance section • Receipt will be acknowledged by email			
Name of Investigator (if reporting from a participating site)			
Signature		Date	
Name of Chief Investigator			
Signature		Date	

Contact Details	
Address for returning reports	Quality Assurance Coordinator Research & Development Room 412, Level 3 Noy Scott House Royal Devon & Exeter Hospital Barrack Road Exeter Devon EX2 5DW
Email:	rde-tr.RandDSafetyReporting@nhs.net
Telephone notifications:	01392 403055 (R&D Non-network office) 01392 403056 (QA Coordinator)