PREGNANCY ON A CLINICAL TRIAL – FOLLOW UP 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. This should follow the **Notification** Form.

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 – Pre-Natal Information (any tests preformed and results)				
Amniocentesis	☐ Yes	☐ No	☐ Result	
Ultrasound	☐ Yes	☐ No	☐ Result	
Maternal serum AFP	☐ Yes	☐ No	☐ Result	
Other				

5 – Pregnancy Outcome						
Carried to term	☐ Yes	☐ No	Week of Delivery		Date of Delivery	
If YES was the delivery	☐ Normal		☐ Forceps/Ventouse		☐ Caesarean	
If NO was the termination	☐ Spontaneous	☐ Planned	☐ Therapeutic		Termination date	

6 – Child Outcome									
Describe the Birth			☐ Normal		☐ Abnormal*		☐ Stillbirth		
Sex	☐ Male	☐ Female	Length		Weight		Head Circumference		
Apgar Scores		1min			5 min		10 min		

7 – 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 Division Room 412 3rd Floor, Noy Scott House Royal Devon & Exeter Hospital Barrack Road Exeter Devon EX2 5DW
Email:	rde-tr.RandDSafetyReporting@nhs.net
Telephone notifications:	01392 403055 01392 403056