Section 1.To be filled up by the Principal Investigator.

1. ***Documents relevant to the Pregnancy should be submitted together with this form.***
2. ***Pregnancy on a clinical trial must be recorded and reported to the Sponsor.***
3. ***It is desirable to follow up the pregnancy but consent must be obtained.***
4. ***The forms are complementary to reduce duplication. This should follow the Notification form***
5. ***Follow-ups to be completed at the end of the pregnancy and 6 months post birth (if applicable)***

SJDIRB Reference Code		**Date of Submission**	DD Month YYYY
Protocol Code		**SJREB Code**	
Protocol Title			
Principal Investigator			
Sponsor/CRO			
Approval Date	DD Month YYYY	**Start Date**	DD Month YYYY

Participant Information	**YES**	**NO**
The participant is **female** and has become pregnant while taking part in a clinical trial		
The participant is **male** whose female partner has become pregnant while **he** is on a trial		
Has consent been given to follow up the pregnancy?		

PATIENT INFORMATION - In Pregnancy Report Forms, the patient is always the mother. For clinical trials and research where patients are allocated an alpha-numeric identifier, the appropriate field ('Patient Initials/Number') should be populated with this information. In the cases where the patient is the female partner of an enrolled male patient (drug exposure via father), the father's patient initials/number should be entered for reference. By using the tick boxes 'father' / 'mother', there is no ambiguity on who is referred to via the patient number.

○ **Mother**	○ **Father**	**Patient Initials/Number:**		**Mother initials:**	

MATERNAL HISTORY

Mother's Birthday	DD Month YYYY	**Mother's Height & Weight**	_____ **cm.**	_____**kg**
Last Menses	DD Month YYYY	**Expected Delivery Date**	DD Month YYYY	
Date of Pregnancy Test	DD Month YYYY	**Date of Positive Blood Test**	DD Month YYYY	

RELEVANT DRUG(S) EXPOSURE BEFORE/DURING PREGNANCY - Up to 3 drugs can be entered, if more drugs have to be reported, the page can be reprinted with the mention 'Supplemental page' added manually. Information on the IP drug and other relevant drugs including the International Nonproprietary Name (INN - preferred) (or trade name/active substance), daily dose, route of administration, batch number and administration dates should be mentioned. Tick boxes allow identification of whether the mother or the father was taking the drug(s).

Drug Name			
Daily dose/s & route of administration			
Batch number			
Treatment start date			
Treatment stop date			
Drug taken by	○ **Father** ○ **Mother**	○ **Father** ○ **Mother**	○ **Father** ○ **Mother**
ACTION TAKEN IN RESPONSE TO THE PREGNANCY			
Drug Maintained	(Drug Name)	(Drug Name)	(Drug Name)
Drug Reduce: New Dose			

Started on	DD Month YYYY	DD Month YYYY	DD Month YYYY
Drug permanently withdrawn	(Drug Name & withdrawal date)	(Drug Name & withdrawal date)	(Drug Name & withdrawal date)
Drug interrupted (From & To)	DD Month YYYY to DD Month YYYY	DD Month YYYY to DD Month YYYY	DD Month YYYY to DD Month YYYY

PREGNANCY OUTCOME					
Carried Term	○ Yes ○ No	**Week of delivery**	DD Month YYYY	**Date of delivery**	DD Month YYYY

If YES was the delivery	○ **Normal**	○ **Forceps/Ventouse**	○ **Caesarean**	
If NO was the delivery	○ **Spontaneous**	○ **Therapeutic**	**Termination Date**	DD Month YYYY
Was the baby still-born?			○ **YES**	○ **NO**
Were there any congenital abnormalities at birth?			○ **YES**	○ **NO**
If with congenital abnormalities at birth, please record the details				

CHILD OUTCOME AT 6 MONTHS		
Has a Birth Defect been recorded	○ **YES**	○ **NO**
Record the details of the birth defect		

ADDITIONAL INFORMATION

THIS REPORT MUST BE SIGNED AND DATED BY THE INVESTIGATOR

1. **Fill in the form and email an electronic copy to:**
2. **Print two copies of the completed form, sign and date**
3. **Send one signed copy to SJDIRB**
4. **Put one signed copy in your Trial Master File in the Pharmacovigilance section**
5. **Receipt will be acknowledged by email**

Name of Primary Investigator	**Signature**	**Date**

Section 2: FOR SJDIRB USE ONLY (To be filled by the Primary Reviewer)

Decision Points	Recommendation
○ Recommend further action ○ Request additional information ○ Continued Monitoring ○ Withdrawal from the Study ○ Specialized Consultations ○ Long-Term Follow-up ○ Pending (if substantial clarifications are necessary prior to reaching a decision)	1. Close monitoring of the pregnancy through regular ultrasounds and prenatal tests. 2. In some cases, it may be recommended that the participant withdraw from the study to minimize potential risks to the fetus. 3. Referral to specialists, such as maternal-fetal medicine specialists or geneticists, for further evaluation and counseling. 4. Continued monitoring of the child's development after birth to assess for any long-term effects of the investigational drug.

Primary Reviewer	**Signature**	**Date**

SJDIRB Final Action

Final Decision	Recommendation/Comments
○ Recommend further action ○ Request additional information ○ Continued Monitoring ○ Withdrawal from the Study ○ Specialized Consultations ○ Long-Term Follow-up ○ Pending (if substantial clarifications are necessary prior to reaching a decision)	(e.g. Proceed with the recommendation of the reviewer or full board meeting last _____)

SJDIRB Officer	Name	Signature	Date
Board/Panel Secretary			
Chair/Panel Lead			