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| **FORM 3.9 PREGNANCY REPORT** |

**Initial Reporting:** For all initial reporting of pregnancy this form must be **completed fully or with as much information as possible** and sent to the WVSU-URERC within **24 hours** of knowledge of the event.

**Follow-up Information:** For subsequent follow-up reporting of a pregnancy, **a new Pregnancy Reporting form should be completed with all new or missing information** filled in and forwarded to the WVSU-URERC as soon as possible.

Please complete electronically where possible. All dates should be written in this format: mmm/dd/yyyy

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| WVSU-URERC Protocol Number |  |
| Sponsor Protocol Number |  |
| Study Protocol Title |  |
| Principal Investigator/ Researcher |  |
| Initial Approval Date |  |
| Date of Last Continuing Review Approval |  |

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| **TYPE OF REPORT** | | |  | **DATE STUDY TEAM BECAME AWARE OF PREGNANCY** |  |  | **REPORT**  **SUBMISSION DATE** |  |
|  | | |  |  |  |  |  |  |
|  |  | Initial |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  | Follow Up |  |  |  |  |  |  |
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| 1. **MOTHER’S DETAILS** | | |
| **Is the mother the trial subject?** Yes □ No □ | | |
| **If the mother is NOT the trial subject, please note the initials and participant study number of the biological father here:**  **Participant Initials:**  **Participant Study Number:** | | |
| **Patient Initials/Number (If the mother is the trial subject):** | **Mother’s Initials:** | |
| **Mother’s Date of Birth:** | **Mother’s height:** cm | **Mother’s weight:** kg |

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| 1. **RELEVANT DRUG(S) EXPOSURE BEFORE/DURING PREGNANCY**   *Up to 3 drugs can be entered, if more drugs have to be reported, replicate this table or use additional sheets. Information on the IP drug and other relevant drugs including the International Non-proprietary 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 □ |

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| 1. **ACTION TAKEN IN RESPONSE TO THE PREGNANCY** | | | |
| **Drug Name (from #2)** |  |  |  |
| **Drug maintained** |  |  |  |
| **Drug reduced** |  |  |  |
| **New daily dose** |  |  |  |
| **Date reduced** |  |  |  |
| **Drug permanently withdrawn** |  |  |  |
| **Date withdrawn** |  |  |  |
| **Drug interrupted** |  |  |  |
| **From** |  |  |  |
| **To** |  |  |  |
| **Not Applicable** |  |  |  |

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| 1. **PREGNANCY INFORMATION** | | | |
| **Date of 1st day of last menstrual period:** | | **Estimated delivery date:** | |
| **Pregnancy test/s** | | | |
| □ **Positive urine test**  **Date:** | □ **Positive blood test**  **Date:** | | □ **Positive ultrasound**  **Date:** |
| **Pregnancy outcome** | | | |
| Did the patient experience any complication during pregnancy? | | * Yes. Specify: * No * NA | |
| Did the patient give birth to (a) live infant(s)? | | * Yes. Date of delivery * No. Specify reason: * NA | |
| Was the infant normal at birth? | | * Yes * No. Specify abnormality and reason: * NA | |
| Additional comment on pregnancy/delivery | |  | |

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| 1. **INFANT(S) INFORMATION** | | | | | | |
| **Infant number** | **Sex** | **Length (cm)** | **Weight (g)** | **APGAR score** | **Exposure during breastfeeding** | **Comment** |
| **1** | **F** □ / **M** □ |  |  |  | **Yes** □ / **No** □ |  |
| **2** | **F** □ / **M** □ |  |  |  | **Yes** □ / **No** □ |  |
| **3** | **F** □ / **M** □ |  |  |  | **Yes** □ / **No** □ |  |

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| 1. **RELEVANT MEDICAL HISTORY** *(with focus on relevant prior gynecological/obstetric history)* |

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|  | **URERC Recommendation (for URERC use only)** | |
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|  |  | No further information or action required |
|  |  |  |
|  |  | Additional information required (indicate information) |
|  |  |  |
|  |  | Recommend further action (indicate action) |
|  |  |  |
|  |  | Pending, if MAJOR clarifications are required |
|  |  | before a decision can be made |
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| Name of Reviewer |  | Signature |  | Date |
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| Reported By/Date |  | Received By (WVSU-URERC Secretariat)/Date |
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