NIDCR Pregnancy Notification and Outcome Report

Protocol #:	PI Name/Site Name:	Participant ID:

Please complete and email (rho_productsafety@rhoworld.com) or fax (1-888-746-3293) this form to NIDCR's CROMS contractor (Rho). If you have general questions about pregnancy reporting, you may contact Rho Product Safety by email or telephone (1-888-746-7231). Note that red italic text is instructional text.

SECTION 1: SOURCE OF INFORMATION
Please list the source(s) of information reported on this form (parent, pediatrician, medical records, OB/GYN etc.):

SECTION 2: REPORT TYPE	
☐ Initial Date: ___ ___ _____ YYYY-MM-DD	☐ Follow-Up Date: ___ ___ _____ YYYY-MM-DD

SECTION 3: DEMOGRAPHICS	
Sex(of study participant): ☐ Female ☐ Male (Partner Pregnancy)	**Age** (of the pregnant female at conception): ____ Age
Weight: ____ ☐ lb ☐ kg **Height:** ____ ☐ in ☐ cm	

SECTION 4: DETAILS OF PREGNANCY			
Date Pregnancy Confirmed __ ___ _____ YYYY-MM-DD	**First Day of Last Menstrual Cycle** __ ___ _____ YYYY-MM-DD		**Expected Delivery Date** __ ___ _____ YYYY-MM-DD
How was the pregnancy confirmed?			
What type of contraception was used at the time of conception? *(check all that apply)*	☐ Abstinence ☐ Barrier ☐ Birth Control Pill ☐ Implant ☐ IUD ☐ Other; specify		
Obstetric History	Gravida (total number of pregnancies):		
	Para (total number of viable births [>20 wks]):		
	Abortus (total number of abortions or miscarriages):		
Pregnancy Status	**Ongoing?** ☐ Yes ☐ No, *(If no, please complete Section 7 Pregnancy Outcome - Maternal)*		
Prenatal Testing ☐ **Yes** ☐ **No**	**Name of Test**	**Date of Test**	**Results** *(if known)*
	Genetic Testing		
	Ultrasound		
	Amniocentesis		
	Maternal AFP		
	Chorionic Villus Sampling		

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	Other; specify:	

Describe any relevant maternal history or concurrent medical conditions (Including but not limited to diabetes, hypertension, tobacco use, alcohol consumption, drug use, other genetic factors, etc). If the information is unknown, please indicate so:

Describe any relevant paternal history or concurrent medical conditions (Including but not limited to diabetes, hypertension, drug use, other genetic factors). If the information is unknown, please indicate so:

Describe any relevant familial history or concurrent medical conditions (Including but not limited to clotting disorders, other genetic factors, etc). If the information is unknown, please indicate so:

Specify any relevant concomitant medications taken 2 weeks prior to and during pregnancy

Medication Name	Dose (with units)	Route of Administration	Start Date (YYYY-MM-DD)	Stop Date (YYYY-MM-DD)	Indication	Frequency

SECTION 5: STUDY DRUG / STUDY DEVICE INFORMATION ☐ N/A

Use the following rows/fields for Study Drug Information; if not applicable please check the box above.

Study Drug	Dose & Unit	Frequency	Route of Administration	Date of First Dose	Date of Last Dose Prior to Pregnancy	Treatment Ongoing?
Study Product				__ __ _____ YYYY-MM-DD	__ __ _____ YYYY-MM-DD	☐ Yes ☐ No If no, did conception occur on treatment? ☐ Yes ☐ No
Study Product (if applicable)				__ __ _____ YYYY-MM-DD	__ __ _____ YYYY-MM-DD	☐ Yes ☐ No

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						If no, did contraception occur on treatment? ☐ Yes ☐ No

Use the following rows/fields for Study Device Information; if not applicable please check the box above. ☐ N/A

Index Procedure:		**Randomization:**	
_____ ___ ___ YYYY-MM-DD	**TIME:** _____ HH:MM (24-hour format)	_____ ___ _____ YYYY-MM-DD	**TIME:** _____ HH MM (24-hour format)
Lot Number: ☐ NA		**Serial Number:** ☐ NA	

Current Location of the Device (check one):

☐ Investigational / Study Site ☐ Sponsor ☐ Subject ☐ Manufacturer

☐ Remains Implanted ☐ Discarded ☐ Unknown ☐ Other:

SECTION 6: PARTICIPANT DISPOSITION

Was the participant withdrawn from the study, per protocol?	☐ Yes ☐ No If Yes, include date: _____ ___ _____ YYYY-MM-DD

The remainder of this form relates to the outcome of the pregnancy. Please complete this section as information is obtained on the outcome of the pregnancy.

SECTION 6: PREGNANCY OUTCOME – MATERNAL

If any SAE criteria are fulfilled for a study participant, also complete and submit SAE form based on reporting procedures per protocol. Please complete to the best of your ability, understanding the participant may not share all details.

Date of Birth: _____ ___ _____ YYYY-MM-DD	☐ Vaginal ☐ Cesarean ☐ Planned ☐ Emergency *(specify reason)*:
Pregnancy Outcome	☐ Not reported by participant ☐ Lost to Follow Up ☐ Full-term Birth (37+ weeks) ☐ Premature Birth If known, add reason and gestational age: ☐ Intrauterine Death (20+ weeks) (Report as an SAE) ☐ Spontaneous Abortion (<20 weeks) **(Report as an SAE)** ☐ Elective Termination *Refer to protocol for specific details regarding reporting* If elective termination, for therapeutic reasons? ☐ Yes ☐ No

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	If Yes, include date: __ ___ _____ YYYY-MM-DD
Were there any maternal complications or abnormal conditions during pregnancy / childbirth? *(Comment on any abnormal conditions, diagnoses, and/or occurrences that were identified during the course of pregnancy and/or birth/delivery.*	☐ Yes ☐ No If Yes, specify: **(If complications meet the criteria of an SAE, report as SAE)** ***Related to study drug or product?** ☐ Yes ☐ No ***If Yes, is it expected or unexpected? If No, please indicate if there is a suspected cause of the maternal complications or abnormality(ies):**

SECTION 7: PREGNANCY OUTCOME – FETAL		
Gestational age	weeks	
Did the pregnancy result in multiple births? *If more than 2 births, please consider creating an appendix at the end of this form to capture all relevant information for the additional baby(ies).*	☐ Yes ☐ No If yes, how many?	
Baby 1	Sex	☐ Female ☐ Male
	Length: ☐ in ☐ cm	Birth Weight: ☐ lbs ☐ kg
	Congenital Anomalies?	☐ Yes* ☐ No
	Post-natal Medical Problems?	☐ Yes* ☐ No
	Total Apgar score: 1 minute ____ 5 minutes: ____ 10 minutes ____ 15 minutes ____ 20 minutes ____ ☐ Unknown	

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<table>
<tr><td></td><td colspan="2">Lactation / Breast feeding? optional – include if your protocol specifies this information will be collected
☐ Yes
Start Date: ____ __ _____ Stop Date (if known): __ __ ____
YYYY-MM-DD YYYY-MM-DD

☐ No</td></tr>
<tr><td rowspan="6">Baby 2</td><td>Sex</td><td>☐ Female ☐ Male</td></tr>
<tr><td>Length: ☐ in ☐ cm</td><td>Birth Weight: ☐ lbs ☐ kg</td></tr>
<tr><td>Congenital Anomalies?</td><td>☐ Yes* ☐ No</td></tr>
<tr><td>Post-natal Medical Problems?</td><td>☐ Yes* ☐ No</td></tr>
<tr><td colspan="2">Total Apgar score: 1 minute: __5 Minutes:_
10 minutes: ____ 15 minutes: ____ 20 minutes:____
☐ Unknown</td></tr>
<tr><td colspan="2">Lactation / Breast feeding? optional – include if your protocol specifies this information will be collected
☐ Yes
Start Date: ____ ___ _____ Stop Date (if known): ___ __ ____
YYYY-MM-DD YYYY-MM-DD

☐ No</td></tr>
<tr><td colspan="3">*Describe any congenital anomalies or post-natal medical problems. If answered Yes above, please indicate if it is related to the study intervention. If related to the intervention, is it expected or unexpected. If not related to the intervention, please indicate if there is a suspected cause of the neonatal abnormality(ies). (If congenital anomaly or other post-natal medical problems meet the criteria of an SAE, report as an SAE):</td></tr>
</table>

SECTION 8: ADDITIONAL INFORMATION *(optional)*
Please provide any additional remarks, other relevant information, or observations related to the pregnancy and/or any further clarification to any of the fields above:

SECTION 9: INVESTIGATOR SIGNATURE	
"To the best of my knowledge, all information entered on these pages for this participant is correct."	
Investigator (print name):	**Date:** ____ ___ _____ YYYY-MM-DD

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Investigator (signature):	YYYY-MM-DD
Person Completing Form (print name):	**Date:** _____ ___ _____ YYYY-MM-DD
Person Completing Form (signature):	

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