

NIDCR Pregnancy Outcome Form
 Email or fax to Rho Product Safety at conclusion of pregnancy

Protocol #: _____	PI Name/Site #: _____	Participant #: _____
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OUTCOME OF PREGNANCY *If any of the serious criteria are fulfilled, also complete and submit the Serious Adverse Event (SAE) Form.*

Unknown/Lost to Follow-Up

Full Term Birth

Premature Birth

Spontaneous Miscarriage: _____
(DD/MMM/YYYY)

Elective Termination: _____ Medical Reason Non-Medical Reason
(DD/MMM/YYYY)

If elective termination, specify reason: _____

DETAILS OF BIRTH/DELIVERY

Date of birth: _____ (DD/MMM/YYYY)

Vaginal

Cesarean

Planned

Emergency (specify reason): _____

Gestational age: _____ weeks

Weight: _____ Sex: Male Female

Total Apgar score: 1 minute: _____ 5 minute: _____

Healthy Baby

Sick Baby (e.g., birth trauma, infection)

Stillbirth

Congenital Anomaly/Birth Defect

Provide additional information if Healthy Baby not checked: _____

Multiple Births? No Yes, specify: number of infants _____ and birth order of this infant _____

If Yes, complete a separate form for each infant.

ABNORMAL CONDITIONS/OCCURRENCES

Comment on any abnormal condition or occurrence regarding course of pregnancy and birth/delivery. Provide signs, symptoms, diagnoses, and probable cause.

Any complications, infections, or illnesses during pregnancy and/or birth/delivery? No Yes

If Yes, specify: _____

<i>Investigator Signature</i>	<i>Date (DD/MMM/YYYY)</i>
<i>Name of Person Completing Form</i>	<i>Date (DD/MMM/YYYY)</i>

Rho Product Safety – Questions? Call 1-888-746-7231 / Fax 1-888-746-3293
 Email address: rho_productsafety@rhoworld.com