

## Ribavirin Pregnancy Registry

### Instructions for completing the OBSTETRIC FOLLOW-UP AT OUTCOME FORM

**General Information:** Provide dates in the ddmonyyyy format (e.g. January 1, 2004 is written 01Jan2004).

#### 1. Fetal Outcome

If there are multiple outcomes (e.g., twins, triplets) provide details for each outcome. Make copies of page 1-2 or indicate the information for each outcome.

- 1.1 **\*Birth Defect Noted:** Was a structural birth defect noted? Check “yes”, “no”, or “unknown”. If yes, list defects on page 2. *Please try to determine if there was a defect present. If this information is unknown, this case cannot be included in the analysis.*
- 1.2 **\*Outcome:** Check one box for outcome: Live infant, spontaneous abortion/miscarriage, elective abortion, or fetal death/stillbirth.
  - For elective abortion, check the reason for the abortion. List specific factors on page 2.
  - For any fetal loss, provide details on page 2, section 3 of the form.
- 1.3 **\*Date of Outcome:** Provide the date of live birth or fetal loss.
- 1.4 **Gender:** Provide the gender of the infant.
- 1.5 **Apgar Scores:** Provide Apgar scores.
- 1.6 **\*Gestational Age:** Provide the gestational age at outcome.
- 1.7 **\*Birth Weight:** Provide the weight of the infant at birth. Provide weight in either grams OR lbs/oz.
- 1.8 **\*Birth Length:** Provide the length of the infant at birth. Provide measurement in either centimeters OR inches.
- 1.9 **Head Circumference:** Provide the infant’s head circumference at birth. Provide measurement in either centimeters OR inches.

#### 2. Birth Defects

\*If a birth defect identified:

- 1) List the major structural or chromosomal birth defect(s).
- 2) Indicate if the defect was attributed to ribavirin therapy (“yes”, “no”, or “unknown”).
- 3) Indicate other factors that may have contributed to the specific birth defect.

#### 3. Fetal Loss (Fetal Death/Stillbirth, Spontaneous Abortion/Miscarriage, or Elective Abortion):

- 1) \*List other factors that may have contributed to this fetal loss.
- 2) Indicate if the factor was attributed to ribavirin therapy (“yes”, “no”, or “unknown”).

**PATIENT MEDICATION, EXPOSURES AND CONCURRENT CONDITIONS (at time of conception and during the pregnancy) – (Form initially completed at registration and updated at each follow-up.)**

**\*Critical fields** - Please try to obtain this information. These fields are the most critical for the analysis of risk.

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The Registry is not designed to monitor all types of events that might occur during pregnancy, labor and delivery, or other neonatal or post-natal events other than defects. If such events occur, the provider is encouraged to contact the manufacturer of the individual product and/or FDA. FDA can be reached by faxing the information to 800-FDA-0178 or at <http://www.fda.gov/medwatch/>

**Ribavirin Pregnancy Registry  
OBSTETRIC FOLLOW-UP AT OUTCOME FORM**

**Fax to: 800-800-1052**

**Mail to: Ribavirin Pregnancy Registry  
1011 Ashes Drive, Wilmington, NC 28405**

FOR OFFICE USE ONLY

Page 1 of 2

Registry ID \_\_\_\_\_

HCP ID \_\_\_\_\_ Baby ID \_\_\_\_\_

Country / State (US) \_\_\_\_\_

Date info received \_\_\_\_\_  Phone

Patient  HCP

OBSTETRIC PROVIDER

**Log ID:** \_\_\_\_\_ **Patient Name:** \_\_\_\_\_ (if authorization received)

**1.  FETAL OUTCOME** (\*Critical fields – at a minimum, please provide this information)

1.1 \*Birth Defect Noted? <sub>1</sub> Yes <sub>2</sub> No <sub>3</sub> Unknown (If yes, list on next page)

1.2 \*Outcome: <sub>1</sub> Live Infant  
<sub>2</sub> Abortion, Spontaneous/Miscarriage  
<sub>3</sub> Abortion, Elective (Reason: <sub>1</sub> Birth defects (sec 2) <sub>2</sub> Other) (list on next page, sect 3)  
<sub>4</sub> Fetal Death/Stillbirth

1.3 \*Date of Outcome: \_\_\_\_\_ dd \_\_\_\_\_ mon \_\_\_\_\_ yyyy

1.4 Gender: <sub>2</sub> Male <sub>1</sub> Female

1.5 Apgar Scores: \_\_\_\_\_ 1 minute  
 \_\_\_\_\_ 5 minute

1.6 \*Gestational Age: \_\_\_\_\_ weeks

1.7 \*Birth Weight: \_\_\_\_\_ lbs \_\_\_\_\_ oz OR \_\_\_\_\_ grams

1.8 \* Birth Length: \_\_\_\_\_ cm OR \_\_\_\_\_ in

1.9 Head Circumference: \_\_\_\_\_ cm OR \_\_\_\_\_ in

\* Critical Fields

**NOTES:**

- If BIRTH DEFECT and/or FETAL LOSS, go to page 2

**Also update the PRENATAL TESTS, MEDICATIONS,  
AND CONCURRENT CONDITIONS FORM**  
(Initiated at registration and updated at each follow-up)

**OBSTETRIC HEALTH CARE PROVIDER INFORMATION**

Name \_\_\_\_\_ Specialty \_\_\_\_\_

Address \_\_\_\_\_ Phone \_\_\_\_\_

\_\_\_\_\_ Fax \_\_\_\_\_

\_\_\_\_\_ Email \_\_\_\_\_

Alternate Contact \_\_\_\_\_

Provider's Signature \_\_\_\_\_ Date \_\_\_\_\_  
 dd mon yyyy

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**Ribavirin Pregnancy Registry  
Obstetric Follow-up At Outcome Form**

Registry ID \_\_\_\_\_ (OFFICE USE ONLY)

Baby ID \_\_\_\_\_

Log ID: \_\_\_\_\_ Patient Name: \_\_\_\_\_ (if authorization received)

OBSTETRIC PROVIDER

Complete this page **ONLY** if there is a **birth defect** and/or a **fetal loss** (fetal death/stillbirth, spontaneous abortion/miscarriage, or elective abortion)

2.  **BIRTH DEFECTS — List birth defects below. (\*Critical information)**

2.1 Birth Defect noted by: (use code #) \_\_\_\_\_

1. Cardiologist	5 Midwife	9 Radiologist
2. Dysmorphologist/ Teratologist	6 Neonatologist	10 Other, specify _____
3. Family Medicine	7 Ob/Gyn	
4. Maternal Fetal Medicine	8 Pediatrician	

2.2 *Birth defect (list each birth defect)	Was the defect attributed to ribavirin: 1 = yes 2 = no 3 = unknown	Other factors that might contribute to this outcome 1 = maternal age 2 = unknown 3 = other, specify
1.		
2.		
3.		
4.		
5.		
6.		

3.  **FETAL LOSS (Fetal death/stillbirth, spontaneous abortion/miscarriage, or elective abortion)**

List factors, other than birth defects, that may have had an impact on the fetal loss.

*Condition (not birth defect) that may have impacted this outcome (list condition)	Was the condition attributed to ribavirin 1 = yes 2 = no 3 = unknown
1.	
2.	
3.	
4.	
5.	
6.	

Thank you for your participation in the Ribavirin Pregnancy Registry

<p>(FOR OFFICE USE ONLY)</p> <p><input type="checkbox"/> <b>Obstetric Follow-Up Status:</b>    <input type="checkbox"/><sub>1</sub> Pending    <input type="checkbox"/><sub>2</sub> Complete    <input type="checkbox"/><sub>3</sub> LTFU</p>
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