Ribavirin Pregnancy Registry

Instructions for completing the PRENATAL TESTS, MEDICATIONS, AND CONCURRENT CONDITIONS FORMS

PATIENT (REGISTRATION ONLY) OBSTETRIC PROVIDER

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

PRENATAL TESTS, MEDICATIONS, AND CONCURRENT CONDITIONS (at time of conception and during during pregnancy)
This form is initiated at Registration and updated at each trimester follow up.

1. **Data Form Completed or Updated:** This form will be updated at the times indicated in this section. The Registry Coordinating Center will check the applicable time period for the updates.
   - For Registration, print and sign name and date at the bottom of the page.
   - For follow-up updates, please sign and date in this section.
2. **Prenatal Tests**
   - 2.1 **Prenatal Test Done:** Indicate if a prenatal test was done.
     - If no, move to section 3: Ribavirin Therapy During Pregnancy
     - If yes, please continue by indicating which test and the date or gestational age in weeks when the test was done, then go to section 2.2.
   - 2.2 **Evidence of a Structural Defect:** Indicate if there was a structural and/or chromosomal defect(s) identified on a prenatal test.
     - If no, move to section 3: Ribavirin Therapy During Pregnancy
     - If yes, please provide the structural and/or chromosomal defect(s) identified and by what test the defect was identified. Also, indicate the date or gestational age the defect was noted, then go to section 3.
3. **Ribavirin Therapy During Pregnancy (including interferon)**
   - **Med Code:** Indicate 1- 11
   - **Note who took ribavirin:** (1=female (pregnant female), 2=male (male sexual partner of pregnant female))
   - **Total Dose:** Provide the total dose and interval (day, wk) with units (e.g., ribavirin 40 mg/week).
   - **Route:** Provide the code 1=oral tablet 2=oral capsule, 3=sub-Q (subcutaneous), 4=IM (intramuscular), 5=Other (If other, specify route.)
   - **Date Treatment Began:** Indicate the date therapy began for each course. See note for Gestation Week Began.
   - **Gestation Week Began:** Indicate the gestation week therapy began (if unknown and a date the therapy began is available, that is sufficient).
   - **Gestation Week Calculated:** To ensure consistent calculations, we have added a box to indicate how the gestation weeks were calculated.
   - **Date Treatment Stopped:** Indicate the date therapy stopped for each course. See note for Gestation Week Began.
   - **Gestation Week Treatment Stopped:** (See note for Gestation Week Began.)
4. **Other Exposures During Pregnancy**
   - **Medication, Product or Exposure:** (Include prescription and OTC medications, nutritional supplements, herbal preparations, immunizations, etc.)
   - **Indication:** Provide the reason for exposure (i.e., a specific symptom or condition).
   - **Total Dose:** (Include units and interval e.g., 100 mg PRN or 50 mg/day)
   - **Date Treatment Began:** (Indicate the date therapy began for each course.)
   - **Gestation Week Began:** (See note for Gestation Week Began in section 3.)
   - **Date Treatment Stopped:** (Indicate the date therapy stopped for each course.)
   - **Gestation Week Treatment Stopped:** (See note for Gestation Week Began in section 3.)
5. **Concurrent Medical Conditions**
   - Complete or update information on concurrent medical conditions other than HCV that are present during this pregnancy (include chronic conditions).
   - If a condition was ongoing at an earlier assessment, but is not ongoing at subsequent assessment, 1) cross out the "ongoing", 2) initial and date the change, and 3) record the date and/or gestation week it was no longer present.
   - If a condition worsened during pregnancy, check box.
6. **Tobacco and Alcohol Use**
   - **Trimester of Use:** (Indicate or update the trimester of use.)
7. **Pregnancy Status**
   - Check whether the pregnancy is ongoing or outcome has occurred at registration and at each follow-up assessment
   - If the outcome has occurred, complete the Ob HCP Pregnancy Follow Up at Outcome Form.

The Registry is not designed to monitor all types of events that might occur during pregnancy, labor and delivery, or other neonatal or postnatal events other than birth defects. If such events occur, the reporter 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
Research Park; 1011 Ashes Drive; Wilmington, NC 28405
Phone: 800-593-2214, Fax: 800-800-1052
Version (Dec 2006, v 1.3)

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Ribavirin Pregnancy Registry
PRENATAL TESTS, MEDICATIONS, AND CONCURRENT CONDITIONS FORM

(Initiated at registration and updated at each follow-up using additional pages if necessary)

FOR OFFICE USE ONLY:
Registry ID _____ Page 1 of 3
Registration date _____ _____ _____ ☐ Phone
1st Tri. date recvd _____ _____ _____ ☐ Phone
2nd Tri. date recvd _____ _____ _____ ☐ Phone
At outcome date recvd _____ _____ _____ ☐ Phone

Fax to: 800-800-1052, Mail to: Ribavirin Pregnancy Registry, 1011 Ashes Drive, Wilmington, NC 28405

Log ID: _____ **Patient Name:** _____ *(if authorization received)*

PATIENT (REGISTRATION ONLY) OBSTETRIC PROVIDER

1. DATA FORM INITIATED OR UPDATED:

Form Type *(note last form chk'd)*	**Completed by**	**Date Completed**
☐ 1) Registration	(at registration complete section at the end of form, page 3)	(date on page 3)
☐ 2) Follow-up (1st Trimester)		
☐ 3) Follow-up (2nd Trimester)		
☐ 4) Follow-up (at outcome)		

2. PRENATAL TESTS *(not required at outcome)*

2.1 Was a prenatal test done?

☐ Unknown *(go to section 3)*
☐ No *(go to section 3)*
☐ Yes (√) test(s) *Include gestation age in weeks for each*
☐ Ultrasound _____ *(gest. age in wks)*
_____ *(gest. age in wks)*
_____ *(gest. age in wks)*
_____ *(gest. age in wks)*
☐ Amniocentesis _____ *(gest. age in wks)*
☐ MSAFP/serum markers _____ *(gest. age [wks])*
☐ Other: _____ *(gest. age in wks)*
(specify test) _____

2.2 Indicate if any of these prenatal tests showed evidence of a major structural or chromosomal defect.

☐ Unknown *(go to section 3)*
☐ No defects detected *(go to section 3)*
☐ Yes (√) test(s) where defect noted and gest. age
☐ Ultrasound _____ *(gest. age [wks])*
☐ Amniocentesis _____ *(gest. age [wks])*
☐ MSAFP/serum markers _____ *(gest. age [wks])*
☐ Other: _____ *(gest. age [wks])*
(specify test) _____
Specify defect _____
_____

3. RIBAVIRIN THERAPY DURING PREGNANCY (including interferon)

*1. Use the med. codes below for medication taken during pregnancy. If not coded **Specify Medication***

1. **REBETOL® (ribavirin)**
2. **COPEGUS® (ribavirin)**
3. **REBETRON® (Rebetol + Intron A)**
4. **ribavirin (trade name unknown)**
5. **peginterferon alpha** *(generally given 1 time per week)*
6. **interferon alpha** *(generally given 3-7 times per week)*
7. **interferon** *(type of interferon unknown)*
8. **RIBASPHERE™ (ribavirin)**
9. **Ribavirin (Sandoz)**
10. **Ribavirin (Teva)**
11. **Ribavirin (Zydus)**

2. In the following table, describe each course or change in route for each applicable therapy

Med. Code *(1-11)* *or* *if no code indicated, please write medication name*	**Note who took the ribavirin** *1=female 2=male*	**Total Dose** *(mg/day or /wk or mg/kg/day) *please indicate*	**Route** *(enter code)* *1 = oral tab 2 = oral cap 3 = sub-Q 4 = IM 5 = Other (specify)*	**Date Treatment Course Began** *(ddmonyyyy)*	**Gestation Week Course Began** *0= w/in 6 mon of conception* **Gest. wk calc:** ☐ *(from LMP)* ☐ *(by U/S)*	**Date Treatment Course Stopped** *(ddmonyyyy) or (✓ if ongoing)*	**Gestation Week Course Stopped** *0= w/in 6 mon of conception* **Gest wk calc:** ☐ *(from LMP)* ☐ *(by U/S)*	**Earliest trimester of exposure** *(code 0, 1, 2, 3)*
						☐ Ongoing		
						☐ Ongoing		
						☐ Ongoing		
						☐ Ongoing		
						☐ Ongoing		
						☐ Ongoing		

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Ribavirin Pregnancy Registry
Prenatal Tests, Medication, and Conditions

Registry ID _____ (OFFICE USE ONLY)

Log ID: _____ **Patient Name:** _____*(if authorization received)*

PATIENT (REGISTRATION ONLY) OBSTETRIC PROVIDER

4. OTHER EXPOSURES DURING PREGNANCY *(include prescription, over-the-counter, nutritional supplements, herbal preparations, immunizations, and other treatments during pregnancy)*

4.1	**Medication or Product** ***(Include Rx, OTC, herbal, topical)***	**Indication**	**Total Dose** *(include units & interval, if applicable or indicate if topical)*	**Date Treatment Course Began** ***(ddmonyyyy)***	**Gestation Week Treatment Began** *(0 = prior to conception)*	**Date Treatment Course Stopped** *(ddmonyyyy) or (✓ if ongoing)*	**Gestation Week Treatment Stopped** *(0 prior to conception)*	***ETE**** *(code 0,1,2,3)*
1						☐ Ongoing		
2						☐ Ongoing		
3						☐ Ongoing		
4						☐ Ongoing		
5						☐ Ongoing		
6						☐ Ongoing		
7						☐ Ongoing		
8						☐ Ongoing		
9						☐ Ongoing		
10						☐ Ongoing		

***ETE = Earliest Trimester of exposure, (code 0=prior to conception, 1= 1st trimester. 2=2nd trimester, 3= 3rd trimester**

5. CONCURRENT MEDICAL CONDITIONS

5.1	**Concurrent Medical Condition**	**Date Condition Began** *(ddmonyyyy)*	**Gestation Week Began** *(0 = prior to conception)*	**Date Condition Stopped** *(ddmonyyyy) (✓ if ongoing)*	**Gestation Week Condition *Stopped***	**Earliest trimester of exposure**	**Worsening during pregnancy** *(✓ if Yes)*
1				☐ Ongoing			☐ Yes
2				☐ Ongoing			☐ Yes
3				☐ Ongoing			☐ Yes
4				☐ Ongoing			☐ Yes
5				☐ Ongoing			☐ Yes
6				☐ Ongoing			☐ Yes
7				☐ Ongoing			☐ Yes
8				☐ Ongoing			☐ Yes

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Ribavirin Pregnancy Registry
Prenatal Tests, Medication, and Conditions

Registry ID _____ (OFFICE USE ONLY)

Log ID: _____ **Patient Name:** _____ *(if authorization received)*

PATIENT (REGISTRATION ONLY) OBSTETRIC PROVIDER

6. TOBACCO AND ALCOHOL USE

	Prior to conception (√)	Trimester of Pregnancy: First (√)	Second (√)	Third (√)
Alcohol ☐ None	☐	☐	☐	☐
Tobacco ☐ None	☐	☐	☐	☐

7. PREGNANCY STATUS

Form Type *(note last form chk'd)*	**Pregnancy Status**
☐ 1) At Registration	☐ ongoing ☐ outcome occurred *(Complete Ob HCP Follow-up at Outcome Form)*
☐ 2) At Follow-up (1st Trimester)	☐ ongoing ☐ outcome occurred *(Complete Ob HCP Follow-up at Outcome Form)*
☐ 3) At Follow-up (2nd Trimester)	☐ ongoing ☐ outcome occurred *(Complete Ob HCP Follow-up at Outcome Form)*
☐ 4) At Follow-up (At Outcome)	*(Complete Ob HCP Follow-up at Outcome Form)*

OBSTETRIC HEALTH CARE PROVIDER INFORMATION (completed at Registration)

Name _____ Specialty _____

Address _____ Phone _____

_____ Fax _____

_____ Email _____

Alternate Contact _____

Provider's Signature _____ Date _____ _____ _____
dd mon yyyy

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