The Antiretroviral Pregnancy Registry
Instructions for completing the FOLLOW-UP FORM

Patient (Log) ID: The Registry assigned number for the patient assigned at registration number *(not required if registering via internet)*.

1. Maternal Information

1.1. **Clinical Study:** Indicate if the patient is in a clinical study and if yes, whether that study is being conducted in pregnant women. If yes, please provide the study/protocol number.

2. Fetal Outcome

If there are multiple outcomes (e.g., twins, triplets) provide details for each outcome. Make copies of page 3 or indicate the information for each outcome.

2.1 **Birth Defect Noted:** Was a structural birth defect noted? Check "yes", "no", or "unknown". If yes, then list defects on the next page. *Please try to determine if a defect was present. If this information is unknown, this case cannot be included in the analysis.*

2.2 **Outcome:** Check one box for outcome (live birth, spontaneous or induced abortion, or stillbirth). For a fetal loss, provide details on page 4, section 4 of the form.

2.3 **Date of Outcome:** Provide the date live birth or fetal loss occurred.

2.4 **Gender:** Provide the gender of the infant.

2.5 **Length:** Provide the length of the infant at birth (indicate "N/A" if not available).

2.6 **Gestational Age:** Provide the gestational age at outcome.

2.7 **Birth Weight:** Provide the birth weight in grams (indicate "N/A" if not available).

2.8 **Head Circumference:** Provide the infant's head circumference at birth (indicate "N/A" if not available).

3. Birth Defects

1) List the structural birth defect(s) and 2) indicate if the defect, in your opinion, was attributed to the antiviral therapy ("yes", "no", or "unknown") and 3) if other factors might have contributed to this outcome.

4. Fetal Loss (Stillbirth, Spontaneous or Induced Abortion)

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

ANTIVIRAL THERAPY DURING PREGNANCY FORM

- **Med Code:** Indicate the code number from the list above. If it is a drug that is not listed, provide the name of the drug.
- **Total Daily Dose:** Provide the total daily dose with units (e.g., stavudine 80 mg, ZDV (IV) 650 mg).
- **Route:** Provide the code "1" for oral, "2" for IV, and "3" for subcutaneous (sub-Q)
- **Pt taking Meds at Conception?:** "1" if yes at conception, "2" if during pregnancy, "3" if unknown.
- **Gestation Week Course Began:** Indicate the gestation week (if unknown and a date the therapy began is available, that is sufficient) when treatment began.
- **Date Treatment Began:** Indicate the date therapy began for each course.
- **Gestation Week Calculated:** At times, we must contact providers when dates and gestation weeks provided are not consistent with the dates for LMP or EDD written on the Registration Form. To ensure that we are calculating from the same date and to save having to contact you, we have added a box for indicating how the gestation weeks were calculated.
- **Gestation Week or Date Therapy was Discontinued or if Continuing Following Delivery:** Provide date or gestation week or if therapy continues through and following delivery, check "ongoing" box. Be sure to check this field for therapies reported at Registration.

You will receive a copy of this form with the information as submitted at Registration. Please update and append any further therapy information on this form.

Please write "unk" or "N/A" on the forms if any information is unknown or not applicable.

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 drug and/or FDA. FDA can be reached by faxing the information to 800-FDA-0178 or at http://www.fda.gov/medwatch/.

Phone: (US, Canada) 800-258-4263 (Toll Free) or 910-256-0238
Phone: (International) +910-256-0238 or (UK, Germany, France) 00800-5913-1359 (Toll Free)
Phone: (Europe): +32-2-714-5028
Internet: www.APRegistry.com
Address: Research Park, 1011 Ashes Drive, Wilmington, NC 28405

CONFIDENTIAL

Revised (December 2007)

ANTIRETROVIRAL PREGNANCY REGISTRY

FOLLOW-UP FORM

FOR OFFICE USE ONLY (3)

Registry Patient ID _____ HCP ID _____

Date Case Closed _____ _____ _____ ☐ Phone

☐ Normal Outcome Verified

Fax to: 800-800-1052 (US, Canada)
910-256-0637 (International) or +32-2-714-5024 (Europe)
00800-5812-1658 (UK, Germany, France)

Patient (Log) ID _____ ***The Registry assigned, non-patient identifying patient ID number***

1. MATERNAL INFORMATION

1.1 Is the patient enrolled in a clinical study? *(treatment or observational study)* ☐ Yes ☐ No ☐ Unknown

If yes, provide the protocol number _____

Was the clinical trial conducted in pregnant women? ☐ Yes ☐ No ☐ Unknown

2. FETAL OUTCOME

2.1 Birth Defect Noted? ☐ Yes *(If yes, list on page 4)* ☐ No ☐ Unknown

FOR REGISTRY USE ONLY

2.2 Outcome: ☐ Live Infant — Baby ID: _____

☐ Abortion, Spontaneous
☐ Abortion, Induced
☐ Stillbirth

If a fetal loss, go to page 4: Defects (section 3) and/or other factors that may have contributed to the fetal loss (section 4)

2.3 Date of Outcome: ____ ____ ____ (M D Y)

2.4 Gender: ☐ Male ☐ Female

2.5 Length: _____ ☐ cm. ☐ in.

2.6 Gestational Age: _____ weeks

2.7 Birth Weight: _____ ☐ grams ☐ lbs/oz.

2.8 Head Circumference: _____ ☐ cm. ☐ in.

NOTES:

- **If DEFECT or FETAL LOSS, go to page 4**
- **Complete the enclosed ANTIVIRAL THERAPY DURING PREGNANCY form. The form includes the initial information provided to the Registry at registration.**

HEALTH CARE PROVIDER INFORMATION

Name _____ Specialty _____

Address _____ Phone _____

_____ Fax _____

_____ Email _____

Alternate Contact _____

Provider's Signature _____ Date ____ ____ ____ (M D Y)

Phone Contact: **US/Canada Phone: 800-258-4263 (Toll Free) or 910-256-0238**
UK, Germany, France Phone: 00800-5913-1359 (Toll Free)
International Phone: +910-256-0238 (US) or +32-2-714-5028 (Europe)
Address: **Research Park, 1011 Ashes Drive, Wilmington, NC 28405**
Internet: **www.APRegistry.com**

CONFIDENTIAL

Revised (December 2007)

Antiretroviral Pregnancy Registry Follow–up Form

FOR OFFICE USE ONLY (4)

Registry Patient ID _____

Patient (Log) ID: _____ ***The Registry assigned, non-patient identifying patient ID number***

Complete this page ONLY if there is a <u>birth defect</u> or information on a <u>fetal loss</u> (stillbirth, spontaneous or induced abortion)

3. BIRTH DEFECTS – *List birth defects below.*

	Birth defect *(list birth defect)*	***Was the defect attributed to antiviral therapy?*** *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.			

4. FETAL LOSS (STILLBIRTH, SPONTANEOUS OR INDUCED ABORTION)

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

1.	
2.	
3.	
4.	

<u>Complete</u> the enclosed ANTIVIRAL THERAPY DURING PREGNANCY Form. The form includes the initial information provided to the Registry at registration.

Thank you for your participation in the Antiretroviral Pregnancy Registry.

Phone Contact: **US/Canada Phone: 800-258-4263 (Toll Free) or 910-256-0238**
UK, Germany, France Phone: 00800-5913-1359 (Toll Free)
International Phone: +910-256-0238 (US) or +32-2-714-5028 (Europe)
Address: **Research Park, 1011 Ashes Drive, Wilmington, NC 28405**
Internet: **www.APRegistry.com**

CONFIDENTIAL

Revised (December 2007)