The Antiretroviral Pregnancy Registry
Instructions for Completing the REGISTRATION FORMS

General Guideline: Date format should always be entered as *DD/MMM/YYYY*

Patient (Log) ID: The Registry assigned Log ID number.

Date first seen during this pregnancy: Provide the date first seen in *DD/MMM/YYYY* format.

1. Maternal Information

Clinical Study: Indicate if the patient is participating in a clinical study by checking "Yes", "No", or "Unknown".

- If no, move to Subsection1.2
- If yes, provide the study protocol number and check "Yes" or "No" if conducted in pregnant woman

Last Menstrual Period (LMP): Provide the LMP date in *DD/MMM/YYYY* format.

Corrected Estimated Date of Delivery (EDD): Provide the EDD based on the 20 week prenatal test, especially if this is the date being used to calculate gestational age for medication exposures and outcome.

Patient Age: Provide age of the pregnant woman at time of conception.

Race: Check the appropriate box for the pregnant woman's race.

2. Prenatal Tests

2.1 **Prenatal Test Done:** Indicate if a prenatal test was done by checking "Yes", "No", or "Unknown".

- If no, move to Section 3: Clinical Indicators.
- If yes, provide the date in *DD/MMM/YYYY* format, or the gestational age, of when the prenatal test was performed and what prenatal test was conducted (ie., Ultrasound, Amniocentesis, MSAFP). If "Other" specify the prenatal test performed.

2.2 **Evidence of a Structural Defect:** Indicate if a structural defect(s) was identified on a prenatal test by checking "Yes", "No" or "Unknown" by each prenatal test done.

- If no, move to Section 3: Clinical Indicators.
- If yes, provide the structural and/or chromosomal defect(s).

3. Clinical Indicators (at the START of pregnancy)

3.1 **Clinical Categories as Defined by the CDC:** www.cdc.gov/mmwr/preview/mmwrhtml/00018871.htm

Check ***all*** appropriate categories as they apply as close to the beginning of the pregnancy as possible.

- **Category A:** Consists of one or more of the CDC defined Category A conditions in a person with documented HIV infection. Conditions in Categories B and C must not have occurred.
- **Category B:** Consists of symptomatic conditions in an HIV-infected person not included in Category C and meeting at least one of the two Category B conditions. For classification purposes, someone previously treated for a Category B condition but who is now asymptomatic should be classified in Category B.
- **Category C:** Includes the clinical conditions listed in the AIDS surveillance case definition. For classification purposes, once a Category C condition has occurred, the person will remain in Category C.

3.2 **CD4 + T-cell Categories:** Check the appropriate range for the counts as they were as close to the beginning of the pregnancy (not applicable should be marked if the patient is not HIV positive).

3.3 **Hepatitis Severity Indicator:** Check the appropriate indication for severity of the hepatitis at a time as close to the beginning of the pregnancy as possible (not applicable should be marked if the patient does not have hepatitis or if Pugh score is not yet known).

ANTIVIRAL THERAPY DURING PREGNANCY FORM

- **Med Code:** Indicate the code number from the list provided. If a drug 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 or Gestational Age Course Began:**
  - Provide start date in *DD/MMM/YYYY* format, ***OR***
  - Provide gestational age course began. If gestational age is known, check the calculation source: LMP or Corrected EDD. This will help to ensure the Registry is calculating from the same date.
- **Date Treatment Stopped or Ongoing:**
  - Provide date, or gestation week, treatment stopped in *DD/MMM/YYYY* format, ***OR***
  - Check "Ongoing" if treatment continues following outcome of pregnancy.

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 the FDA. FDA can be reached by faxing the information to 800-FDA-0178 or at http://www.fda.gov/Safety/MedWatch/default.htm

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

Revised (April 2010)

ANTIRETROVIRAL PREGNANCY REGISTRY
REGISTRATION FORM

Fax to: 800-800-1052 (US, Canada)
+910-256-0637 (International) or +32-2-714-5024 (Europe)
00800-5812-1658 (UK, Germany, France)
888-259-5618 (Brazil)

FOR OFFICE USE ONLY (1)

Registry Patient ID _____ HCP ID _____

Prospective ☐ Retrospective ☐ 100% provider ☐

Country _____ State _____

Report type Original U/L ☐ MP ☐ Current U/L ☐ MP ☐

Registry date of notification _____ _____ _____ ☐ Phone

Patient (Log) ID: _____ ***Registry assigned ID number or Sponsor MCN***

Note: To help assure patient anonymity the Registry uses a Registry assigned patient ID to refer to your patient to obtain follow-up and outcome information.

Date patient first seen during this pregnancy

Date: _____ _____ _____
M D Y

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

1.2 Last Menstrual Period _____ _____ _____
DD MMM YYYY

1.3 Corrected EDD _____ _____ _____ *(e.g., by ultrasound)*
DD MMM YYYY

1.4 Patient Age: _____ *(at conception)*

1.5 Race: ☐ White ☐ Black ☐ Hispanic ☐ Asian ☐ Other (specify) _____

2. PRENATAL TESTS

2.1 Was a prenatal test done?

☐ No *(go to section 3)*

☐ Yes *(complete below and question 2.2)*

Date when test(s) done:

(✓) test(s)		2.2 Is there evidence of a structural defect from one or more of these prenatal tests?
☐ Ultrasound	_____ date	☐Yes ☐No ☐Unknown. If yes, Specify defect _____
☐ Ultrasound	_____ date	☐Yes ☐No ☐Unknown. If yes, Specify defect _____
☐ Ultrasound	_____ date	☐Yes ☐No ☐Unknown. If yes, Specify defect _____
☐ Amniocentesis	_____ date	☐Yes ☐No ☐Unknown. If yes, Specify defect _____
☐ MSAFP/serum markers	_____ date	☐Yes ☐No ☐Unknown. If yes, Specify defect _____
☐ Other:	_____ date	☐Yes ☐No ☐Unknown. If yes, Specify defect _____

☐ Unknown *(go to section 3)*

3. CLINICAL INDICATORS (at the ***START*** of pregnancy)

3.1 Clinical Categories *(√all that apply at the **start** of pregnancy)*:

☐ A. Asymptomatic, acute (primary) HIV or PGL*
☐ B. Symptomatic, not (A) or (C) conditions
☐ C. Other AIDS-indicator conditions and/or CD4<200
☐ D. HIV prophylaxis
☐ E. Hepatitis B (HBV)
☐ F. Hepatitis C (HCV)
☐ Unknown

*PGL-persistent generalized lymphadenopathy

For additional descriptions of categories refer to the 1993 CDC revised classification system, December 1992 issue of MMWR

3.2 CD4+ T-cell Categories *(at **start** of pregnancy)*

☐ ≥ 500 μL
☐ 200-499 μL
☐ <200 μL
☐ Not applicable

3.3 Hepatitis Severity Indicator *(at **start** of pregnancy):*

☐ A. Compensated liver disease (Pugh score <7)
☐ B. Decompensated liver disease (Pugh score ≥7)
☐ C. Not applicable

Complete applicable information on: ANTIVIRAL THERAPY DURING PREGNANCY Form

HEALTH CARE PROVIDER INFORMATION

Name _____ Specialty _____

Address _____ Phone _____

_____ Fax _____

Alternate Contact _____ Email _____

Provider's Signature _____ Date _____ _____ _____
M D Y

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)
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ANTIRETROVIRAL PREGNANCY REGISTRY
ANTIVIRAL THERAPY DURING PREGNANCY

(Initiated at registration and completed at follow-up)

FOR OFFICE USE ONLY (2)

Registry ID_____

☐ Update

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

Complete as much of this page as applicable at Registration. A copy of this form will be sent to you in the expected month of delivery for completion.

4. ANTIVIRAL THERAPY DURING PREGNANCY

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

1. Abacavir (ZIAGEN®, ABC)
1.1 Abacavir generic - Hetero
2. Didanosine (VIDEX®,VIDEX® EC, ddI)
2.1 Didanosine generic – Teva Pharmaceuticals
2.2 Didanosine generic – Aurobindo
2.3 Didanosine generic - Mylan
2.99 Didanosine (unknown manufacturer)
3. Efavirenz (SUSTIVA®, EFV)
3.1 Efavirenz (STOCRIN®, EFV)
3.2 Efavirenz generic - Hetero
3.99 Efavirenz (unknown manufacturer)
4. Lamivudine (EPIVIR®, 3TC)
4.1 Lamivudine generic – Hetero
4.2 Lamivudine+tenofovir df generic – Hetero
4.3 Lamivudine generic – Apotex
4.4 Lamivudine generic - Aurobindo
4.99 Lamivudine (unknown manufacturer)
5. Lamivudine+zidovudine (COMBIVIR®, ZDV+3TC)
5.1 Lamivudine+zidovudine generic - Hetero
5.2 Lamivudine+zidovudine generic – Teva Pharmaceuticals
5.99 Lamivudine+zidovudine (unknown manufacturer)
6. Nelfinavir (VIRACEPT®, NFV)
7. Nevirapine (VIRAMUNE®, NVP)
7.1 Nevirapine generic - Hetero
7.99 Nevirapine (unknown manufacturer)
8. Ritonavir (NORVIR®, RTV)
9. Saquinavir (FORTOVASE®, SQV-SGC)
10. Saquinavir mesylate (INVIRASE®, SQV-HGC)
11. Stavudine (ZERIT®, d4T)
11.1 Stavudine generic – Mylan
11.2 Stavudine generic – Aurobindo
11.3 Stavudine generic – Cipla
11.4 Stavudine generic - Hetero
11.99 Stavudine generic – unknown manufacturer
12. Zalcitabine (HIVID®, ddC)
13. Zidovudine (RETROVIR®, ZDV)
13.1 Zidovudine oral generic - Ranbaxy
13.2 Zidovudine oral generic – Teva/GSK
13.3 Zidovudine oral generic – Roxane/BI
13.4 Zidovudine oral generic – Aurobindo
13.5 Zidovudine oral generic – Cipla
13.6 Zidovudine oral generic – Mylan
13.7 Zidovudine oral generic – Hetero
13.8 Zidovudine oral generic – HEC Pharm
13.99 Zidovudine oral (unknown manufacturer)
14. Amprenavir (AGENERASE®, APV)
15. Indinavir (CRIXIVAN®, IDV)
16. Delavirdine mesylate (RESCRIPTOR®, DLV)
17. Lopinavir+ritonavir (KALETRA®, ALUVIA®, LPV/r)
18. Abacavir+lamivudine+zidovudine (TRIZIVIR®, TZV)
19. Tenofovir disoproxil fumarate (VIREAD®, TDF)
19.1 Tenofovir disoproxil fumarate generic - Hetero
19.99 Tenofovir disoproxil fumarate (unknown manufacturer)
20. Adefovir dipivoxil (HEPSERA®, ADV)
21. Enfuvirtide (FUZEON®, T-20)
22. Atazanavir sulfate (REYATAZ®, ATV)
23. Emtricitabine (EMTRIVA®, FTC)
24. Fosamprenavir calcium (LEXIVA®, FOS)
25. Abacavir+lamivudine (EPZICOM®, EPZ)
26. Tenofovir disoproxil fumarate+emtricitabine (TRUVADA®, TVD)
27. Entecavir (BARACLUDE®, ETV)
28. Tipranavir (APTIVUS®, TPV)
29. Efavirenz+tenofovir disoproxil fumarate+emtricitabine (ATRIPLA™, ATR)
30. Telbivudine (TYZEKA®, SEBIVO ®, LdT)
31. Darunavir (PREZISTA™, DRV)
32. Raltegravir (ISENTRESS™, RAL)
33. Maraviroc (SELZENTRY™, CELSENTRI™, MVC)
34. Etravirine (INTELENCE™, ETR)
35. Rilpivirine (EDURANT™, TMC278)
36. Rilpivirine+Emtricitabine+Tenovfovir Disoproxil Fumarate (COMPLERA®, CPA; EVIPLERA®, EPA)

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

***Med. Code* (1-34) or if no code indicated, please write medication name and indicate if generic**		***Total Daily Dose (mg/day or mg/kg/hr)***	***Route (enter code) 1 = oral 2 = IV 3 = sub-Q***	***Pt Taking Med. at Conception? 1 = Yes 2 = No 3 = Unknown***	***Date Treatment Course Began (DD/MMM/YYYY)* *OR* *Gestational Age Course Began (0 weeks = prior to conception)*** If gestational age, calculation source: ☐ *(LMP)* ☐ *(corrected EDD)*	***Date Treatment Stopped (DD/MMM/YYYY) OR Ongoing?*** (Note: Ongoing = ongoing Following delivery)
Course						
						or ☐ ongoing
						or ☐ ongoing
						or ☐ ongoing
						or ☐ ongoing

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