GENERAL ROUTINE FORMS

P²C² HIV

ELIGIBILITY CHECKLIST

FORM # 01

INSTRUCTIONS

Complete this form at the time of patient enrollment. Enrollment is not complete until identification numbers have been assigned by the computer; therefore, it is important that the form be entered as soon as it is completed.

      (Note: Enter the date the form is completed in the "Enrollment date" field; only in unavoidable circumstances, should "Enrollment date" be different than "Date entered".)

ITEM #	INSTRUCTIONS/NOTES
Institution #	Use the following numbers:
	10 - Baylor College of Medicine
	11 - University of Texas Medical School
	20 - The Children's Hospital, Boston / Harvard Medical
	21 - Boston City Hospital
	30 - Mt. Sinai Medical Center
	31 - Beth Israel Medical Center
	40 - Columbia-Presbyterian Medical Center
	50 - U.C.L.A. School of Medicine
	51 - Children's Hospital, Los Angeles
	52 - U.S.C. County Hospital

1   Indicate to which group the patient is being enrolled.

      Group I: Infants and children (29 days - 13 years) with documented vertically transmitted HIV-infection.

      Group II: Fetuses and infants (less than or equal to 28 days of age) of HIV-infected mothers.

      If Group I, complete question 2 - 6 and 8 - 10.
      If Group II patient, complete question 10 - 13.

      (Note: Refer to Table 2 of the Protocol for a complete list of inclusion and exclusion criteria.)

2a   The child's date of birth must be greater than the enrollment date minus 29 days.

2b   If the child was born prior to 4/1/85, the investigator must be able to document, with reasonable medical certainty, that the child contracted the infection from the mother through vertical transmission.

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ELIGIBILITY CHECKLIST

FORM # 01

ITEM #	INSTRUCTIONS/NOTES

3a Indicate if the child is asymptomatic or symptomatic infection.

3b Due to maternal antibodies, antibody testing is not a reliable means to test for infection in children 18 months of age or younger.

> Asymptomatic children 18 months of age or younger must have a positive culture to document HIV infection.
>
> Children 18 months or younger with P2 symptoms must have no less than positive antibody tests and evidence of both cellular and humoral immune deficiency. A positive culture is desirable.

5 The child must have vertically transmitted disease. If sexually abused, the child does not fit the inclusion criteria.

6 Indicate if the child has been diagnosed with a secondary cancer. The CDC categorizes children with secondary cancer as P-2E. These children are not eligible for this study.

7a Enter the type of Group II enrollment.

7b If prenatal enrollment, enter the estimated gestational age of the fetus (weeks).

7c If postnatal enrollment enter the date of birth. The date of birth must be within 28 days of the date of enrollment.

8a Indicate if documented evidence of the mother's HIV infection is available.

8b If documentation of infection is not available, a brief explanation must be given. In addition, the PI's justification for enrolling the child on study must also be included.

9 Informed consent must be obtained prior to enrollment.

10b The computer will not assign more than one ID# for a participating mother. Enter the mother's ID#.

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ELIGIBILITY CHECKLIST

NOTE: Enrollment is not complete until the eligibility information has been entered into the computer system and a patient number assigned. This form must be entered on the same day of completion.

DF_ENROL

Enrollment date: __ __/__ __/__ __
(mm/dd/yy)

Form #: | 0 1 |

Completed by: _____ - CERTNO
(print name)   (cert. #)

Institution #: INSTNO

- -

1. In which group do you wish to enroll the patient? ....   GROUP
        1 - Group I
        2 - Group II

    GROUP I: Complete questions 2 - 6 and 8 - 10
    GROUP II: Complete questions 7 - 10

Group I

2. a. Enter the child's date of birth (mm/dd/yy) .... __ __/__ __/__ __   BIRTHDATE

    Complete 2b if the child's date of birth is prior to 4/1/85:

    b. Has vertical transmission of HIV infection been   Q2B
        documented with reasonable medical certainty? ....
            0 - no
            1 - yes

3. a. Does this child have asymptomatic or symptomatic   INFSYM
        infection? ....
            1 - asymptomatic (P1 category)
            2 - symptomatic (P2 category)

    If the child is asymptomatic and is 18 months of age or younger, complete 3b:

    b. Has the child had a positive HIV <u>culture</u>? ....   HIVCUL
            0 - no
            1 - yes
                                                            DT_HIVPOS
4. Enter the date of positive HIV test (mm/dd/yy)........ __ __/__ __/__ __

5. Is there any evidence of sexual abuse involving this   SEXABUSE
    child? ....
            0 - no
            1 - yes

6. Has the child been diagnosed with secondary cancer (P-2E)?   CLASS_E
            0 - no
            1 - yes

    SKIP TO ITEM 8a.

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ELIGIBILITY CHECKLIST

Group II

7. a. Is this a prenatal or postnatal enrollment? ....   *NATAL*
        1 – prenatal
        2 – postnatal

If prenatal enrollment, complete 7b; If postnatal enrollment, complete 7c:

    b. What is the gestational age of the fetus (age   *AGEGEST*
        in weeks)? ....
                                        BIRTHDATE

    c. Enter the newborn's date of birth. (mm/dd/yy)..... __ __/__ __/__ __

Group I and II

8. a. Is medical record documentation, of the mother's   *MOTHSTAT*
        HIV infection available? ....
        0 – no
        1 – yes

If no, complete 8b:

    b. Please explain: _____*EXPLAIN*_____

9. Has the informed consent been obtained for this study?   *INFCONS*
        0 – no
        1 – yes

10. a. Does this child have a brother or a sister who has
        also been registered on this study? ....
        0 – no
        1 – yes

If yes, complete 10b:

    b. What is the mother's identification number? .....   *MIDNO* __ __-__ __ __ __-__

IF ALL ELIGIBILITY CRITERIA HAVE BEEN MET, THE SYSTEM WILL ASSIGN AN IDENTIFICATION NUMBER FOR THE PATIENT AND MOTHER. ENTER THESE NUMBERS BELOW:

PATIENT ID #: __-__ *IDNO* __ __-__   **MOTHER'S ID #:** __-__ *MIDNO* __-__
        (system assigned)   (system assigned)

Entered by: __ *CERTMENT* __   Date entered: __ __/*DT-FHENT*/__ __
          (cert. #)   (mm/dd/yy)

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Form 01

Additional Variables added for use at the Coordinating Center

SUBGRP   HIV status for **Group II** patients; Subgroups are
- A   HIV-infected
- B   HIV-uninfected
- blank   HIV-status unknown

DT_ASG   Date assigned to subgroup

HOWDET   How HIV status determined
- *   exception
- C   culture
- A   antibody testing
- P   fetal probe

INOUT   Randomized
- 0   out
- 1   in
- 2   sibling of previously randomized in child

DT_RANDM Date randomized

CONFIRM   HIV-negative status confirmed?
- 1   yes

IIBLOST   Group IIB children lost to follow up prior to initiation of randomization
- 1   date lost <= date randomized
- 2   date lost > date randomized
- 3   lost, not randomized

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PERINATAL HISTORY

FORM # 03

INSTRUCTIONS

This form is to be completed on Group II participants at the time of delivery. Part A pertains to the biological mother, Part B to the newborn.

ITEM #	INSTRUCTIONS/NOTES

1   Enter the number of pregnancies <u>including</u> this pregnancy.
[range: 1 - 12]

2   Enter the number of births. (Note: Multiple births, such as twins and triplets, count as one. Still births are included.)
[range: 1 - 12]

3   Enter the number of therapeutic abortions. [range: 0 - 9]
        Therapeutic abortion - induced to save the health or life of the mother.

4   Enter the number of spontaneous abortions. [range: 0 - 9]
        Spontaneous abortion - occurring naturally.

5   Enter the number of prenatal visits (outpatient) made to the obstetrician's office during this pregnancy. [range: 0 - 30]

6   Enter hemoglobin at delivery in grams per deciliter.
[range: 5.0 - 20.0]

7   Enter the mother's pre-pregnancy weight. Record in kilograms.
(lbs. ÷ 2.2 = kg) [range: 25 - 200]

8   Enter the mother's height. Record in centimeters.
(inches x 2.54 = cm) [range: 120 - 205]

9   Enter the total weight gain of the mother during this pregnancy. Record in kilograms. (lbs + 2.2 = kg) [range: 0 - 50]

11 - 21   Indicate if complications were present during the pregnancy by responding "0" (no) or "1" (yes) to <u>each</u> item.

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PERINATAL HISTORY

FORM # 03

ITEM #	INSTRUCTIONS/NOTES
22 - 32	Indicate if the mother had taken medications during the course of her pregnancy by responding "0" (no) or "1" (yes) to each medication listed.
33	Enter the gestational age in weeks. This is by standard examination. [range: 20 - 45]
34	Enter the birth weight of the newborn. Record in grams. (lbs x 453.6 = gms) [range: 300 - 6000]
35	Enter the length of the newborn at birth. Record in centimeters. (inches x 2.54 = cm) [range: 20.0 - 99.9]
36	Enter the head circumference of the newborn. Record in centimeters. (inches x 2.54 = cm) [range: 20 - 50]
37a - 37b	Enter the Apgar score at 1 and 5 minutes. [range: 1 - 10]
39	Enter the number of offspring produced with this pregnancy including the child. [range: 1 - 6]
41-51	Indicate if the newborn had any one of the complications listed. Respond to each item.
52a	Refers to oxygen beyond the delivery room.
52b	If oxygen was administered, enter the total number of days. Count any portion of a day as one day. [range: 1 - 999]
52c	Enter the FIO₂ maximum. This does not include oxygen administered in the delivery room. [range: 0.21 - 1.00]
53b	Enter total number of days for intermittent mandatory ventilation. Count any portion of a day as one day. [range: 1 - 999]
53c	Enter the peak inspiratory pressure in centimeters of H_2O pressure. [range: 0 - 70]

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PERINATAL HISTORY

FORM # 03

ITEM #	INSTRUCTIONS/NOTES
54b	Indicate the duration in days. Count any portion of a day as one day. [range: 1 - 999]
56a - 56d	Indicate if the newborn was discharged on medications. Respond to each item listed with either "0" (no) or "1" (yes).

P²C² STUDY

PERINATAL HISTORY

GROUP II MOTHERS AND GROUP II NEONATES

Patient's ID #: ___ - ___ __JDNO__ __ - __

Completed by: _____

(print name)

Form #: | 0 3 | DT-FORM

Date Completed: __ __/__ __/__ __

(mm/dd/yy)

Code missing data items as follows:

F5 - Unknown   F7 - Not done
F6 - Not applicable   F8 - Date unknown

PART A: OBSTETRICAL HISTORY

MATERNAL HISTORY

1. Gravida (number of) ....   GRAVIDA

2. Para (number of).......................................   PARA

3. Therapeutic Abortion (number of) ....   THERABOR

4. Spontaneous Abortion (number of) ....   SPABOR

INFORMATION SPECIFIC TO THIS PREGNANCY

5. Prenatal Visits (number of) ....   PREVISIT

6. Hemoglobin at delivery (g/dl) ....   HBDEL

7. Pre-pregnancy weight (kg) ....   PREWT

8. Height (cm) ....   HEIGHT

9. Weight gain this pregnancy (kg) ....   GAIN

10. a. Urine testing for illicit drugs performed on mother   UTPERFM

      0 - no

      1 - yes

    If yes, complete 10b and 10c:

    b. Date of test .... __ __/__ __/__ __   DT-UTM

    c. Urine test results ....   UTRESM

      0 - negative

      1 - positive

    If positive, complete 10d and 10e:

    Results (respond to each):

      0 - negative

      1 - positive

    d. Cocaine/Crack ....   UTRESHC

    e. Other (Specify: _____ UTRESHSP _____)   UTRESHO

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PERINATAL HISTORY

Response to items 11 - 32:
   0 = no
   1 = yes

COMPLICATIONS OF THIS PREGNANCY

11. Bleeding ....   _BLEED_
12. Oligohydramnios ....   _OLIGO_
13. Diabetes (including gestational) ....   _DIABETES_
14. Preeclampsia or hypertension ....   _PREECLAM_
15. Prolonged rupture of membrane (> 24 hours) ....   _RUPTMEM_
16. Hospitalization for complication of pregnancy ....   _HOSPCOMP_

   Specify reason(s) for hospitalization (include dates):
   _____ _HOSCOSP_ _____

   _____

17. Positive RPR/VDRL ....   _RPR_
18. Gonococcus (GC) ....   _GONO_
19. Chlamydia ....   _CHLAMY_
20. Herpes Simplex Virus (HSV) ....   _HSV_
21. Other genital infections ....   _OTHGENIT_
   (Specify: _____ _OTHGENSP_ _____)

MEDICATIONS DURING THIS PREGNANCY

22. Lithium ....   _LITHIUM_
23. Anticoagulant ....   _ANTICOAG_
24. Dilantin ....   _DILANTIN_
25. Accutane ....   _ACCUTANE_
26. Tetracycline ....   _TETRACYC_
27. Trimethadione ....   _TRIMETH_
28. Valproic acid ....   _VALPRIC_
29. AZT ....   _AZTMEDS_
30. Vitamins and iron ....   _VITIRON_
31. Antibiotics ....   _ANTIBIO_
32. Other (Specify: _____ _OMPREGSP_ _____)   _OTHMEDPH_

P²C² STUDY
PERINATAL HISTORY

PART B: NEONATAL INFORMATION/NEWBORN

33. Gestational age by standard examination (weeks) ...... *GESTAGE*

34. Birth Weight (gm) .... *BIRTHWT* _ _ _ _

35. Length (cm) .... *LENGTH* _ _ . _

36. Head Circumference (cm) .... *HEADCIR* __ _ _

37. Apgar Score:

    a. 1 minute .... *APGAR1* _ _

    b. 5 minute .... *APGAR5* _ _

38. Type of delivery .... *DELTYPE* _
       1 = vaginal; vertex   3 = cesarean section
       2 = vaginal; breech

39. Number of fetuses .... *FETUSES* _

40.   a. Urine testing for illicit drugs performed on newborn *UTPERF* _
        0 = no
        1 = yes

If yes, complete 40b and 40c:

    b. Date of test .... *DT_UT* _ _/_ _/_ _

    c. Urine test results .... *UTRESULT* _
        0 = negative
        1 = positive

If positive, complete 40d and 40e:

Results (respond to each):
        0 = negative
        1 = positive

    d. Cocaine/Crack .... *UTRES COC*

    e. Other (Specify: _____*UTRESOSP*_____) *UTRESOTH*

COMPLICATIONS

Response to questions 41 - 51:
        0 = no
        1 = yes

41. Respiratory distress syndrome (RDS) .... *RSPDIST*

42. Sepsis (positive blood culture) .... *SEPSIS*

43. Patent ductus arteriosus (PDA) .... *PATDUCT*

44. Pneumothorax / Pulmonary Interstitial Emphysema (PIE) *PTHORAX*

45. Intraventricular hemorrhage (grade III or IV) .... *VENTHEM*

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PERINATAL HISTORY

46. Necrotizing enterocolitis (NEC) ....   *ENTERCL*
47. Right ventricular hypertrophy (RVH) ....   *VENTHYP*
48. Meconium aspiration ....   *MECON*
49. Bronchopulmonary dysplasia (BPD) ....   *BRDYSPL*
50. Congenital heart defects (CHD) ....   *CHD*
51. Other (Specify: _____*OTHCMPSP*_____)   *OTHCMPPH*

NEWBORN RESPIRATORY MANAGEMENT

52. a. Oxygen ....   *OXYADM*
        0 = no
        1 = yes

   If yes, complete 52b and 52c:

     b. Duration (days) ....   __ *OXYDUR*
     c. FIO₂ maximum (beyond the delivery room)..........   __.*OXYFIO2*

53. a. Intermittent mandatory ventilation (IMV) ....   *INTERVNT*
        0 = no
        1 = yes

   If yes, complete 53b - 53c:

     b. Give duration (days) ....   __ *VNTDUR*
     c. Peak inspiratory pressure (PIP) maximum (cm H₂0)...   *PKPRESS*

54. a. Continuous positive airway pressure (CPAP) ....   *POSAIR*
        0 = no
        1 = yes

   If yes, complete 54b:

     b. Give duration (days) ....   __ *PADAYS*

DISCHARGE

55. Date of discharge (mm/dd/yy) ....   *DT-DCHG*
                                                          __ __/__ __/__ __
56. Discharge medications (respond to each):
        0 = no
        1 = yes
     a. Oxygen ....   *DISOXY*
     b. Bronchodilators ....   *DISBRON*
     c. Diuretics ....   *DISDIUR*
     d. Other (Specify: _____*DISOTHSP*_____)   *DISOTH*

_____   *DT FMENT*
Entered by: ___*CERT_NO*___   Date entered: __ __/__ __/__ __
           (cert. #)   (mm/dd/yy)

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PATIENT MEDICAL HISTORY
(GROUP I PATIENTS)

FORM # 04

INSTRUCTIONS

Complete this form for Group I patients during the enrollment period. This form is completed one time only. The information collected on this form must be supported by the patient's medical record.

ITEM #	INSTRUCTIONS/NOTES
2	If the biological parents are not of the same race, enter the patient's race as "9" (other) and specify in the space provided. These groupings are per the CDC.
3	Enter the gestational age by best obstetric estimation (in weeks). [range: 20 - 45] Gestational age is estimated by the following: 1. Last menstrual period 2. Early ultrasound examination 3. Serial physical examination
4	Enter the birth weight of the patient in grams. (lbs x 453.6 = grams) [range: 300 - 6000]
6	This number will include the patient and all other living or dead offspring from the pregnancy. [range: 0 - 6]
7a & 7b	These items refer to respiratory management during the postnatal hospital confinement of the child.
10a	This excludes the confinement of the child immediately following birth.
10c	If response to 10a is yes, specify the main reason for each hospitalization in the space provided. Use only the spaces which are appropriate. [40 characters]
11,12,13,14	At least one of the tests listed must be entered with a positive response in order for this patient to participate in this study.
17	If the patient is asymptomatic, enter the subclass.
18a - 18e	If the patient is symptomatic, enter the P2 symptoms and the date of diagnosis for each.

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PATIENT MEDICAL HISTORY

(GROUP I PATIENTS)

IDNO

Patient's ID #: ___-__ __ __-__   Form #: | 0 4 | *DT-FORM*

Completed by: _____   Date Completed: __ /__ /__
              (print name)   (mm/dd/yy)

Code missing data items as follows:

        F5 — Unknown   F7 — Not done
        F6 — Not applicable   F8 — Date unknown

RESPONSES TO THE FOLLOWING SHOULD BE SUPPORTED BY THE PATIENT'S MEDICAL RECORD.

1. Patient's sex ....   *SEX1* ___

        1 — male
        2 — female

2. Patient's race ....   *RACE1* ___

        1 — White Non-Hispanic
        2 — Black Non-Hispanic
        3 — Hispanic
        4 — Asian/Pacific Islander
        5 — American Indian/Alaskan Native
        9 — Other (Specify: _____ *RACE1SP*)

POSTNATAL PERIOD

3. Gestational age (by best obstetric estimation [wks])   *GESTAGE1* ___

4. Birth weight (gm) ....   *BIRTHWT1* __ __ __ __

5. Type of delivery ....   *DELTYPE1* ___

        1 — vaginal; vertex
        2 — vaginal; breech
        3 — cesarean section

6. Number of fetuses ....   *FETUSES1* ___

7. Respiratory management during initial confinement:

    a. Oxygen administered ....   *OXYADM1* ___

        0 — no
        1 — yes

    b. On respirator ....   *RESPIRAT* ___

        0 — no
        1 — yes

Patient #: ___-___ ___ ___-___

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PATIENT MEDICAL HISTORY
(GROUP I PATIENTS)

8. Discharge medications (respond to each):
   0 - no
   1 - yes

   a. Oxygen ....

   b. Bronchodilators ....

   c. Diuretics ....

   d. Others (Specify: _____*DIS1SP*_____)

   DISOXY 1

   DISBRON 1

   DISDIUR 1

   DISOTH 1

9. Complications during the postnatal period (respond to each):
   0 - no
   1 - yes

   a. Respiratory distress syndrome (RDS) ....

   b. Sepsis (positive blood culture) ....

   c. Patent ductus arteriosus (PDA) ....

   d. Pneumothorax / Pulmonary Interstitial Emphysema (PIE)

   e. Intraventricular hemorrhage (grade III or IV) ....

   f. Necrotizing enterocolitis (NEC) ....

   g. Right ventricular hypertrophy (RVH) ....

   h. Meconium aspiration ....

   i. Bronchopulmonary dysplasia (BPD) ....

   j. Congenital heart defects (CHD) ....

   k. Other (Specify: _____*OTHCP1SP*_____)

   RSPDIST 1

   SEPSIS 1

   PATDUCT 1

   PTHORAX 1

   VENTHEM 1

   ENTERCL 1

   VENTHYP 1

   MECON 1

   BRDYSPL 1

   CHD 1

   OTHCHPMH

PAST HOSPITALIZATIONS

PASTHOSP

10. a. Has the child been hospitalized in the past?
    0 - no
    1 - yes

    If yes, complete 10b and 10c:

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PATIENT MEDICAL HISTORY
(GROUP I PATIENTS)

b. How many times? ....   _Tx HOSP_

c. Indicate the main reason for each hospitalization:

First Hospitalization: _____ _NAR HOSP 1_____

Second Hospitalization: _____ _NAR HOSP 2_____

Third Hospitalization: _____ _NAR HOSP 3_____

Fourth Hospitalization: _____ _NAR HOSP 4_____

HIV AND OTHER TESTING

Items 11 - 14: Indicate if the test was performed (first column). If the response is "1" (yes), enter the date of the test and the test result.

		Test Performed 0 = no 1 = yes	Date of Test (mm/dd/yy)	Results 0 = negative 1 = positive 3 = equivocal
11.	Western Blot	_WBPERF_	__/__/__ _DT-WB1_	_WB1_
12.	ELISA performed	_ELISA1_	__/__/__ _DT-ELI1_	_ELI1_
13.	HIV culture	_HIVCULT_	__/__/__ _DT-HIV1_	_HIV1_
14.	p24 antigen test	_P24AT_	__/__/__ _DT-P241_	_P241_
15.	EBV testing	_EBVDONE_	__/__/__ _DT-EBVT_	_EBVRESUL_

SYMPTOMS

16. Enter the CDC class AT THE TIME OF ENROLLMENT ....   _CDCSYMP_
          1 - P1
          2 - P2

IF P1, COMPLETE ITEM 17; IF P2, COMPLETE ITEM 18.

17. Enter the P1 subclass ....   _P1SUB_
          1 - A (normal immune function)
          2 - B (abnormal immune function)
          3 - C (immune function not tested)

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PATIENT MEDICAL HISTORY
(GROUP I PATIENTS)

P2 SYMPTOMS

Nonspecific findings
More than two months persistence of two
or more unexplained:
01 = Fever
02 = Failure to thrive or > 10% weight loss
03 = Hepatomegaly
04 = Splenomegaly
05 = Lymphadenopathy (≥ 0.5 cm in two or more
      sites)
06 = Parotitis
07 = Diarrhea (with three or more loose stools
      daily persistently or recurrently)

Progressive neurologic disease
11 = Loss of developmental milestones or
      intellectual ability
12 = Impaired brain growth (acquired microcephaly
      and/or brain atrophy on scan)
13 = Progressive symmetric motor deficits (with
      two or more of paresis, abnormal tone,
      pathologic reflexes, ataxia, or gait
      disturbance)

Lymphoid interstitial pneumonitis
21 = LIP (see CDC criteria)

Secondary infectious diseases
31 = PCP
32 = Chronic cryptosporidiosis
33 = Disseminated toxoplasmosis (onset after 1
      month of age)
34 = Extraintestinal strongyloidiasis
35 = Chronic isosporiasis
36 = Candidiasis (esophageal, bronchial, or
      pulmonary)
37 = Extrapulmonary cryptococcoses
38 = Disseminated histoplasmosis
39 = Mycobacterial infection (noncutaneous,
      extrapulmonary or disseminated)

40 = CMV infection (onset after 1 month of age);
41 = Coccidioidomycosis (extrapulmonary or
      disseminated)
42 = Nocardiosis
43 = Progressive multifocal leukoencephalopathy
44 = Herpes simplex virus (chronic, mucocutaneous
      or disseminated ; onset after 1 month of
      age)

Recurrent serious bacterial infections
Two or more within 2 years:
51 = Sepsis
52 = Meningitis
53 = Pneumonia
54 = Abscess of internal organ
55 = Bone or joint infection

Other infections
61 = Oral candidiasis (persisting two months)
62 = Herpes stomatitis (two or more episodes of)
63 = Herpes zoster (multidermitomal or
      disseminated)

Other diseases possibly caused by HIV infection
71 = Hepatitis
72 = Arrythmia
73 = Cardiomyopathy
74 = Nephropathy
75 = Anemia
76 = Thrombocytopenia
77 = Eczema
78 = Seborrhea
79 = Molluscum contagiosum

99 = Other

(Specify:___ *P2SYMSP* ___)

___

18.   Enter the P2 symptoms for this patient (use as many fields as needed):

		P2 Code	Date of Diagnosis
a.	Primary	*P2SYM1*	_ _/DT-P21_ _/_ _
b.	Secondary	*P2SYM2*	_ _/DT-P22_ _/_ _
c.	Secondary	*P2SYM3*	_ _/DT-P23_ _/_ _
d.	Secondary	*P2SYM4*	_ _/DT-P24_ _/_ _
e.	Secondary	*P2SYM5*	_ _/DT-P25_ _/_ _

___

Entered by: _ *CERT-NO* _   Date entered: _ _/DT-FMENT_ _/_ _
       (cert. #)   (mm/dd/yy)

Form # 04.04   Rev. 09/25/91

P²C² HIV

NOTIFICATION OF BIRTH

FORM # 05

INSTRUCTIONS

This form is to be completed at the time of birth for Group II patients enrolled prenatally, and at the time of enrollment for Group II patients enrolled postnatally.

ITEM #   INSTRUCTIONS/NOTES

3   These groupings are per the CDC.

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NOTIFICATION OF BIRTH

GROUP II PRENATAL AND POSTNATAL PATIENTS

Patient's ID #: ___-___ ___ ___-___   *IDNO*

Form #: __0__ __5__

Completed by: _____
(print name)

Date: __ __/__ __/__ __
DT-FORM
(mm/dd/yy)

1. Patient's date of birth   (mm/dd/yy) .... __ __/__ __/__ __   *DT-BIRTH*

2. Patient's sex .... __
        1 - male
        2 - female
SEX

3. Patient's race/ethnicity .... __
        1 - White Non-Hispanic
        2 - Black Non-Hispanic
        3 - Hispanic
        4 - Asian/Pacific Islander
        5 - American Indian/Alaskan Native
        9 - Other (Specify:_____ *RACESP* ____)
RACE

Entered by: _____ *CERT-NO*
(cert. #)

Date entered: __ __/__ __/__ __   *DT-FMENT*
(mm/dd/yy)

Form # 05.00   Rev. 06/01/91

P²C² HIV

POSTMORTEM STUDIES: PART I

FORM # 06

INSTRUCTIONS

This is an "as needed" form and is to be completed by the pathologist along with Part II and III.

ITEM #   INSTRUCTIONS/NOTES

4a-4k   Enter the organ weight for each organ listed. Indicate if the organ
               is fresh or formalin fixed. An entry must be made in each field
               shown. If a weight was not taken, enter "F7" for not done.

5 - 9   Cardiovascular measurements are to be recorded in centimeters.

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POSTMORTEM STUDIES: PART I
ORGAN WEIGHT AND CARDIOVASCULAR MEASUREMENTS

GROUPS I AND II PATIENTS

IDNO

Patient's ID #: ___ - ___ ___ ___ - ___   Form #: | 0 6 |

DT-FORM

Completed by: _____   Date Completed: ___ /___ /___
                    (print name)   (mm/dd/yy)

Code missing data items as follows:

F5 - Unknown   F6 - Not applicable   F7 - Not done

1. Date of autopsy (mm/dd/yy) .... ___ /___ /___ *DT-AUTOP*

2. Body weight (kg) .... ___ ___ . ___ *BDWT*

3. Body length (cm) .... ___ ___ ___ . ___ *BDLGTH*

4. Organ weight (gm):

		Weight (grams)	Type 1 = fresh 2 = formalin fixed
a.	Heart	___ ___ ___ . ___ *HTWT*	*THTY*
b.	Right lung	___ ___ ___ . ___ *RLUNGWT*	*RLUNGTY*
c.	Left lung	___ ___ ___ . ___ *LLUNGWT*	*LLUNGTY*
d.	Liver	___ ___ ___ . ___ *LIVERWT*	*LIVERTY*
e.	Spleen	___ ___ ___ . ___ *SPLEENWT*	*SPEENTY*
f.	Right kidney	___ ___ ___ . ___ *RKIDWT*	*RKIDTY*
g.	Left kidney	___ ___ ___ . ___ *LKIDWT*	*LKIDTY*
h.	Right adrenal gland	___ ___ ___ . ___ *RADRENWT*	*RADRENTY*
i.	Left adrenal gland	___ ___ ___ . ___ *LADRENWT*	*LADRENTY*
j.	Brain	___ ___ ___ . ___ *BRAINWT*	*BRAINTY*
k.	Thymus	___ ___ ___ . ___ *THYMUSWT*	*THYMUSTY*

Form # 06.00   Rev. 12/01/92

Patient #: ___-___ ___ ___-___

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POSTMORTEM STUDIES: PART I
ORGAN WEIGHT AND CARDIOVASCULAR MEASUREMENTS

<u>HEART</u>

5. Valve circumferences (cm):

    a. Tricuspid (TV) ....

    b. Pulmonary (PV) ....

    c. Mitral (MV) ....

    d. Aortic (AV) ....

    VAL VET RI
    __ __.__ __

    VALVEPUL
    __ __.__ __

    VALVEMIT
    __ __.__ __

    VALVEART
    __ __.__ __

6. Ventricular wall thickness (cm):

    Right Ventricle -

    a. Inflow tract (RVI) ....

    b. Outflow tract (RVO) ....

    c. Maximal (RVM) ....

    RVIN WT
    __.__ __

    RVOUTWT
    __.__ __

    RVMAXWT
    __.__ __

    Left Ventricle -

    d. Inflow tract (LVI) ....

    e. Outflow tract (LVO) ....

    f. Maximal (LVM) ....

    LVINWT
    __.__ __

    LVOUTWT
    __.__ __

    LVMAXWT
    __.__ __

7. Chamber dimension (cm):

    Right ventricle -

    a. Inflow tract (RVIT) ....

    b. Outflow tract (RVOT) ....

    RVINCD
    __ __.__ __

    RVOUTCD
    __ __

    Left ventricle -

    c. Inflow tract (LVIT) ....

    d. Outflow tract (LVOT) ....

    LVINCD
    __ __.__ __

    LVOUTCD
    __ __

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POSTMORTEM STUDIES: PART I
ORGAN WEIGHT AND CARDIOVASCULAR MEASUREMENTS

8. External cardiac dimensions: (cm)

   a. Maximal "breadth" .... *MAX BRTH* __ __.__ __

   b. Maximal "a-p" .... *MAX AP* __ __.__ __

   c. Base-apex length .... *BASE AP* __ __.__ __

   d. Ascending aorta (AA) .... *PM AA* __ __.__ __

   e. Main pulmonary artery (MPA) .... *PM M PA* __ __.__ __

   f. Thoracic aorta (TA) .... *PM TA* __ __.__ __

   g. Ductus arteriosus external (DA - E) .... *PM DA E* __ __.__ __

   h. Ductus arteriosus internal (DA - I) .... *PM DA I* __ __.__ __

9. Vessel diameter measurements (cm):

   a. Ascending aorta (AA) .... *VD AA* __ __.__ __

   b. Main pulmonary artery (MPA) .... *VD MPA* __ __.__ __

   c. Thoracic aorta (TA) .... *VD TA* __ __.__ __

   d. Internal diameter ductus arteriosus (PDA-I) ..... *VD PDA I* __ __.__ __

   e. External diameter ductus arteriosus (PDA-E) ..... *VD PDA E* __ __.__ __

Entered by: __ *CERT- NO* __ (cert. #)   Date entered: __ *DT-FMENT* __ (mm/dd/yy)

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POSTMORTEM STUDIES: PART II

FORM # 07

INSTRUCTIONS

This is an "as needed" form and is to be completed, along with Part I and III, by the pathologist when an autopsy is performed.

ITEM #	INSTRUCTIONS/NOTES
3a - 3f	If organisms are identified in the heart, record the specifics in 3b - 3f. Use as many lines as needed. All items in a line must be entered. For example, if an organism is written in the narrative field, it must also be coded in SNOMED, the site must be identified and the method must be recorded.

Complete each line of information <u>as needed</u> and enter "F6" in the first field immediately following the last entry. "F6" designates that entry is complete.

ORGANISM NARRATIVE:
    Write out the organism identified in the biopsy.

ORGANISM CODE:
    Code the organism using the four digit SNOMED Etiology codes (codes with "E" prefix). The prefix has already been provided on the form. Enter the four digit code number.

    If the appropriate code cannot be found in the SNOMED Indices, enter E-0001.

SITE CODE:
    Use the codes listed on the form to record the site.

METHOD IDENTIFIED:
    Use the codes listed on the form to record the method in which the organism was identified. If other diagnostic methods were used, enter "9" (other) and specify in the field provided.

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POSTMORTEM STUDIES: PART II

FORM # 07

ITEM #   INSTRUCTIONS/NOTES

3b - 3e   Example: Mycobacterium found in endocardium by culture.
(continued)

Organism (narrative)	Code (SNOMED)	Site Code (See above)	Method Identified (See above)
b. _Mycobacterium_	E-_2_ _0_ _0_ _0_	_2_	_1_
c. _F6_	E-__ __ __ __	__	__

4a - 4f   If histologic abnormalities are identified, complete items b - f as
5a - 5f   needed. When documenting histologic changes of epicardial vessels
                (item 4b - 4f) or vessels outside of the heart (5b - 5f),
                "additional site codes" must be used to further identify the site.
                When documenting inflammation, fibrosis or degeneration, "additional
                abnormality codes" must be used to further identify the pathological
                changes.

                Complete each line of information as needed and enter "F6" in the
                first field immediately following the last line of entry.

                Examples: a.   Moderate inflammation of the endocardium with
                                 neutrophils and eosinophils

                            b.   Severe myocardial fibrosis, diffuse

                            c.   Moderate necrosis of the left epicardial vessel
                                 (intima, media and adventitia)

                The above would be entered in the following manner:

Site	Abnormality	Degree	* Additional Site Code	** Additional Abnormality Code		
a. _0_ _1_	_1_	_2_	__	_ _3_	_ _4_	_ _F6_
b. _0_ _3_	_3_	_3_	__	_1_ _2_	_ _F6_	_ _F6_
c. _2_ _1_	_8_	_2_	_6_	__ __	__ __	__ __
d. _F6_ __	__	__	__	__ __	__ __	__ __

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POSTMORTEM STUDIES: PART II
CARDIOVASCULAR ABNORMALITIES

GROUPS I AND II PATIENTS

Patient's ID #: ___I b N0___ - ___ ___ ___ - ___   Form #: | 0 7 | DT- FORM

Completed by: _____   Date Completed: __ __/__ __/__ __
                     (print name)   (mm/dd/yy)

Code missing data items as follows:

     F5 - Unknown   F6 - Not applicable   F7 - Not done

CANATOMY

1.   a. Coronary anatomy ....
        0 - normal
        1 - abnormal

    If abnormal, complete 1b:

                        CANATHEM

    b. Describe abnormality: _____

    _____

STMALFOR

2.   a. Structural malformations ....
        0 - no
        1 - yes

    If yes, complete 2b:

                  STMALMEM

    b. Describe: _____

    _____

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POSTMORTEM STUDIES: PART II
CARDIOVASCULAR ABNORMALITIES

3.   a.   Organisms identified ....   *HTORG*

                0 - no
                1 - yes

If yes, complete 3b - 3f as needed:

Site	Method Codes (If more than one applies,
1 = endocardium	1 = culture enter the most definitive method.)
2 = myocardium	2 = stain
3 = pericardium/epicardium	3 = electron microscopy
4 = vascular	9 = other (Specify: _____)
5 = valve	

	Organism (narrative)	Organism Code (SNOMED)	Site Code (See above)	Method Code (See above)
b.	*HTNARR1*	E-_ *HTORG1*	*HTSITE1*	*HTMETH1*
c.	*HTNARR2*	E-_ *HTORG2*	*HTSITE2*	*HTMETH2*
d.	*HTNARR3*	E-_ *HTORG3*	*HTSITE3*	*HTMETH3*
e.	*HTNARR4*	E-_ *HTORG4*	*HTSITE4*	*HTMETH4*
f.	*HTNARR5*	E-_ *HTORG5*	*HTSITE5*	*HTMETH5*

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POSTMORTEM STUDIES: PART II
CARDIOVASCULAR ABNORMALITIES

PMHTABN

4.   a. Histologic abnormalities identified in the heart?
         0 = no
         1 = yes

If yes, complete 4b - 4f as needed:

Site codes		Abnormality codes	Degree codes

1 = Endocardium
2 = Epicardium
3 = Myocardium
4 = Tricuspid valve
5 = Pulmonary semilunar
    valve
6 = Mitral valve
7 = Aortic valve
EPICARDIAL VESSELS
21 = Left *
22 = Right *
23 = Anterior Descending *
24 = Posterior Descending *
25 = Circumflex *
	INTRAMYOCARDIAL VESSELS
	31 = Right atrial
	32 = Right ventricular
	33 = Left atrial
	34 = Left ventricular
	35 = R inflow ventricular
	36 = R outflow ventricular
	37 = L inflow ventricular
	38 = L outflow ventricular
	39 = Ventricular septum
		1 = Inflammation **
		2 = Thrombosis
		3 = Fibrosis **
		4 = Elastosis
		5 = Hypertrophy
		6 = Atrophy
		7 = Degeneration **
		8 = Necrosis
		9 = Interstitial hypercellularity
		    (non-inflammatory)
			1 = slight
			2 = moderate
			3 = severe

* Additional Site Codes	** Additional Abnormality Codes		
An additional code is required for epicardial vessels. Specify: 1 = Intima 2 = Media 3 = Adventitia 4 = Intima & media 5 = Media & adventitia 6 = Intima, media & adventitia	Additional codes are required for the following abnormalities. (Space is provided if more than one code is applicable.) **Inflammation** (cell types) 1 = cell not specified 2 = lymphocytes 3 = neutrophils 4 = eosinophils 5 = macrophages 6 = plasma cells	**Fibrosis** 11 = focal interstitial 12 = diffuse 13 = focal replacement	**Degeneration** 21 = vacuolar 22 = granular 23 = myocytolysis

	Site	Abnormality	Degree	* Additional Site Code	** Additional Abnormality Codes		
b.	HSITE1	HABN1	HDEGREE1	HEPSITE1	HINFLAM1	HFIBRO1	HDEGEN1
c.	HSITE2	HABN2	HDEGREE2	HEPSITE2	HINFLAM2	HFIBRO2	HDEGEN2
d.	HSITE3	HABN3	HDEGREE3	HEPSITE3	HINFLAM3	HFIBRO3	HDEGEN3
e.	HSITE4	HABN4	HDEGREE4	HEPSITE4	HINFLAM4	HFIBRO4	HDEGEN4
f.	HSITE5	HABN5	HDEGREE5	HEPSITE5	HINFLAM5	HFIBRO5	HDEGEN5

Patient #: ___-___ ___ ___-___

P²C² HIV

POSTMORTEM STUDIES: PART II
CARDIOVASCULAR ABNORMALITIES

HACV

5. a. Histologic abnormalities identified in cardiovascular system?

     0 = no
     1 = yes

   If yes, complete 5b - 5f as needed:

Site codes	Abnormality codes	Degree codes
1 = Right renal artery 2 = Left renal artery 3 = Suprarenal artery 4 = Superior messenteric artery 5 = Inferior messenteric artery 6 = Proximal left carotid artery 7 = Carotid a. at circle of wills 8 = Middle cerebral artery *CVOTHSIT* 9 = Other (Specify _____)	1 = Inflammation ** 2 = Thrombosis 3 = Fibrosis ** 4 = Elastosis 5 = Hypertrophy 6 = Atrophy 7 = Degeneration ** 8 = Necrosis 9 = Interstitial hypercellularity (non-inflammatory)	1 = slight 2 = moderate 3 = severe

Additional Site Codes	** Additional Abnormality Codes
An additional code is required for **all** vessels. Specify: 1 = Intima 2 = Media 3 = Adventitia 4 = Intima & media 5 = Media & adventitia 6 = Intima, media & adventitia	Additional codes are required for the following abnormalities. (Space is provided if more than one code is applicable.) **Inflammation** (cell types) **Fibrosis** **Degeneration** 1 = cell not specified 11 = focal interstitial 21 = vacuolar 2 = lymphocytes 12 = diffuse 22 = granular 3 = neutrophils 13 = focal replacement 23 = myocytolysis 4 = eosinophils 5 = macrophages 6 = plasma cells

	Site	Abnormality	Degree	Additional Site Code	** Additional Abnormality Codes		
b.	*CVSITE1*	*CVABN1*	*CVDEG1*	*CVASITE1*	*CVAABN11*	*CVAABN12*	*CVAABN13*
c.	*CVSITE2*	*CVABN2*	*CVDEG2*	*CVASITE2*	*CVAABN21*	*CVAABN22*	*CVAABN23*
d.	*CVSITE3*	*CVABN3*	*CVDEG3*	*CVASITE3*	*CVAABN31*	*CVAABN32*	*CVAABN33*
e.	*CVSITE4*	*CVABN4*	*CVDEG4*	*CVASITE4*	*CVAABN41*	*CVAABN42*	*CVAABN43*
f.	*CVSITE5*	*CVABN5*	*CVDEG5*	*CVASITE5*	*CVAABN51*	*CVAABN52*	*CVAABN53*

Entered by: ___ ___ ___
               (cert. #)

Date entered: ___ ___/___ ___/___ ___
                   (mm/dd/yy)

Form # 07.00   Rev. 12/01/92

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POSTMORTEM STUDIES: PART III

FORM # 08

INSTRUCTIONS

This is an "as needed" form and is to be completed, along with Part I and II, by the pathologist when an autopsy is performed.

ITEM #	INSTRUCTIONS/NOTES

7a - 7b   If a non-diagnostic abnormality is found, it is to be described here. The details of the abnormality will be documented in items 8a - 8e.

8a - 8e   If the response to 7a was "1" (yes), complete 8a - 8e as needed.

Complete each line of information <u>as needed</u> and enter "F6" in the first field immediately following the last line of entry.

Examples: a.   Severe vascular thrombosis
         b.   Moderate focal interstitial parenchymal fibrosis

	Site	Abnormality	Degree	* Additional Codes		
a.	2	2	3	__ __	__ __	__ __
b.	1	3	2	1 1	__ F6	__ F6
c.	F6	__	__	__ __	__ __	__ __

9a - 9f   If an infectious disease is identified, complete 9b - 9f as needed.
11a - 11f   (If identified by special cultures complete 11b - 11f as needed.)

Complete each line of information as needed and enter "F6" in the first field immediately following the last line of entry.

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POSTMORTEM STUDIES: PART III

FORM # 08

ITEM #   INSTRUCTIONS/NOTES

9a - 9f
11a - 11f
(continued)   ORGANISM NARRATIVE:
                    Each organism is to be written in the space provided.

               ORGANISM CODE:
                    Use the Etiology codes found in the SNOMED code book.   The
                    prefix is provided; enter the SNOMED code number.

                    If the appropriate code cannot be found in the SNOMED Indices,
                    enter "E-0001".

               METHOD IDENTIFIED (Item 9b - 9f):
                    Use the method codes listed. If "9" (other) is used, specify
                    the method in the space provided.

               SITE CODE (Item 11b - 11f):
                    Use the site codes provided on the form. If "9" (other) is
                    used , specify the site in the space provided.

               Example: Organisms isolated -   a. Mycobacterium avium
                                                 b. Respiratory syncytial virus
                                                 c. Pneumocystis carinii.

	Organism (narrative)	Organism Code (SNOMED)	Method
b.	Mycobacterium avium	E- 2 0 0 0	1
c.	Respiratory syncytial virus	E- 3 3 7 0	1
d.	Pneumocystis carinii	E- 4 3 3 1	1
e.	F6	E- __ __ __ __	__

12 - 14   Document the immediate and contributing cause of death. If only one
               contributing cause is entered, complete item 13 and enter "F6" in
               the narrative of item 14.   If there were no contributing causes,
               enter "F6" in the narrative field in item 13 (skip item 14).

               Code the cause of death using SNOMED codes. The topography should
               be coded when applicable. If the code for topography cannot be
               found in the SNOMED indices, enter "T-00001". If the topography is
               not applicable, enter "T-00002".

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POSTMORTEM STUDIES: PART III

FORM # 08

ITEM #   INSTRUCTIONS/NOTES

12 - 14   Code morphology, function, disease, and etiology as applicable.
(continued)   Coding must be as complete as possible. Use as many fields as
              needed to accurately code the cause of death.   If the SNOMED code
              for the cause of death cannot be found in the SNOMED Indices, enter
              "D-00001".   If only one or two fields are needed to code the cause
              of death, enter "D-00002" (not applicable) for fields not needed.

              Example: Immediate cause of death -   Septicemia
                        Contributing cause of death - Streptococcus pneumonia

12.   Narrative: _____Septicemia_____

T - 0   X   0   0   0   F - 0   1   1   2   0

                               D - 0   0   0   0   2   (not applicable)

                               D - 0   0   0   0   2   (not applicable)

13.   Narrative: _____Streptococcus pneumonia_____

T - 2   8   0   0   0   M - 4   0   0   0   0

                               E - 2   5   0   0   __

                               D - 0   0   0   0   2   (not applicable)

14.   Narrative: ___F6_____

T - __ __ __ __ __   __ - __ __ __ __ __

                               __ - __ __ __ __ __

                               __ - __ __ __ __ __

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POSTMORTEM STUDIES: PART III
LUNG STUDIES AND FINAL IMPRESSION

GROUPS I AND II PATIENTS

JDNO

Patient's ID #: ___ - ___ ___ ___ - ___   Form #: | 0 8 | *DT FORM*

Completed by: _____   Date Completed: ___ __/__ __/__ __
                        (print name)   (mm/dd/yy)

Code missing data items as follows:

    F5 — Unknown   F6 — Not applicable   F7 — Not done

LUNG

1.   Volume: *RLUNG VOL*

    a. Right lung (ml) ....   __ __ __ __.__

                                                              LLUNG VOL

    b. Left lung (ml) ....   __ __ __ __.__

                                                                LUNGMAL

2.   a. Structural Malformations ....   __
             0 — no
             1 — yes

    If yes, complete 2b:

    b. Describe: _____ *LUNG MAL 2* _____

    _____

                                                        PNEUMO PM

3.   Pneumothorax ....   __
             0 — no
             1 — yes

                                                        IEMPHY

4.   Interstitial emphysema ....   __
             0 — no
             1 — yes

Patient #: ___-__ __ __-__

P²C² HIV

POSTMORTEM STUDIES: PART III
LUNG STUDIES AND FINAL IMPRESSION

LUNGLES

5. a. Inflammatory lesions found ....
        0 = no
        1 = yes

    If yes, complete 5b - 5i:

    b. Bronchopneumonia ....   PMBPNEU

    c. Lobar pneumonia ....   PMLPNEU

    d. Bronchitis PMBRON1

    e. Bronchiolitis PMBRON2

    f. Vasculitis ....   PMVASCU

    g. Pleuritis ....   PMPLEUR

    h. Bronchiectasis PMBRON3

    i. Other (Specify: _____ P M0 TH L2 _____)   PMOTHLES

LUNGNON

6. a. Non-inflammatory lesions found ....
        0 = no
        1 = yes

    If yes, complete 6b - 6h:

    b. LIP ....   PMLIP

    c. PLH ....   PMPLH

    d. Polyclonal polymorphic B cell lymphoproliferative
        disorder ....   PMPOLY

    e. DIP ....   PMDIP

    f. Diffuse alveolar damage ....   PMALV

    g. Chronic passive congestion and/or edema ......   PMCHRON

    h. Other (Specify: _____ PMNONO2 _____)   PMNONOTH

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Patient #: ___-___ ___ ___-___

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POSTMORTEM STUDIES: PART III
LUNG STUDIES AND FINAL IMPRESSION

LGNONBG

7.   a.   Non-diagnostic abnormalities found ....
         0 = no
         1 = yes

     If no, skip to question 9.   If yes complete 7b and item 8.

     b.   Describe: _LG NONDG2_

8.   Assessment of non-diagnostic abnormalities − Complete
     8a to 8e as needed to document pathologic changes present:

Site codes	Abnormality codes	Degree codes
1 = Parenchyma 2 = Vascular 3 = Pleura	1 = Inflammation * 2 = Thrombosis 3 = Fibrosis * 4 = Hemorrhage 5 = Necrosis 6 = Desquamative change 7 = Degeneration * 8 = Deposition of calcium	1 = slight 2 = moderate 3 = severe

* Additional codes are required for the
following abnormalities (Space is provided
if more than one code is applicable.):

Inflammation (cell types)	Fibrosis	Degeneration
1 = cell not specified 2 = lymphocytes 3 = neutrophils 4 = eosinophils 5 = macrophages 6 = plasma cells	11 = focal interstitial 12 = diffuse 13 = focal replacement	21 = vacuolar 22 = granular 23 = myocytolysis

	Site	Abnormality	Degree	* Additional Codes		
a.	LSITE1	LABN1	LDEGREE1	LINFLAM1	LFIBRO1	LDEGEN1
b.	LSITE2	LABN2	LDEGREE2	LINFLAM2	LFIBRO2	LDEGEN2
c.	LSITE3	LABN3	LDEGREE3	LINFLAM3	LFIBRO3	LDEGEN3
d.	LSITE4	LABN4	LDEGREE4	LINFLAM4	LFIBRO4	LDEGEN4
e.	LSITE5	LABN	LDEGEES	LINFLAM5	LFIBRO5	LDEGEN5

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Patient #: ___-__ __ __-__

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POSTMORTEM STUDIES: PART III
LUNG STUDIES AND FINAL IMPRESSION

LUNGORG

9.   a. Organisms identified in the lung ....

        0 – no
        1 – yes

If yes, complete 9b – 9f as needed:

Method Codes   (If more than one code applies,
1 = culture   enter the most definitive method.)
2 = histologic
3 = electron microscopy
9 = other (Specify: _____)

Organism (narrative)	Organism Code (SNOMED)	Method Idenified (See above codes)
b. *LGNARR 1*	E- *LGORG1*	*LGHETH1*
c. *LGNARR 2*	E- *LGORG2*	*LGHETH2*
d. *LGNARR 3*	E- *LGORG3*	*LGHETH3*
e. *LGNARR 4*	E- *LGORG4*	*LGHETH4*
f. *LGNARR 5*	E- *LGORG5*	*LGHETH5*

OTHER STUDIES

10.   Other special studies:
        0 – no
        1 – yes

    a. Conduction system studies ....

PHCONT

    b. Electron microscopy ....

PHEM

    c. Other (Specify: _____ *PHOTHST2* _____)

PHOTHST

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Patient #: ___-__ __ __-__

P²C² HIV

POSTMORTEM STUDIES: PART III
LUNG STUDIES AND FINAL IMPRESSION

OSCP

11. a. Other special cultures performed: . . . .
        0 - no
        1 - yes

    If yes, complete 11b - 11f as needed

Site of Culture Code
1 = nasopharyngeal swab for viral culture
2 = blood culture for bacteria, mycobacteria, fungus, and virus
3 = spleen for viral culture
9 = other (Specify: _____)

	Organism (narrative)	Organism Code (SNOMED)	Site Code (See above codes)
b.	OSCNAR1	E- OSCORG1	OSCSIT1
c.	OSCNAR2	E- OSCORG2	OSCSIT2
d.	OSCNAR3	E- OSCORG3	OSCSIT3
e.	OSCNAR4	E- OSCORG4	OSCSIT4
f.	OSCNAR5	E- OSCORG5	OSCIT5

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Patient #: ___-__ __ __-__

P²C² HIV

POSTMORTEM STUDIES: PART III
LUNG STUDIES AND FINAL IMPRESSION

FINAL IMPRESSION

Code cause of death using SNOMED codes. Topography should always be coded when appropriate and entered in the field indicated with the "T" prefix. Code morphology, function, disease and etiology as applicable. Use as many fields as needed to thoroughly code the cause of death.

12. Immediate cause of death − _____*PHCAUSE1*_____
(narrative)

T - _*PHTOP1*_   __-_ *PHMPH1*

__-_ *PMDIS1*

__-_ *PMETIO1*

13. Contributing cause of death −_____*PHCAUSE2*_____
(narrative)

T - _*PHTOP2*_   __-_ *PHMPH2*

__-_ *PMDIS2*

__-_ *PMETIO2*

14. Contributing cause of death −_____*PHCAUSE3*_____
(narrative)

T - _*PHTOP3*_   __-_ *PHMPH3*

__-_ *PMDIS3*

__-_ *PMETIO3*

Entered by: _*CERT-NO*_   Date entered: __ _*DT-FMENT*_/__ /__ __
(cert. #)   (mm/dd/yy)

Form # 08.00   Rev. 12/01/92

P²C² STUDY

CDC P2 SYMPTOM STATUS
(GROUP I AND IIa PATIENTS)

FORM # 09

INSTRUCTIONS

Complete this form for Group I and Group IIa patients at 6 month intervals. The information should be supported by the patient's medical record.

Routine Schedule:

> Group I and IIa - Complete this form at month 6, 12, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72 and 78.

ITEM #	INSTRUCTIONS/NOTES
-	Code and enter the P2 symptoms for diagnoses that have occurred in the patient since the form was last completed. Once a symptom has been entered, it is not necessary to repeat the entry on subsequent forms, even if the condition is present during the interval.

(See page 2 of these instructions for a list of P2 symptoms. Refer to Appendix 6 of this Forms Manual for the CDC 1994 Revised Classification System for HIV Infection in Children.)

Rev. 08/26/96

P2 SYMPTOM CODES

Nonspecific findings

01 = Fever, persistent (lasting for > 1 month)
02 = Failure to thrive
03 = Hepatomegaly
04 = Splenomegaly
05 = Lymphadenopathy (≥ 0.5 cm in two or more sites)
06 = Parotitis
07 = Diarrhea (with three or more loose stools daily persistently or recurrently)
* 08 = Recurrent or persistent URI, sinusitis, or otitis media
* 09 = Dermatitis

Wasting Syndrome

** 10 = Wasting Syndrome (see CDC 1994 classification system)

Progressive neurologic disease (AIDS Encephalopathy)
11 = Loss of developmental milestones or intellectual ability
12 = Impaired brain growth (acquired microcephaly and/or brain atrophy on scan)
13 = Progressive symmetric motor deficits (with two or more of paresis, abnormal tone, pathologic reflexes, ataxia, or gait disturbance)

Lymphoid interstitial pneumonitis
21 = LIP / PLH

Secondary infectious diseases
31 = PCP
32 = Chronic cryptosporidiosis (with diarrhea persistent for > 1 month)
33 = Toxoplasmosis (onset before 1 month of age;[see code 47 for toxoplasmosis of the brain])
34 = Extraintestinal strongyloidiasis
35 = Chronic isosporiasis (with diarrhea persistent for > 1 month)
36 = Candidiasis (esophageal, tracheal, bronchial, or pulmonary)
37 = Extrapulmonary cryptococcoses
38 = Disseminated histoplasmosis (at site other than or in addition to the lungs or cervical/hilar lymph nodes)
39 = Mycobacterial infection (noncutaneous, extrapulmonary or disseminated)
40 = CMV infection in an organ other than liver, spleen or lymph nodes (onset after 1 month of age)
41 = Coccidioidomycosis (at a site other than or in addition to lungs or cervical or hilar lymph nodes)
42 = Nocardiosis
43 = Progressive multifocal leukoencephalopathy
44 = Herpes simplex virus causing a mucocutaneous ulcer that persists for > 1 month; or HSV bronchitis, pneumonitis, or esophagitis for any duration affecting a child > 1 months of age
* 45 = Varicella, disseminated (complicated chicken pox)
* 46 = Salmonella (nontyphoid) septicemia, recurrent
* 47 = Toxoplasmosis of the brain (onset after 1 month of age)

Recurrent serious bacterial infections
Two or more within 2 years:
51 = Bacterial sepsis
52 = Bacterial meningitis
53 = Bacterial pneumonia
54 = Bacterial abscess of an internal organ
55 = Bone or joint bacterial infection

Other infections
61 = Oral candidiasis (persisting two months in a child > 6 months of age)
62 = Herpes stomatitis (two or more episodes)
63 = Herpes zoster (multidermitomal/ disseminated; or two distinct episodes)

Secondary Cancers
* 65 = Kaposi's sarcoma
* 66 = Lymphoma, primary, in brain
* 67 = Lymphoma, small, noncleaved cell (Burkitt's), or immunoblastic or large cell lymphoma of B-cell or unknown immunologic phenotype
* 68 = Leiomyosarcoma

Other diseases possibly caused by HIV infection
71 = Hepatitis
72 = Arrythmia
73 = Cardiomyopathy
74 = Nephropathy
75 = Anemia
76 = Thrombocytopenia
77 = Eczema
78 = Seborrhea
79 = Molluscum contagiosum
* 80 = Neutropenia
99 = Other

* New codes added (02/03/96 form revision)
** New code added (08/26/96)

P²C² STUDY

CDC P2 SYMPTOM STATUS

(GROUP I and IIa PATIENTS)

Patient's ID #: _IDNO_ ___-__ __ __-__

Completed by: _____
(print name)

Form #: | 0 9 | _DT_FORM_

Date Completed: __ __/__ __/__ __
(mm/dd/yy)

Visit: Month ___ _VISMTH_

Code missing data items as follows: F6 = Not applicable   F8 = Date unknown

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75 = Anemia
76 = Thrombocytopenia
77 = Eczema
78 = Seborrhea
79 = Molluscum contagiosum
* 80 = Neutropenia
99 = Other

(Specify: _SPECP2SM_

* New codes added (02/03/96 form revision)
** Code added (08/26/96 form revision)

1. Enter the P2 symptom codes for diagnoses that have occurred since this form was last completed. It is not necessary to repeat those symptoms previously entered. (Responses to the following should be supported by the patient's medical record. Use as many fields as needed):

	P2 Code	Date of Diagnosis		P2 Code	Date of Diagnosis
a.	_CDCP21_	_DT_P2D1_ __ __/__ __/__ __	e.	_CDCP25_	_DT_P2D5_ __ __/__ __/__ __
b.	_CDCP22_	_DT_P2D2_ __ __/__ __/__ __	f.	_CDCP26_	_DT_P2D6_ __ __/__ __/__ __
c.	_CDCP23_	_DT_P2D3_ __ __/__ __/__ __	g.	_CDCP27_	_DT_P2D7_ __ __/__ __/__ __
d.	_CDCP24_	_DT_P2D4_ __ __/__ __/__ __	h.	_CDCP28_	_DT_P2D8_ __ __/__ __/__ __

Entered by: ___ _CERT_NO_

Date entered: __ __/__ __/__ __ _DT_FMENT_

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P²C² HIV

MORTALITY REVIEW FOR PATIENT AND FETUS

FORM # 10

INSTRUCTIONS

This is an "as needed" form and must be completed if the patient/fetus expires during the study period. The form **must** be completed by the physician directly involved in the care of the patient (Exception: SNOMED coding in item 7 and 8 should be completed by the Nurse Coordinator.) If an autopsy was performed, the primary care physician should consult with the pathologist.

ITEM #	INSTRUCTIONS/NOTES

6a - 6d

If the response to any of these items is **yes**, a copy of the certificate/report/summary must be sent to the CCC. Be sure to remove the patient name, and include the study ID number. Send to:

P²C²HIV Clinical Coordinating Center
The Cleveland Clinic, Desk P-19
9500 Euclid Avenue
Cleveland OH 44195

6e

A brief narrative summary from the attending physician relating to the events surrounding the patient's demise, is **required**. This summary should be sent along with the documents itemized in 6a-6d.

7a

If the response is **yes**, the corresponding investigative report must be sent to the CCC. Be sure to remove the patient name, and include the study ID number.

10

Wasting -

1) persistent weight loss > 10% of baseline, or
2) downward crossing of at least two of the following percentile lines on the weight-for-AGE chart (ie. 95th, 75th, 50th, 25th, 5th) in a child ≥ 1 year of age, or
3) < 5th percentile on a weight-for-HEIGHT chart on two consecutive measurements, ≥ 30 days apart PLUS
   a) chronic diarrhea (i.e. at least two loose stools per day for ≥ 30 days), or
   b) documented fever (for ≥ 30 days, intermittent or constant)

11

Failure to thrive - Drop from normal growth curves on the standard height and weight charts, and below the 5th percentile.

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MORTALITY REVIEW FOR PATIENT AND FETUS

FORM # 10

16 - 17   **DEATH INFORMATION**

<u>Main Cause of Death (only one)</u> - Enter the <u>main</u> cause of death. Only one condition can be the main cause.

The main cause of death is defined as "the single final disease, injury or complication directly causing the death." *[Taken from the 1989 U.S. Standard Certificate of Death]* In most circumstances, the main cause should be more specific than the mode of dying (i.e. cardio-pulmonary arrest should <u>not</u> be designated as the immediate cause of death).

<u>Contributing Cause</u> - Record the contributing causes of death (all that apply.) If there were no contributing causes of death, enter "F2" (not apply) in the narrative of the first line in this section.

The contributing cause of death are "The conditions, if any, leading to the immediate cause of death". *[Taken from the 1989 U.S. Standard Certificate of Death]*

<u>Conditions present but not contributing</u> - Record the conditions present but not contributing to death (all that apply.) If there were no other conditions present, enter "F2" (not apply) in the narrative of the first line in this section.

CAUSE NARRATIVE:
       The condition should be written in the space provided.

CAUSE CODE:
       Code the condition using the codes provided on the form. If cause of death was due to infection, code the etiology in SNOMED; if due to other, code the site and diagnosis in SNOMED; if due to drug use, enter the SNOMED drug code under etiology.

SITE CODE (SNOMED) :
       Code the site codes using SNOMED topography codes. If the code for topography cannot be found in the SNOMED indices, enter "T-00001". If the topography code is not applicable, enter "T-00002".

DIAGNOSIS CODE (SNOMED):
       Code the diagnosis. Use the SNOMED Function (prefix F), Disease (prefix D) or Morphology (prefix M) codes. The prefix must precede the code number. Refer to the alphabetic index, Volume II, for the complete listing of diagnoses.

       Some <u>disease</u> code numbers are only four digits in length. Use as many spaces as needed. Begin the entry from the far left and enter a zero for the last digit.

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MORTALITY REVIEW FOR PATIENT AND FETUS

FORM # 10

<u>ITEM #</u>   <u>INSTRUCTIONS/NOTES</u>

16 - 17 cont.

Example: Wasting syndrome, D-4690

<u>D</u> - <u>4</u> <u>6</u> <u>9</u> <u>0</u> <u>0</u>

If the cause cannot be found in the SNOMED Indices, enter "D-00001".

ETIOLOGY:

For <u>infectious diseases, death due to illicit drug use and trauma</u>, enter the etiology code. The prefix has been provided. If the code cannot be found in the SNOMED Indices, enter "E-0001".

(NOTE: SNOMED Coding should be completed by the Nurse Coordinator.)

CODING EXAMPLE

Example -   Main cause of death: Pneumocystis carinii pneumonia
            Contributing cause of death: Wasting syndrome

a. **Main cause of death:**

Narrative	Cause Code (See Above)	Site Code (SNOMED)	Diagnosis Code (SNOMED)	Etiology Code (SNOMED)
Pneumocystis carinii pneumonia	1 9	T - 2 8 0 0 0	D - 7 5 0 7 1	E - 4 3 3 1

b. **Contributing Causes:**

Narrative	Cause Code (See Above)	Site Code (SNOMED)	Diagnosis Code (SNOMED)	Etiology Code (SNOMED)
Wasting syndrome	6 6	T - 0 0 0 0 2	D - 4 6 9 0 0	E - _ _ _ _
F2	_ _	T - _ _ _ _ _	_ - _ _ _ _ _	E - _ _ _ _

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P²C² HIV

Mortality Review

Form #: | 1 0 |

DT- FORM

Mother's ID #: ___-__ __ __-__   *HJDNO*

Date Completed: __ __/__ __/__ __
(mm/dd/yy)

Patient ID #: ___-__ __ __-__   *JDNO*

Completed by: _____
(print name)

Code no/yes questions as follows: 0 - no
                                     1 - yes

Code missing data items as follows: F5 - Unknown
                                     F6 - Not applicable

1. Date of death .... __ __/__ __/__ __ *DT-DEATH*

2. Where did the patient/fetus die? .... *LOCDEATH* __

      1 - hospital
      2 - home
      3 - hospice
      9 - other (Specify: _____*LOCSPEC*_____)

3. Was the patient DNR? .... *DNR* __

4. Was an autopsy performed? .... *AUTOP* __

5. a. Was the patient hospitalized at the time of death?   *HOSPATD* __

      If yes, enter date of admission .... __ __/__ __/__ __ *DT-ADM*

6. Is the following information available? (send copy of each to the CCC):

   a. Death certificate .... *DEATHCRT* __

   b. Autopsy Report .... *FINAUTOP* __

   c. Hospital discharge summary at the time of death   *HOSPDIS* __

   d. Hospital discharge summary from stay immediately preceding death (not including stay at time of death)   *HOSPDISP* __

   e. Attending physician's summary of events surrounding patient's demise (REQUIRED) .... *APSUMMRY* __

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Mortality Review

7. a. Was a coroner's investigation performed? .... *CORINVES*

If yes, complete 7b and 7c:

b. Name and address of investigation body:

_____ *NAMEADDR* _____

c. Are those findings available now? (Send copy to CCC) *AVAILABL*

8. Did the patient have MAI? .... *MR-MAI*

If yes, how was it diagnosed? _____ *MR-MAISP* _____

9. Did the patient have encephalopathy? .... *MR-ENCEPH*
   0 - no
   1 - yes, HIV encephalopathy
   2 - yes, other encephalopathy

10. Did the patient have wasting? .... *MR-WASTE*

11. Did the patient have failure to thrive? .... *MR-THRIVE*

12. Did the patient have chronic lung disease? .... *MR-CLD*

    If yes, did it contribute to death? .... *MR-CLDC*

13. Did the patient have chronic cardiac disease? .... *MR-CCD*

    If yes, did it contribute to death? .... *MR-CCDC*

14. a. Was death in utero? .... *DEATHUTR*

If yes, complete 14b - 14d.

b. Is delivery record available? .... *DELIVREC*

c. Is placenta report available? .... *PLACREP*

d. Gestational age in weeks? .... *GESTATIO*

15. Was death related to HIV infection? .... *RELHIV*

IF DEATH IN UTERO, COMPLETE ITEM 16
IF DEATH NOT IN UTERO, COMPLETE ITEM 17.

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Mortality Review

16. <u>Death in utero</u> – Code the main cause of death (only one), contributing causes of death (all that apply), and conditions present at death (all that apply). If cause due to infection, code the etiology; If due to other, code the site and diagnosis; If due to illicit drug use, code the drug under etiology.

Cause Codes

Infection (Include SNOMED site, diagnosis and etiology codes with this category):
        10 = Chorioamnionitis
        11 = Funisitis
        12 = Villitis
        13 = Fetal infection with hydrops

Malformation / Genetic disease:
        20 = Malformation / genetic disease

Abnormality of Uteroplacental Circulation:
        30 = Abruption / retoplacental hematoma
        31 = Abnormal placental size

Fetal Growth Retardation
        40 = Fetal growth retardation

Maternal Disease
        50 = Illicit drug use (Code drug under etiology)
        51 = Diabetes
        59 = Other (Include SNOMED Site and diagnosis code)

Other:
        99 = Other (Include SNOMED Site and diagnosis code)

a. **Main cause of death:**

Narrative	Cause Code (See Above)	Site Code (SNOMED)	Diagnosis Code (SNOMED)	Etiology Code (SNOMED)
IuNAR1	IuCAUS1 T - IuSITE1	— - IuDIA1	E - IuETI1

b. **Contributing Causes:**

Narrative	Cause Code (See Above)	Site Code (SNOMED)	Diagnosis Code (SNOMED)	Etiology Code (SNOMED)
IuNAR2	IuCAUS2 T - IuSITE2	— - IuDIA2	E - IuETI2
IuNAR3	IuCAUS3 T - IuSITE3	— - IuDIA3	E - IuETI3
IuNAR4	IuCAUS4 T - IuSITE4	— - IuDIA4	E - IuETI4
IuNAR5	IuCAUS5 T - IuSITE5	— - IuDIA5	E - IuETI5
IuNAR6	IuCAUS6 T - IuSITE6	— - IuDIA6	E - IuETI6

c. **Conditions present but not contributing:**

Narrative	Cause Code (See Above)	Site Code (SNOMED)	Diagnosis Code (SNOMED)	Etiology Code (SNOMED)
IuNAR7	IuCAUS7 T - IuSITE7	— - IuDIA7	E - IuETI7
IuNAR8	IuCAUS8 T - IuSITE8	— - IuDIA8	E - IuETI8
IuNAR9	IuCAUS9 T - IuSITE9	— - IuDIA9	E - IuETI9
IuNAR10	IuCAUS10 T - IuSITE10	— - IuDIA10	E - IuETI10
IuNAR11	IuCAUS11 T - IuSITE11	— - IuDIA11	E - IuETI11

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Mortality Review

17. <u>Death Not in Utero</u> — Code the main cause of death (only one), contributing causes of death (all that apply), and conditions present at death (all that apply). If cause due to infection, code the etiology; If organ failure, prematurity or other, code the site and diagnosis; If traumatic death, code the site, diagnosis and etiology; If drug reaction, code the drug under etiology.

<u>Cause Codes</u>
Infection (Include SNOMED topography, diagnosis and etiology codes with this category):
- 15 = Bacterial
- 16 = Viral
- 17 = Fungal
- 18 = Sepsis (type unknown)
- 19 = Other

Organ Failure (Include SNOMED site and diagnosis codes with this category):
- 60 = Cardiac
- 61 = Pulmonary
- 62 = Renal
- 63 = Neurologic
- 64 = Hepatic
- 65 = Multiple organ failure
- 66 = Wasting
- 69 = Other

Trauma (Include SNOMED site, diagnosis and etiology codes):
- 70 = Accidental
- 71 = Non-accidental
- 72 = Suspicious for induced

Complications of prematurity (Include SNOMED site and diagnosis codes):
- 80 = Complications of prematurity

Other:
- 90 = Adverse drug reaction (Specify the drug using SNOMED etiology codes)
- 99 = Other (Include SNOMED site and diagnosis codes).

a. Main cause of death:

Narrative	Cause Code (See Above)	Site Code (SNOMED)	Diagnosis Code (SNOMED)	Etiology Code (SNOMED)
NuNAR1	NuCAUS1 T - NUSITE1		__ - NuδIA1	E - NUETI1

b. Contributing Causes:

Narrative	Cause Code (See Above)	Site Code (SNOMED)	Diagnosis Code (SNOMED)	Etiology Code (SNOMED)
NuNAR2	NuCAUS2 T - NuSITE2		__ - NuδIA2	E - NuETI2
NuNAR3	NuCAUS3 T - NuSITE3		__ - NuδIA3	E - NuETI3
NuNAR4	NuCAUS4 T - NuSITE4		__ - NuδIA4	E - NuETI4
NuNAR5	NuCAUS5 T - NuSITE5		__ - NuδIA5	E - NuETI5
NuNAR6	NuCAUS6 T - NuSITE6		__ - NuδIA6	E - NuETI6

c. Conditions present but not contributing:

Narrative	Cause Code (See Above)	Site Code (SNOMED)	Diagnosis Code (SNOMED)	Etiology Code (SNOMED)
NuNAR7	NuCAUS7 T - NuSITE7		__ - NuδIA7	E - NuETI7
NuNAR8	NuCAUS8 T - NuSITE8		__ - NuδIA8	E - NuETI8
NuNAR9	NuCAUS9 T - NuSITE9		__ - NuδIA9	E - NuETI9
NuNAR10	NuCAUS10 T - NuSITE10		__ - NuδIA10	E - NuETI10
NuNAR11	NuCAUS11 T - NuSITE11		__ - NuδIA11	E - NuETI11

Entered by: __ __ __
(cert. #)

Date entered: __ __/__ __/__ __
(mm/dd/yy)

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