AS NEEDED FORMS

P^2C^2 STUDY

Clinical Research Nurse Survey

FORM # 85

On 3/25/96 , this survey was mailed directly to each Nurse Coordinator on the P^2C^2 study. The following instructions were included:

INSTRUCTIONS

1. You are asked to complete the enclosed survey and return it by Friday, April 5, 1996 to the Nurse Coordinator at your designated clinical center where the survey data will be entered.

2. Enter your CCC assigned certification number on the form. Do not include your name.

3. When responding to the survey questions, consider your past and current activities within the P^2C^2 study.

4. If you have any questions about the survey as you are completing it, contact Diane Carp or Gloria Xanthos at Mount Sinai School of Medicine by E-mail or phone at (212) 241-1849.

P^2C^2 Clinical Research Nurse Survey

Form #: 8 5

Enter your Cert. number: NUR-CERT
(Cert. # of individual completing this survey)

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

Please respond to all yes/no questions using the following codes:

0 = no
1 = yes

Demographics

1. Enter you institution number ..... INST-NO

2. How long have you been working on the P^2C^2 Study? ..... HOWLONG
   1 = < 1 year
   2 = 1 – 2 years
   3 = 3 – 4 years
   4 = ≥ 5 years, but not before 09/01/90
   5 = Since the commencement of the study

3. a. Was the P^2C^2 Study your first job in research? ..... FIRSTJOB

   If no, response to 3b.

   b. How many years of research experience did you have prior to the P^2C^2 Study. ..... YRSEXPP
      1 = < 1 year
      2 = 1 – 2 years
      3 = 3 – 4 years
      4 = ≥ 5 years

4. How may years of nursing experience do you have since graduation from your basic nursing program (include years working on the P^2C^2 Study) ..... YRSEXPG
   1 = < 2 years
   2 = 2 – 4 years
   3 = 5 – 7 years
   4 = 8 – 10 years
   5 = > 10 years

5. Indicate previous nursing experience prior to P²C² .

a.	None	PENONE
b.	Adult (including med/surg, ICU, floor nursing)	PEADULT
c.	Pediatrics (including med/surg, ICU, floor nursing)	PEPEDS
d.	Neonatal (includes critical care)	PENEONAT
e.	Emergency room	PEER
f.	Outpatient clinic	PEOUTPT
g.	Maternal and child care	PEMATCHD
h.	Pulmonary	PEPULM
i.	Cardiology	PECARD
j.	HIV/AIDS	PEHIV
k.	Nurse educator	PEEDUCA
l.	Nurse administrator	PEADMIN
m.	Research	PERESEAR
n.	Other : (specify: PEOTHSP)	PEOTHER

Characteristic of Current Position and Responsibilities

6. What is your JOB TITLE in P²C²? ..... JOBTITLE
   1 = Nurse Coordinator
   2 = Clinical Research Nurse
   3 = Pulmonary Research Nurse
   4 = Cardiology Research Nurse
   5 = Study Nurse
   9 = Other (specify: TITLESP)

7. What is your nursing classification at your specific site? CLASSIF
   1 = Nurse Clinician
   2 = Nurse Practitioner
   3 = Staff Nurse
   4 = LPN
   9 = Other (specify: CLASSP)

8. Document degrees held (four spaces provided): DEGREE1 DEGREE2 DEGREE3 DEGREE4

1 = BSN
2 = MSN/MS
3 = MA
4 = BA
5 = PHD
6 = Associates
7 = Nurse Diploma
9 = Other (specify: DEGREESP)

9. Do you have a certification for HIV counselling? ..... COUNSEL

10. a. During your employment with P²C², have you pursued further education? ..... FURTHED

If yes, describe: FURTHSP

11. a. Did you have a written job description of your P²C² position when you started with P²C²? ..... WRITTEND

If yes, complete 11b:

b. Do you think the job description was adequate? ..... ADEQUD

If no, please explain: ADEQUDSP

12. Have you developed a job description since joining P²C²? DEVDESCR

If yes, explain briefly why you developed it:

DEVDESSP

13. At your center, to whom do your directly report? REPORT

1 = Principal Investigator
2 = Nurse Coordinator
3 = Cardiology department
4 = Pulmonary department
5 = Nursing department
6 = I.D. department
7 = Pediatric department
9 = Other (specify: REPORTSP)

14. a. Do you work part-time or full-time on the P²C² Study? .... PARTFULL
    1 = part-time
    2 = full-time

    b. How many hours per week do you work on the P²C² Study? ... HOURWORK

15. a. Are you directly involved with any other clinical studies? OTHSTUD

If yes, respond to the following and indicate hours spent on each per week

	0 =no 1 = yes	No. of Hours
b. ACTG	ACTGST	ACTGHRS
c. WITS	WITSST	WITSHRS
d. Other (specify: OTHSTSP)	OTHST	OTHHRS

16. a. Have you been involved in P²C² nursing ancillary studies? ANCSTUDY

If yes, indicated which ones (respond to each)

b. DHST ..... ANDHST

c. Teddi Tops ..... ANTEDTOP

d. One sedation for cardiac and pulmonary procedures ..... ANONESED

17. Have you been, or are you involved in any of the following related to the P²C² Study?

a. Prepared an article..... PREPART

b. Publication ..... PREPPUB

c. Poster session ..... PREPPOST

d. Presentation ..... PREPPRE

e. Roundtable discussion ..... PREPDISC

f. Abstract ..... PREPABS

g. Other (specify: PREPOTSP) PREPOTH

18. Do you have responsibilities outside of the P²C² Study at your site? (i.e. responsibilities in clinical areas or other areas of your department) ..... RESPON

If yes, please specify: RESPONSP

19. Do you carry a "beeper" at work? .... BEEPER

20. Are you responsible for being on call for P^2C^2 patients outside of work hours? .... OUTSIDE

21. Are you ever required to work overtime for P^2C^2? .... OVERTIME

* *
* ITEMS 22 - 29 REFER TO YOUR EXPERIENCES WHILE WORKING ON THE *
* P^2C^2 STUDY. *
* *

22. Have you ever performed the following activities?

Respond to questions 22a through 22nn using the codes provided below:

0 = never
1 = sometimes
2 = often
3 – always

a. Screen and interview prospective study employees ..... ACTSCREN

b. Orient new study staff members .... ACTORIEN

c. Evaluate study staff members performances .... ACTEVAL

d. Supervise staff .... ACTSTAFF

e. Organize regular meeting with PI and or subsite ...... ACTMEET

f. Inservice education .... ACTEDUIN

g. Recruit study participants .... ACTRECRU

h. Enroll study patients .... ACTENROL

i. Involved in retention of cohort .... ACTRETEN

j. Develop patient education materials .... ACTEDUM

k. Educate families regarding HIV/AIDS .... ACTEDUFM

l. Educate clients regarding study protocols, procedures and treatment plans .... ACTEDUCL

m. Act as resource person for families and physicians ACTRESOR

n. Retrieve patient test results .... ACTRESUL

o. Refer clients to other care areas when necessary ACTREFER

p. Follow up on hospitalized patients .... ACTHOSP

q. Schedule appointment for study visits .... ACTSCHED

22. continued ...

Respond to questions 22a through 22nn by using the following codes:

0 = never
1 = sometimes
2 = often
3 = always

r.	Schedule appointments for non-study visits	ACTSCHVS
s.	Arrange patient transportation to study visits	ACTTRANS
t.	Escort patients to various hospital departments	ACTESCOR
u.	Provide emotional support and caring to enrolled families	ACTEMOTI
v.	Approach families for autopsy	ACTAUTOP
w.	Coordinate autopsy procedures	ACTCORAU
x.	Attend funeral/memorial services of deceased clients	ACTFUNER
y.	Solicit donations to give to clients	ACTDONA
z.	Travel to other hospitals to collect data/perform tests	ACTDATAT
aa.	Travel to other sites for P²C² meetings	ACTMEETT
bb.	Obtain medical records for review	ACTMRREV
cc.	Participate nursing conference calls with the CCC	ACTCALLS
dd.	Conduct reviews required by CCC	ACTREVIE
ee.	Prepare an annual report	ACTREPOR
ff.	Manage budgets	ACTBUDG
gg.	Perform general clerical duties (i.e. xeroxing, filing)	ACTDUTY
hh.	Data entry	ACTDATAE
ii.	Data editing	ACTEDIT
jj.	Investigate data discrepancies	ACTDATAD
kk.	Complete study forms	ACTCOMPL
ll.	Respond to queries and various requests via e-mail	ACTEMAIL
mm.	Run consistency checks	ACTCONCH
nn.	Review study forms completed by other departments	ACTREVFM

23. Have you performed or assisted with the following procedures. Indicate frequency. If there are other study related activities that you feel are important to identify, list under other (items 23r - 23u).

		Performed/Assisted (0 = No, 1 = Perform, 2 = Assist)	Frequency (1 = Sometimes, 2 = Often, 3 = Always)
a.	Obtain lab specimens	PALAB	PALABF
b.	Venipuncture	PAVEN	PAVENF
c.	Physical assessment	PAPHYS	PAPHYSF
d.	EKG	PAEKG	PAEKGF
e.	Holter Monitor application	PAHOLTR	PAHOLTRF
f.	PFT	PAPFT	PAPFTF
g.	Echocardiogram	PAECHO	PAECHOF
h.	Spirometry	PASPIRO	PASPIROF
i.	Chest x-ray	PACXR	PACXRF
j.	CT scan	PACTSCN	PACTSCNF
k.	Bronchoscopy	PABRON	PABRONF
l.	Lung biopsy	PALUNG	PALUNGF
m.	DHST administration	PADHST	PADHSTF
n.	DHST readings	PADHSTR	PADHSTRF
o.	Immunizations	PAIMMU	PAIMMUF
p.	Administration of patient sedation	PAADMIN	PAADMINF
q.	Monitoring of sedated patient	PASED	PASEDF
r.	Other (specify: PAOTH1SP)	PAOTH1	PAOTH1F
s.	Other (specify: PAOTH2SP)	PAOTH2	PAOTH2F
t.	Other (specify: PAOTH3SP)	PAOTH3	PAOTH3F
u.	Other (specify: PAOTH4SP)	PAOTH4	PAOTH4F

24. Have you interacted with the following departments? (Respond to each using the codes listed below.)

0 = never 2 = often
1 = sometimes 3 = always

a.	Pediatric pulmonary	INPEDS
b.	Pediatric cardiology	INCARD
c.	Radiology	INRAD
d.	Nuclear Medicine	INNUCM
e.	Pediatric Infectious disease	ININTDIS
f.	ACTG	INACTG
g.	WITS	INWITS
h.	WIC	INWIC
i.	ER	INER
j.	OR	INOR
k.	PICU	INPICU
l.	Inpatient	ININPT
m.	Outpatient	INOUTPT
n.	Medical records	INMEDREC
o.	Laboratory	INLAB
p.	Pathology	INPATH
q.	Clinical Research Center (CRC)	INCLIN
r.	Dietary	INDIET
s.	Social service	INSOCIAL
t.	Pharmacy	INPHAR
u.	Transport services	INTRANS
v.	Adult HIV/AIDS services	INHIV
w.	Biomedical engineering	INBIO
x.	Print shop	INPRINT
y.	Other (specify: INOTHSP)	INOTH

25. Did you interact with the following departments in earlier phases of the study?

0 = never
1 = sometimes
2 = often
3 = always

a. Prenatal clinic ..... INEPRE
b. NICU ..... INENICU
c. Newborn nursery ..... INENEWB
d. Labor and delivery ..... INELABOR
e. Nuclear medicine ..... INENUC
f. Other (specify: INEOTHSP) INEOTH

26. Indicate off-site agencies that you have interacted with while on the P²C² Study.

a. Nonparticipant hospitals ..... INOHOSP
b. Home care agencies ..... INOHOME
c. Foster care agencies ..... INOFOST
d. Preschool/school centers ..... INOPRES
e. Day care agencies ..... INODAYC
f. Satellite clinic ..... INOSATT
g. Other (specify: INOOTHSP) INOOTH

27. Indicate the number of times you have participated in the following:

a. Annual Nurse Coordinator Workshop ..... WORKSHOP

b. Steering Committee Meeting (**excluding** the joint session with the Steering Committee at the Annual Nurse Coordinator Workshop) ..... PARSCM

28. Have you participated in the following activities?
0 = no
1 = yes

a. Study subcommittee meeting(s) (Cardiac, ID, Publications etc.) SCMEET

(If yes, identify subcommittee(s): SCMEETSP)

b. Study subcommittee conference call (s) ..... SCCALL

(If yes, identify subcommittee(s): SCCALLSP)

29. Outside of the regularly scheduled meetings and conference calls, have you had <u>direct</u> contact with the NIH or its representatives to discuss P^2C^2 related matters? ..... NIHCON
0 = no
1 = yes

If yes, please describe below:

NIHCONSP

30. Have you employed other activities at your center to facilitate the study? ..... OTHACT

If yes, describe and explain below. (Please consider this carefully. Include soliciting of patient incentives, organization of parties, personal anecdotes etc.)

OTHACTSP

Entered by: CERT-NO (cert. #)

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

P^2C^2 HIV

FEEDING INTERVENTION

FORM # 86

INSTRUCTIONS

This form is to be completed for all Group I and II patients. Document the first episode of feeding intervention, which occured at any time since the patient's enrollment, and lasted for more than two months. (We will allow a window of three months prior to enrollment.)

Patient records must be reviewed, and data entered by April 15, 1997.

(NOTE: If the review was not completed prior to the deadline, a missing form must be entered.)

P²C² STUDY
FEEDING INTERVENTIONS

GROUPS I AND II PATIENTS

Patient's ID #: ___-___ ___ ___-___ (JDNO) Form #: 8 6

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

Code missing data items as follows: F5 = Unknown F8 = Date unknown

1. Has the patient had feeding intervention for a period of **more than two months** at anytime while enrolled on the P²C² study, administered for a period of more than two months? ..... ___
   0 = no
   1 = yes

2. Indicate the feeding intervention this patient has undergone for a period of **more than two months**? ..... (FITYPE)
   1 = Gastrostomy tube
   2 = Nasogastric tube
   3 = Parenteral nutrition (hyperalimentation)

3. Start date of intervention ..... __/__/__ (DT-FISTR)

4. Starting weight (kg) ..... ___.___ (FISTRWT)

5. Starting height (cm) ..... ___.___ (FISTRHT)

6. Stop date of intervention ..... __/__/__ (DT-FJSTP)

7. Ending weight (kg) ..... ___.___ (FISTPWT)

8. Ending height (cm) ..... ___.___ (FISTPHT)

9. Comments: _____ (FJCOMM)

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

Form # 86.01 03/20/97

New Variables added 2/17/99

P^2C^2 STUDY

PRIMARY CARETAKER EXIT INTERVIEW

FORM # 87

INSTRUCTIONS

Data for Form 87 is to be obtained directly from the caretakers of Group I, IIa and IIb children currently enrolled in the P^2C^2 study. This form is to be completed by the interviewer in the presence of the primary caretaker or by telephone contact with the primary caretaker. For the purpose of this exit interview the "primary caretaker" is defined as the person living with and assuming the daily care for the child who is the participant in the P^2C^2 study. Data collected for this form is limited to information about the child and caretaker pertaining only to the period of time that the child has been followed in the P^2C^2 study. A Spanish speaking translator is required for caretakers who speak only Spanish. To control for the caretaker's inability or difficulty with reading, the interviewer will state each question and record each response. The Interview Introduction will be read to the caretaker at the beginning of the interview. It should be individualized for each child. This exit interview is to be completed between **December 1, 1996 and January 31, 1997.**

ITEM #	INSTRUCTIONS/NOTES
(PART I)	
1 - 19	Explain to the caretaker that in the first part of the interview you will ask questions that have choices for answers. The caretakers should select from the choices given. Repeat questions and choices as needed to obtain the caretaker's response.
15	Examples of assisitive devices include: wheelchairs, braces, hearing aides, supplemental oxygen, feeding tubes, gastric buttons, etc. Please note devices on the form.
(PART II)	
20 a - u	Prior to proceeding through Part II read through the list of choices that are available for items 20 a-u (choices 0 through 3). Proceed with the interview by reading each item to the caretaker to elicit a response. It may be necessary to re-state the response choices when reading each item. An index card containing the response choices may be used to help with the responses in the in-person interviews. For phone interviews you may need to read the response choices with each item. If caretakers have difficulty rating the services, you can probe for their rating by asking, "If you had to pick one of the choices, which do you think comes closest to what you think about the service?"

P^2C^2 STUDY

PRIMARY CARETAKER EXIT INTERVIEW

FORM # 87

ITEM #	INSTRUCTIONS/NOTES
(PART III)	
21 - 28	Explain that you will ask each question for the purpose of eliciting a response. Inform the caretakers that you will be recording their responses and that there are no "right or wrong" answers. Allow sufficient time for the caretaker to reflect on the questions. Repeat the questions as needed. Interviewer silence and probing may help to elicit responses. Such probes as "How is that?", "In what ways?", or "Is there anything else?" can be used. Record only direct verbal responses.

P^2C^2 HIV

PRIMARY CARETAKER EXIT INTERVIEW

GROUPS I AND II PRIMARY CARETAKERS*

TO BE COMPLETED BY THE INTERVIEWER

Form #: 8 7

Patient ID #: ___-___ ___ ___-___ (IDNO)

Interviewer: _____ (print name) - _____ (INT-CERT cert.#) Date: __/__/__ (DT-FORM mm/dd/yy)

Form Instructions

*** Primary Caretaker - the person living with and assuming the daily care for the child. It should be the person who has usually brought the child for the P^2C^2 study visits.**

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

Part I

1. What is your relationship with the child who has been followed in the P^2C^2 Study? (CHILDREL)
   - 1 = biological parent
   - 2 = biological grandparent
   - 3 = non-kinship foster parent
   - 4 = kinship foster parent
   - 5 = adoptive parent
   - 6 = relative (specify: _____ OTHRELAT)
   - 9 = other (specify: _____ OTHERSP)

2. What is your age? ..... (YOURAGE)

3. What is your gender? ..... (YOURGEND)
   - 1 = male
   - 2 = female

4. What is your race/ethnicity? ..... (YOURRACE)
   - 1 = White Non-Hispanic
   - 2 = Black Non-Hispanic
   - 3 = Hispanic
   - 4 = Asian/Pacific Islander
   - 5 = American Indian/Alaskan Native
   - 9 = other (specify: _____ OTHERRAC)

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

P²C² HIV

PRIMARY CARETAKER EXIT INTERVIEW

5. Use the following codes to respond to items 5a - 5c:
   1 = English
   2 = Spanish
   9 = other (specify: LANGSPEA)

   a. What language do you usually speak ..... LANGHOME

   b. What language is usually spoken in the child's home? LANGCHLD

   c. What language does the child usually speak? ..... LANGOTH

6. How would you describe your health status? ..... YOURHLTH
   1 = excellent
   2 = good
   3 = fair
   4 = poor

7. How long have you had primary responsibility for the care of this child? (years/months) [use decimal to enter a portion of a year if needed]
   PRIMEYRS (years) PRIMEMTH (months)

8. a. Are you responsible for the care of other children or adults? CAREOTH
      0 = no
      1 = yes

   If "1" (yes), complete items 8b - 8e (include the child on study in the count):

   b. Number of children less than 3 years of age? NUMLESS3

   c. Number of children 3 to 5 years of age? NUM3TO5

   d. Number of children 6 to 18 years of age? NUM6TO18

   e. Number of adults? ..... NUMADULT

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

P²C² HIV

PRIMARY CARETAKER EXIT INTERVIEW

9. a. At any point during the time the child has been in your care (see item 7) were you employed?..... EMPLOYED
   0 = no
   1 = yes

   If "1" (yes), complete 9b - 9c:

   b. Number of years part-time ..... EMPLOYPT

   c. Number of years full-time ..... EMPLOYFT

10. Which of the following income sources are used to support this child? :
    0 = no
    1 = yes

    a. Caretaker's employment ..... INCOMECA

    b. Other household resident's employment ..... INCOMEHR

    c. Welfare ..... INCOMWLF

    d. SSI ..... INCOMESS

    e. Other ..... INCOMECT

    (Specify: INCOMESP)

11. What is your highest level of education? ..... EDULEVEL
    0 = no formal education
    1 = primary or grade school
    2 = < 12 years of secondary or high school
    3 = high school graduate
    4 = some college
    5 = college graduate

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

P^2C^2 HIV

PRIMARY CARETAKER EXIT INTERVIEW

12. Have you been actively involved in an educational training program or formal academic program during the period this child was in your care ..... EDUCTRAIN
    0 = no
    1 = yes

    If "1" (yes), please specify: EDUSPEC

13. Use the following codes for items 13a and 13b:

1 = walk	4 = car service
2 = bus	5 = taxi
3 = subway/train	6 = personal car

    a. What method of transportation do you usually use to take this child to P^2C^2 study appointments? ..... TRANSUSU

    b. What method of transportation do you usually use to take this child to health care appointments **other than** for the P^2C^2 Study? ..... TRANSOTH

14. How long does it usually take via the usual method of transportation to get to the medical center where the P^2C^2 visits are done? (Note if the child has to attend more than 1 site for visits, complete the information for each site.)
    1 = < 30 minutes
    2 = 30 = 60 minutes
    3 = 61 – 90 minutes
    4 = 91 – 120 minutes
    9 = Other (specify: TIMESPEC)

    a. Primary P^2C^2 site ..... TIMEPRIM

    b. Secondary P^2C^2 site ..... TIMESECO

15. Does the child require assistive devices? ..... ASSIST
    0 = no
    1 = yes
    If "1" (yes), describe: ASSISTSP

P^2C^2 HIV

PRIMARY CARETAKER EXIT INTERVIEW

16. a. Do you have daily assistance in caring for the child? DAILYAST
0 = no
1 = yes

If "1" (yes), indicate which of the following provides assistance; and if the individual either accompanies you on study visits or takes the child to the P^2C^2 study visits.

	Assistance with Care (0 = no, 1 = yes)	Assistance with Visits (0 = no, 1 = accompanies on visit, 2 = takes child to visit)
b. Relative	AWCREL	AWVREL
c. Friend	AWCFRND	AWVFRND
d. Home health aide	AWCHHA	AWVHHA
e. Other	AWCOTH	AWVOTH

(Specify: AWCOTHSP)

17. In general the P^2C^2 visits: VISITS
1 = were short
2 = were a manageable length of time
3 = took too long

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

P^2C^2 HIV

PRIMARY CARETAKER EXIT INTERVIEW

18. Where does the child receive primary health care? ..... PRIMHLTH
    1 = this P^2C^2 study site
    2 = other P^2C^2 study site
    3 = off site not related to P^2C^2

19. a. Did the child attended a program/school while on the P^2C^2 Study? ..... ATTENDPR
    0 = no
    1 = yes

If "1" yes, indicate the type of program/school, the duration, the average length of a day and the frequency of attendance (complete items 18b - 18d as needed)

	Type 1 = day care 2 = nursery school/preschool 3 = head start program 4 = early intervention 5 = elementary, secondary or high school	**Duration** (years / months)	**Length of a Typical Day** 1 = half days 2 = full days	**Frequency** (no. of days per week)
b.	PRTYPE1	PRDURYR1 PRDURMO1	PRLENGTH1	PRFRQ1
c.	PRTYPE2	PRDURYR2 PRDURMO2	PRLENGTH2	PRFRQ2
d.	PRTYPE3	PRDURYR3 PRDURMO3	PRLENGTH3	PRFRQ3

P^2C^2 HIV

PRIMARY CARETAKER EXIT INTERVIEW

PART II

20. How helpful were the following services/items to you, that were available through the P^2C^2 Study Centers (rate each item).
    0 = service not supplied
    1 = not helpful
    2 = somewhat helpful
    3 = very helpful

a. Transportation to study visits ..... SERTRANS
b. Reimbursement for travel/parking expenses ..... SERREIM
c. Availability for transportation ..... SERAVAI
d. Meal coupons ..... SERMEAL
e. Coupons for food stores ..... SERCOUP
f. Coupons for retail stores ..... SERRETA
g. School supplies ..... SERSCH
h. Stickers ..... SERSTICK
i. Clothing ..... SERCLOTH
j. Child care products ..... SERCCP
k. Parties ..... SERPART
l. Toys ..... SERTOYS
m. Activities to occupy the child during the visit ... SEROCC
n. Coordinating child's appointments ..... SERCCA
o. Coordinating child and mother's appointments ..... SERCCMA
p. Assistance with scheduling/rescheduling appointments SERSCHED
q. Calling to remind caretakers about appointments .. SERREM
r. Obtaining information for other forms (WIC,camp, etc.) SERFORMS
s. A rest place for moms during visits ..... SERREST
t. Accompanying the caretaker and child during the visit SERACCM
u. Phone contact with the study nurses ..... SERPHONE

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

P^2C^2 HIV

PRIMARY CARETAKER EXIT INTERVIEW

PART III

21. Indicate the reasons you have continued to participated in the P^2C^2 Study.

REASCON

22. What service provided by the study, was most helpful for your continuing with study?

SERVICES

23. What part of the study did you find most difficult?

DIFFICUL

24. What suggestions would you make to future study participants, that would help them stay with a study over time?

SUGGST

25. What do you think are benefits for you and your child from participating in such a study?

BENEFIT

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

P²C² HIV

PRIMARY CARETAKER EXIT INTERVIEW

26. From time to time everyone has missed scheduled appointments. What were some of the reasons that may have caused you to miss an appointment?

MISSEDAP

27. What are your thoughts about this study ending?

ENDINGST

28. Is there anything else you would like to add?

ANYADD

****

29. This interview was conducted .....
    1 = in person
    2 = over the telephone

INTVIA

Entered by: CERT-NO
(cert. #)

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

P^2C^2 HIV

NON-CARDIAC, NON-PULMONARY COMPLICATIONS

FORM # 91

INSTRUCTIONS

This form is to be completed for each new non-cardiac, non-pulmonary illness diagnosed. More than one diagnosis may be documented on the form if occurring during the same episode.

Intercurrent and Chronic Illness:

Groups I and II - Complete this form when a final diagnosis has been made.

ITEM #	INSTRUCTIONS/NOTES
1 - 4	Complete as needed. Each item listed (a - d) must be completed for each diagnosis made. Enter "F6" in the first field immediately following the last entry.
a	**DATE OF DIAGNOSIS:** Indicate the date the diagnosis was made.
b	**NARRATIVE:** The diagnosis must be written in the space provided.
c	**SITE CODE:** Code the site of disease. Use the SNOMED 5 digit topography codes. The prefix has been provided, enter the code number only. If the site is not found in the SNOMED Indices or a site cannot be assigned (see general instructions), use the following conventions: T-00001 = Code not found/unable to code T-00002 = Site code not applicable

P^2C^2 HIV

NON-CARDIAC, NON-PULMONARY COMPLICATIONS

FORM # 91

ITEM #	INSTRUCTIONS/NOTES
d	**DIAGNOSIS CODE:** 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 disease code numbers are four digits in length. When entering these codes, use as many spaces as needed. Start the entry from the left and leave the last space blank. Example: Wasting syndrome, D-4690 D - 4 6 9 0 ___ If the diagnosis cannot be found in the SNOMED Indices, enter "D-00001".

P^2C^2 HIV

NON-CARDIAC, NON-PULMONARY COMPLICATIONS

FORM # 91

CODING EXAMPLE

Example: 1. Urinary tract infection
2. Lymphopenia

1. Diagnosis:

a. Date of diagnosis (mm/dd/yy) ..... 0 8 / 0 5 / 9 0

b. Narrative - Urinary tract infection

c. Site code (SNOMED) ..... T - 0 0 0 0 2

d. Diagnosis code (SNOMED) ..... D - 6 5 0 1 ___

(Note: Site could be coded as T-70100 [urinary tract], but the code D-6501 incorporates the site and condition is one code. Code site as T-00002 [not applicable].)

2. Diagnosis:

a. Date of diagnosis (mm/dd/yy) ..... 0 8 / 1 0 / 9 0

b. Narrative - Lymphopenia

c. Site code (SNOMED) ..... T - 0 X 2 1 0

d. Diagnosis code (SNOMED) ..... M - 5 9 1 0 0

(Note: Site code is required in order to fully describe the diagnosis.
T-0X210 [blood lymphocyte cell,NOS] + M-59100 [cytopenia] = lymphopenia)

3. Diagnosis:

a. Date of diagnosis (mm/dd/yy) ..... ___ ___/___ ___/___ ___

b. Narrative - F6

c. Site code (SNOMED) ..... T - ___ ___ ___ ___ ___

d. Diagnosis code (SNOMED) ..... ___ - ___ ___ ___ ___ ___

P^2C^2 HIV

NON-CARDIAC, NON-PULMONARY COMPLICATIONS

GROUPS I AND II PATIENTS

Patient's ID #: ___-___ ___ ___-___ (IDNC) Form #: 9 1

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

Code missing data items as follows:

F5 = Unknown F6 = Not applicable F8 = Date unknown

1. Diagnosis:
   a. Date of diagnosis (mm/dd/yy) ..... __ __/__ __/__ __ (DT_NCP1)
   b. Narrative - _____ (NCP1NARR)
   c. Site code (SNOMED) .....T-__ ___ ___ ___ (SITENCP1)
   d. Diagnosis code (SNOMED) .....___-__ ___ ___ ___ ___ (DIAGNCP1)

2. Diagnosis:
   a. Date of diagnosis (mm/dd/yy) ..... __ __/__ __/__ __ (DT_NCP2)
   b. Narrative - _____ (NCP2NARR)
   c. Site code (SNOMED) .....T-__ ___ ___ ___ (SITENCP2)
   d. Diagnosis code (SNOMED) .....___-__ ___ ___ ___ ___ (DIAGNCP2)

3. Diagnosis:
   a. Date of diagnosis (mm/dd/yy) ..... __ __/__ __/__ __ (DT_NCP3)
   b. Narrative - _____ (NCP3NARR)
   c. Site code (SNOMED) .....T-__ ___ ___ ___ (SITENCP3)
   d. Diagnosis code (SNOMED) .....___-__ ___ ___ ___ ___ (DIAGNCP3)

Patient #: ___-___ ___ ___-___

P²C² HIV

NON-CARDIAC, NON-PULMONARY COMPLICATIONS

4. Diagnosis:

   a. Date of diagnosis (mm/dd/yy) ..... __/__/__ DT_NCP4

   b. Narrative - _____ NCP4NARR _____

   c. Site code (SNOMED) .....T-__ ____ SITENCP4

   d. Diagnosis code (SNOMED) .....___-__ ____ DIAGNCP4

Entered by: ___ ___ CERT-NO
(cert. #)

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

P^2C^2 HIV

PARTICIPATION IN OTHER STUDIES (PATIENT)

FORM # 92

INSTRUCTIONS

The purpose of this form is to document other study information. Enter each study into the data base one time only.

ITEM #	INSTRUCTIONS/NOTES
1 - 4	Complete items 1 - 4 as needed. "Study code", "protocol number", and "treatment (no/yes)" must be completed for each study identified. All other items are to be completed only if treatment is administered as a part of the study.

Complete each line of information as needed and enter "F6" in the first field immediately following the last entry. The "F6" designates that entry is complete, and additional fields are not applicable. It is not necessary to write "F6" in each space shown. (See example)

STUDY CODE:

Use the codes provided at the top of the form. If the participant is on a study other than those listed in 1-3, enter the code "9"(other) and write in the name of the study in the "Specify other study" field.

PROTOCOL NUMBER:

Enter the protocol number if applicable. If the study does not use protocol numbers, enter "F6" (not applicable). If unknown, enter "F5". (See example)

TREATMENT (NO/YES):

Indicate if treatment is administered as a part of the study by entering "0" (no) or "1" (yes). If "0" is entered, the documentation is complete for that line. If "1" is entered, document the treatment information by completing the remaining items in the row.

P^2C^2 HIV

PARTICIPATION IN OTHER STUDIES (PATIENT)

FORM # 92

TREATMENT IDENTIFIER:
If a code is assigned to the treatment regimen, enter that code. (See example)

START DATE:
Enter the date the treatment was started in the format mm/dd/yy.

SPECIFY TREATMENT:
If the treatment regimen is known, write it in the space provided. If unknown, for example if blinded, enter "F5" (unknown).

EXAMPLE : The participant is involved in following three studies:

1. WITS
2. ACTG
3. Study XYZ, Protocol #710, no treatment

COMPLETE THE FORM IN THE FOLLOWING MANNER:

Study Codes
1 = WITS (Women and Infants HIV Transmission Study)
2 = ACTG (Pediatric AIDS Clinical Trial Group)
3 = IVIG (Intravenous Immunoglobulin vs. Placebo)
9 = Other

	Study Code	Protocol Number	Treatment (no/yes)	Complete if Treatment: Treatment Identifier	Complete if Treatment: Start Date	Complete if Treatment: Specify Treatment (If Known)
1.	1	F6 _ _ _	0	_ _	_ _/_ _/_ _	
	Specify other study:					
2.	2	_ 1 2 8	1	F6 _	0 1/0 1/9 0	Two dose AZT
	Specify other study:					
3.	9	0 7 1 0	0	_ _	_ _/_ _/_ _	
	Specify other study:	Study XYZ				
4.	F6	_ _ _ _	_	_ _	_ _/_ _/_ _	
	Specify other study:					

P^2C^2 HIV

PARTICIPATION IN OTHER STUDIES (PATIENT)

GROUPS I AND II PATIENTS

Patient's ID #: ___-IDNO___-___ Form #: 9 2

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

Code missing data items as follows:

F5 = Unknown F6 = Not applicable F8 = Date unknown

Study Codes

1 = WITS (Women and Infants HIV Transmission Study)
2 = ACTG (AIDS Clinical Trials Group)
3 = IVIG (Intrvenous Immunoglobulin vs. Placebo)
9 = Other

	Study Code	Protocol Number	Treatment (0=no/1=yes)	Treatment Identifier	Start Date (Complete if Treatment)	Specify Treatment (If known)
1.	STUDYCD1	PROTO1	TRTDONE1	TRTCODE1	DT-TRT1 __/__/__	TREAT1
	Specify other study:		STUDYOT1			
2.	STUDYCD2	PROTO2	TRTDONE2	TRTCODE2	DT-TRT2 __/__/__	TREAT2
	Specify other study:		STUDYOT2			
3.	STUDYCD3	PROTO3	TRTDONE3	TRTCODE3	DT-TRT3 __/__/__	TREAT3
	Specify other study:		STUDYOT3			
4.	STUDYCD4	PROTO4	TRTDONE4	TRTCODE4	DT-TRT4 __/__/__	TREAT4
	Specify other study:		STUDYOT4			

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

P^2C^2 HIV

DISCONTINUED FOLLOW-UP/RETURN TO FOLLOW-UP

FORM # 93

INSTRUCTIONS

This is an "as needed" form and is used to document the reason for discontinued follow-up. This form applies to both the mother and the patient.

ITEM #	INSTRUCTIONS
1	Enter the date of the last contact with the patient, mother or guardian. The last contact may be the date of the last visit or date of the last phone contact. Documentation in a medical record of contact by another department will also apply. The date is entered in the format mm/dd/yy.
2	Choose the correct response to indicate the reason follow-up is discontinued. If the response is "other", specify the reason in the space provided. *Note: Noncompliance with appointments (code #2) is no longer considered an appropriate reason for discontinuation for follow-up. This code will not be accepted by the computer.*
3	Provide a detailed description of the measures taken to keep the patient on study.
4	Indicate if authorization to discontinue follow-up was obtained from the nurse coordinator and principal investigator. The form must be signed by the nurse coordinator and initialed by the principal investigator.
5	At initial entry for a discontinued follow-up, the "returned to follow-up" field will be entered as "F8". If a patient returns to the study, the original form should be pulled, and edited by entering the date returned. This should be followed by an edit to the database. If the child is discontinued a second time, a second Form 93 must be completed.

P^2C^2 STUDY

DISCONTINUED FOLLOW-UP / RETURN TO FOLLOW-UP

GROUPS I AND II PATIENTS

Patient's ID #: ___-___ IDNO ___-___ Form #: 9 3

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

DISCONTINUED FROM FOLLOW-UP

1. Last date of contact (mm/dd/yy) ..... DT_FUP __/__/__

2. Follow-up discontinued due to: ..... WHYSTOP
   - 1 = patient/mother withdrawal
   - 2 = noncompliance with appointments *(Do Not Use)*
   - 3 = child lost to follow-up
   - 4 = moved
   - 9 = other (Specify: _____ SPECIFYO)

3. Describe measures taken to keep the patient on study:

   _____ DFMEMO

   _____

   _____

4. Authorized by Nurse Coordinator and Principal Investigator (must be signed below) ..... NCPIAUTH
   - 0 = no
   - 1 = yes

   Signature of Nurse Coordinator:

   _____

   Initialed by (Principal Investigator):

   _____

RETURNED TO FOLLOW-UP

5. Patient returned to follow-up (mm/dd/yy) ..... DT_RETUR __/__/__

Entered by: ___ CERT_NO
(cert. #)

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

P^2C^2 HIV

DEATH NOTIFICATION FOR PATIENT AND FETUS

FORM # 94

INSTRUCTIONS

This is an "as needed" form and must be completed if the patient/fetus expires during the study period.

ITEM #	INSTRUCTIONS/NOTES
2	If an autopsy is performed on this participant, Form # 97 (Postmortem Studies form) must be completed in addition to this form.
3 - 5	Document the immediate cause of death as well as any contributing causes. Each entry must be coded in SNOMED and will include the site, diagnosis and etiology (organism). Etiology will be coded for infectious diseases only.

NARRATIVE:

Write out the immediate cause of death.

TOPOGRAPHY:

Code the site of the disease which caused the death. Use the SNOMED 5 digit topography codes (codes with the prefix of "T"). The prefix has been provided, enter the code number only. Be a specific as possible.

If the site is not found in the SNOMED Indices or a site cannot be assigned (see general instructions), use the following conventions:

T-00001 = Code not found/unable to code
T-00002 = Site code not applicable

P^2C^2 HIV

DEATH NOTIFICATION FOR PATIENT AND FETUS

FORM # 94

ITEM #	INSTRUCTIONS/NOTES

3 - 5 (continued)

CAUSE:

Code the cause of death. 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 disease code numbers are only four digits in length. Use as many spaces as needed. Begin the entry from the far left and leave the last space blank.

Example: Wasting syndrome, D-4690

D - 4 6 9 0 ___

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

ORGANISM:

For infectious diseases only. Enter the appropriate code for the organism which caused the disease. The prefix has been provided. If the code cannot be found in the SNOMED Indices, enter "E-0001". Enter "E-0002" if this field is not applicable.

P^2C^2 HIV

DEATH NOTIFICATION FOR PATIENT AND FETUS

FORM # 94

CODING EXAMPLE

Example: Immediate cause of death: PCP
Contributing cause of death: AIDS

3. Immediate cause of death

   a. Narrative - Pneumocystis carinii pneumonia

   b. Topography (SNOMED T - codes)..... T - 2 8 0 0 0

   c. Cause (SNOMED M, F or D - codes) ..... M - 4 0 0 0 0

   d. Organism (SNOMED E - codes) ..... E - 4 3 3 1

4. a. Were there contributing causes 1
   0 = no
   1 = yes

   b. Narrative - Acquired immune deficiency syndrome

   c. Topography (SNOMED T - codes)..... T - 0 9 0 0 0

   d. Cause (SNOMED M, F or D - codes) ..... D - 4 6 3 5 ___

   e. Organism (SNOMED E - codes) ..... E - 3 4 8 0

P^2C^2 HIV

DEATH NOTIFICATION FOR PATIENT AND FETUS

GROUPS I AND II PATIENTS

Patient's ID #: ___-___ ___ ___-___ JDNO Form #: 9 4

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

Code missing data items as follows:

F5 = Unknown F6 = Not applicable

---

1. Date of death (mm/dd/yy) ..... __/__/__ DT-DEATH

2. a. Has an autopsy been performed? ..... AUTOPSY
   0 = no
   1 = yes
   If an autopsy was not performed, complete item 2b.
   If an autopsy was performed, Forms 06, 07 and 08 (Postmortem Studies) must be completed in addition to this form.

   b. Indicate the reason the autopsy was not performed: NO AUTOPSY
   1 = autopsy not requested
   2 = permission denied / family
   3 = permission denied / custodial care
   4 = expired elsewhere (P^2C^2 study not notified immediately following death)
   9 = other (specify: _____ SPNOAUT)

3. Immediate cause of death (use SNOMED coding system)

   a. Narrative - _____ CAUSE1

   _____

   b. Topography (SNOMED T - codes)..... T-__ __ __ __ __ TOP1

   c. Cause (SNOMED M, F or D - codes) ..... ___-__ __ __ __ __ DISEASE1

   d. Organism (SNOMED E - codes) ..... E-__ __ __ __ ETIO1

P²C² HIV

DEATH NOTIFICATION FOR PATIENT AND FETUS

4. a. Were there contributing causes ..... CCAUSE
   0 = no
   1 = yes

   If yes, complete 4b - 4e. If no, stop here.

   b. Narrative - CAUSE2

   c. Topography (SNOMED T - codes)..... T - TOP2

   d. Cause (SNOMED M, F or D - codes) ..... - DISEASE2

   e. Organism (SNOMED E - codes) ..... E - ETIO2

5. a. Additional contributing cause ..... ACCAUSE
   0 = no
   1 = yes

   If yes, complete 5b - 5e. If no, stop here.

   b. Narrative - CAUSE3

   c. Topography (SNOMED T - codes)..... T - TOP3

   d. Cause (SNOMED M, F or D - codes) ..... - DISEASE3

   e. Organism (SNOMED E - codes) ..... E - ETIO3

(NOTE: In addition to this form, Form 10 [Mortality Review] must be completed by the primary care physician for complete reporting of cause of death.)

Entered by: CERT-NO (cert. #)

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

P^2C^2 HIV

DEATH NOTIFICATION FOR MOTHERS IN GROUPS I AND II

FORM # 95

INSTRUCTIONS

This is an "as needed" form and must be completed if the biological mother expires during the study period.

ITEM #	INSTRUCTIONS/NOTES
2 - 4	Document the immediate cause of death as well as any contributing causes. Each entry must be coded in SNOMED and will include the site, diagnosis and etiology (organism). Etiology will be coded for infectious diseases only.

NARRATIVE:

Write out the immediate cause of death.

TOPOGRAPHY:

Code the site of the disease which caused the death. Use the SNOMED 5 digit topography codes (codes with the prefix of "T"). The prefix has been provided, enter the code number only. Be a specific as possible.

If the site is not found in the SNOMED Indices or a site cannot be assigned (see general instructions), use the following conventions:

T-00001 = Code not found/unable to code
T-00002 = Site code not applicable

P^2C^2 HIV

DEATH NOTIFICATION FOR MOTHERS IN GROUPS I AND II

FORM # 95

ITEM #	INSTRUCTIONS/NOTES

2 - 4 (continued)

CAUSE:

Code the cause of death. 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 disease code numbers are only four digits in length. Use as many spaces as needed. Begin the entry from the far left and leave the last space blank.

Example: Wasting syndrome, D-4690

D - 4 6 9 0 ___

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

ORGANISM:

For infectious diseases only. Enter the appropriate code for the organism which caused the disease. The prefix has been provided. If the code cannot be found in the SNOMED Indices, enter "E-0001". Enter "E-0002" if this field is not applicable.

P^2C^2 HIV

DEATH NOTIFICATION FOR MOTHERS IN GROUPS I AND II

FORM # 95

CODING EXAMPLES

Example: Immediate cause of death: PCP
Contributing cause of death: AIDS

3. Immediate cause of death

   a. Narrative - Pneumocystis carinii pneumonia

   b. Topography (SNOMED T - codes)..... T - 2 8 0 0 0

   c. Cause (SNOMED M, F or D - codes) ..... M - 4 0 0 0 0

   d. Organism (SNOMED E - codes) ..... E - 4 3 3 1

4. a. Were there contributing causes 1
   0 = no
   1 = yes

   b. Narrative - Acquired immune deficiency syndrome

   c. Topography (SNOMED T - codes)..... T - 0 9 0 0 0

   d. Cause (SNOMED M, F or D - codes) ..... D - 4 6 3 5 ___

   e. Organism (SNOMED E - codes) ..... E - 3 4 8 0

P^2C^2 HIV

DEATH NOTIFICATION (MOTHER)

(Death Occuring While on Study)

Mother's ID #: ___-___ MIDNO ___-___ Form #: 9 5

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

Code missing data items as follows:

F5 = Unknown F6 = Not applicable

1. Date of death (mm/dd/yy) ..... DT_MDTH __/__/__

2. Immediate cause of death (use SNOMED coding system)

   a. Narrative - MCAUSE1

   b. Topography (SNOMED T - codes)..... T - MTOP1

   c. Cause (SNOMED M, F or D - codes) MMORPH1

   d. Organism (SNOMED E - codes) ..... E - METIO1

3. a. Were there contributing causes ..... MCCAUSE
   0 = no
   1 = yes

   If yes, complete 3b - 3e. If no, stop here.

   b. Narrative - MCAUSE2

   c. Topography (SNOMED T - codes)..... T - MTOP2

   d. Cause (SNOMED M, F or D - codes) MMORPH2

   e. Organism (SNOMED E - codes) ..... E - METIO2

Patient # ___-___ ___ ___-___

P^2C^2 HIV

DEATH NOTIFICATION (MOTHER)

4. a. Additional contributing cause ..... MACAUSE
   0 = no
   1 = yes

   If yes, complete 4b - 4e. If no, stop here.

   b. Narrative - MCAUSE3

   c. Topography (SNOMED T - codes)..... T - MTOP3

   d. Cause (SNOMED M, F or D - codes) ..... ___ - MMORPH3

   e. Organism (SNOMED E - codes) ..... E - METIO3

Entered by: ___ (CERT-NO) (cert. #)

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

P^2C^2 HIV

PARTICIPATION IN OTHER STUDIES (MOTHER)

FORM # 96

INSTRUCTIONS

The purpose of this form is to document other study information on the mother. Complete this form at the time of enrollment. Enter each study into the data base one time only.

ITEM #	INSTRUCTIONS/NOTES
1 - 4	Complete items 1 - 4 as needed. "Study code", "protocol number", and "treatment (no/yes)" must be completed for each study identified. All other items are to be completed only if treatment is administered as a part of the study. Complete each line of information as needed and enter "F6" in the first field immediately following the last entry. The "F6" designates that entry is complete, and additional fields are not applicable. It is not necessary to write "F6" in each space shown. (See example) **STUDY CODE:** Use the codes provided at the top of the form. If the participant is on a study other than those listed in 1-3, enter the code "9"(other) and write in the name of the study in the "Specify other study" field. **PROTOCOL NUMBER:** Enter the protocol number if applicable. If the study does not use protocol numbers, enter "F6" (not applicable). If unknown, enter "F5". (See example) **TREATMENT (NO/YES):** Indicate if treatment is administered as a part of the study by entering "0" (no) or "1" (yes). If "0" is entered, the documentation is complete for that line. If "1" is entered, document the treatment information by completing the remaining items in the row.

P^2C^2 HIV

PARTICIPATION IN OTHER STUDIES (MOTHER)

FORM # 96

TREATMENT IDENTIFIER:
If a code is assigned to the treatment regimen, enter that code. (See example)

START DATE:
Enter the date the treatment was started in the format mm/dd/yy.

SPECIFY TREATMENT:
If the treatment regimen is known, write it in the space provided. If unknown, for example if blinded, enter "F5" (unknown).

EXAMPLE : The participant is involved in following two studies:
1. WITS
2. Study ABC, Protocol #015, Treatment AZT

COMPLETE THE FORM IN THE FOLLOWING MANNER:

Study Codes
1 = WITS (Women and Infants HIV Transmission Study)
2 = ACTG (Pediatric AIDS Clinical Trial Group)
9 = Other

	Study Code	Protocol Number	Treatment (no/yes)	Complete if Treatment: Treatment Identifier	Complete if Treatment: Start Date	Complete if Treatment: Specify Treatment (If Known)
1.	1	F6 ___ ___ ___	0	___ ___	__/__ __/__ __	_____
	Specify other study: _____					
2.	9	___ 0 1 5	1	F6 ___	0 1/0 1/9 0	AZT
	Specify other study: ABC					
3.	F6	___ ___ ___ ___	___	___ ___	__/__ __/__ __	_____
	Specify other study: _____					
4.	___	___ ___ ___ ___	___	___ ___	__/__ __/__ __	_____
	Specify other study: _____					

P^2C^2 HIV

PARTICIPATION IN OTHER STUDIES (MOTHER)

GROUPS I & II MOTHERS

Patient's ID #: ___-MIDNO-___ Form #: 96

Completed by: _____ (print name) Date Completed: DT-FORM (mm/dd/yy)

Code missing data items as follows:

F5 = Unknown F6 = Not applicable F8 = Date unknown

Study Codes
1 = WITS (Women and Infants HIV Transmission Study)
2 = ACTG (Aids Clinical Trials Group)
9 = Other

	Study Code	Protocol Number	Treatment (0=no/1=yes)	Treatment Identifier	Start Date	Specify Treatment (If known)
					Complete if Treatment	
1.	MSTUDCD1	MPROTO1	MTRTDN1	MTRTCD1	MDT-TRT1 __/__/__	MTREAT1
	Specify other study:		MSTUDOT1			
2.	MSTUDCD2	MPROTO2	MTRTDN2	MTRTCD2	MDT-TRT2 __/__/__	MTREAT2
	Specify other study:		MSTUDOT2			
3.	MSTUDCD3	MPROTO3	MTRTDN3	MTRTCD3	MDT-TRT3 __/__/__	MTREAT3
	Specify other study:		MSTUDOT3			
4.	MSTUDCD4	MPROTO4	MTRTDN4	MTRTCD4	MDT-TRT4 __/__/__	MTREAT4
	Specify other study:		MSTUDOT4			

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

P^2C^2 HIV

CONSENT REFUSAL

FORM # 99

INSTRUCTIONS

Complete this form for all eligible candidates who were approached for informed consent, but who refused. Not more than one form should be completed per candidate. If the individual is approached multiple times, the data is to be collected at the initial refusal, only.

> (NOTE: If the candidate enrolls at a later date, the initial refusal data will remain in the database. The original refusal will not be voided. Also, there will be no mechanism to cross check the original refusal with the enrolled patient.)

ITEM #	INSTRUCTIONS/NOTES
1a	Indicate the group for which the candidate was eligible.
1b & 1c	Indicate sex and race for Group I patients and Group II postnatally enrolled patients.
5a - 5c	Indicate the reasons why the guardian refused informed consent. Respond to each item.

P^2C^2 HIV

CONSENT REFUSAL

Computer assigned number: CRIDNO ___-___ ___ ___ ___ Form #: 99

Completed by: _____ Date completed: DT-FORM __/__/__
(print name) (mm/dd/yy)

---

1. a. Candidate considered for ..... CRGROUP
   1 = Group I
   2 = Group II prenatal
   3 = Group II postnatal

   If response for 1a is "1" or "3", complete 1b and 1c:

   b. Sex ..... CRSEX
   1 = male
   2 = female

   c. Date of birth ..... CRDOB __/__/__

2. Race ..... CRRACE
   1 = White non-Hispanic
   2 = Black non-Hispanic
   3 = Hispanic
   4 = Asian/Pacific Islander
   5 = American Indian/Alaskan Native
   9 = other (Specify: CRRACESP _____)

3. Legal guardian approached for the study: ..... CRGUARD
   1 = child's biological mother
   2 = child's biological father
   9 = other
   (Specify: CRGUARSP _____)

4. Referred to study group by ..... CRREF
   1 = OB/GYN department
   9 = other
   (Specify: CRREFSP _____)

P^2C^2 HIV

CONSENT REFUSAL

5. Guardian refused informed consent due to (respond to each item listed) :

   0 = no
   1 = yes

a.	Approached for too many studies	CRREAS1
b.	Uneasy about invasive procedures	CRREAS2
c.	Study of no value to the participants	CRREAS3
d.	No one available to provide informed consent	CRREAS4
e.	Patient expired	CRREAS5
f.	Other	CRREAS6

(Specify: CRREASOT)

Entered by: CERTNO (cert. #)

Date entered DT_FHENT (mm/dd/yy)