QUALITY OF LIFE ASSESSMENT - REVISED

(For Ages 12 - 20 Years) QL4005(000)/00-00-00

NIAID AIDS CLINICAL TRIALS GROUP

Patient Number ☐☐ ☐☐☐☐ ☐ Date of Patient Visit ☐☐☐ ☐☐ ☐☐☐☐ (mmm dd yyyy)

Protocol Number ☐☐☐☐☐☐ Institution Code ☐☐☐☐☐☐

Form Week ☐☐☐ *Seq No. ☐ **Step No. ☐ Key Operator Code ☐☐☐

* Enter a "1" if this is the first of this form for this date. Designate subsequent forms on same date with a 2, 3, etc.
**Enter the subject's current study step number. Enter '1' if the study does not have multiple steps.

INSTRUCTIONS TO THE STUDY COORDINATOR:

- The following questionnaire should be given to the parent/guardian prior to the clinical exam and preferably in a quiet secluded area (i.e., exam room or other office). The parent/guardian must be able to read at the sixth-grade level at a minimum to complete the form herself/himself. If not, the Study Nurse should complete the form with the individual, using the QUALITY OF LIFE SCALES provided in the CRF Notebook. This questionnaire should only be given to parent/guardian whose children are between 12 and 20 years of age.
- **Pages 1 - 2 of this clinic form must be completed by the Study Nurse.** DO NOT SHOW PAGES 1 - 2 OF THIS FORM TO THE PATIENT. Pages 3 - 8 are completed by the parent/guardian. Before giving the questionnaire to the parent/guardian, please fill out the header(s) and DETACH PAGES 1 - 2.
- It is important to be familiar with the content and format of the questionnaire before giving it to study participants. At the first visit, please begin by explaining to the parent/guardian the format of the questions and how to complete them.
- Each question is in the same general format and contains several items. Note that the patient is always asked to CIRCLE a number or make an "X" or "✓" next to the appropriate category.
- Collect the completed questionnaire before the clinical exam. Before going on, review the questionnaire for omissions. If the participant missed any of the questions, point this out and have him/her complete the omission.

CLINIC SECTION:

QUESTIONS 1 TO 7 ARE TO BE COMPLETED BY THE STUDY NURSE:
*COMPLETE QUESTION 1 AND 2 WITH THE HELP OF THE PARENT/GUARDIAN, **PRIOR** TO GIVING THE QUESTIONNAIRE.*

1. Since the last visit, have any of the following occurred? (1-Yes, 2-No,
   At Entry: Have any of the following occurred within the last 12 months 3-Not Known)

a.	Parent lost job:	☐
b.	Family member left home:	☐
c.	Loss of housing or had to move:	☐
d.	Loss of entitlement: (food stamps, AFDC, etc.)	☐
e.	Loss of health insurance:	☐
f.	Family member hospitalized:	☐
g.	Family member very sick:	☐
h.	Change of caretaker:	☐
i.	Separation of parents:	☐
j.	Divorce of parents:	☐
k.	Jail sentence of parent:	☐
l.	Marriage of parent:	☐
m.	Birth of sibling:	☐
n.	Mother starting to work:	☐
o.	Beginning school or moving to new school:	☐
p.	Change in financial status of parents:	☐
q.	Loss of close friend(to child):	☐
r.	Death in family:	☐

If Death in family, who died? ☐

1-Mother
2-Father
3-Brother or sister (stepbrother, or stepsister)
4-Grandparent
9-Other family member

Pt. No. ☐☐ ☐☐☐☐ ☐ * Seq. No. ☐ Step No. ☐ Date ☐☐☐ ☐☐ ☐☐☐☐
mmm dd yyyy

(1-Yes, 2-No)

2. Is the subject HIV-infected? ..... ☐
   If No, go to question 4.
   a. Does the subject know he/she is infected? ..... ☐
      If Yes, complete 'a1.'
      a1. Age when subject first knew their infection status: *(Enter -1 if unknown)*..... ☐☐
   b. Is the subject in school? ..... ☐
      If No, go to question 3.
   c. Does the school know the diagnosis? ..... ☐

NOTE: The following questions should not be asked of the parent/guardian. (1-Yes, 2-No, 3-Not Known)

3. Has the parent/guardian signed a DNR order on this subject? ..... ☐

4. Has the subject enrolled or been enrolled in hospice care? ..... ☐

*ANSWER THE FOLLOWING ITEMS **AFTER** PARENT/GUARDIAN COMPLETES THE QUESTIONNAIRE OR **AFTER** YOU ASCERTAIN THAT THIS IS NOT POSSIBLE:*

5. How was the questionnaire completed? ..... ☐
   If "4", complete 'a' and STOP.
   1 - Self Administered by the parent/guardian
   2 - Face-to-face interview that you conducted
   3 - Phone interview
   4 - Not completed
   9 - Other, specify

   If Other, specify: [30] _____

   a. If **"4"** - Not completed, indicate the reason: ..... ☐
      1 - Parent/guardian refused
      2 - Patient missed clinic visit
      3 - There was not enough time at this visit
      9 - Other reason

      If Other, specify: [30] _____

6. Who responded to the questions? ..... ☐
   If "6" or "7", subject should only complete Section IV questions A1 and 2, B1, 2, 5, 6, 7, Section V questions B1-6, and C, and Section VI questions 1 - 20.
   1 - Biological Mother
   2 - Biological Father
   3 - Other Relative, specify
   4 - Adoptive Parent
   5 - Foster Parent
   6 - Emancipated minor
   7 - Subject themself (no longer in care of parent/guardian)
   9 - Other, specify

   If Other or Other Relative, specify: [30] _____

7. What language was the questionnaire given in? ..... ☐
   1-English
   2-Spanish
   3-French
   4-Creole
   9-Other

   If Other, specify: [30] _____

   a. What is the primary language spoken at home? ..... ☐
      1-English
      2-Spanish
      3-French
      4-Creole
      9-Other

      If Other, specify: [30] _____

Date Form Keyed: (DO NOT KEY)_____/_____/_____

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Form Week ☐☐☐ * Seq. No. ☐ **Step No. ☐ Key Operator Code ☐☐☐

* Enter a "1" if this is the first of this form for this date. Designate subsequent forms on same date with a 2, 3, etc.
**Enter the subject's current study step number. Enter '1' if the study does not have multiple steps.

INSTRUCTIONS TO PARENT/GUARDIAN:

Please answer the following questions by circling the best response. There are no right or wrong answers. If you don't know what a particular question means do not hesitate to ask the study nurse. Please do your best to answer all questions.

I. General Health Ratings. These statements ask about the health and behavior of your child.

A. On a scale from 1 to 10 (1 being the very worst, and 10 being the very best):

HOW HAS YOUR CHILD BEEN FEELING, ON THE AVERAGE, DURING THE PAST 3 MONTHS?

(Please circle a number between 1 and 10 in each question)

		The Very Worst He/She Ever Felt ↓									The Very Best He/She Ever Felt ↓
1.	Overall, in general?	1	2	3	4	5	6	7	8	9	10
2.	Physically?	1	2	3	4	5	6	7	8	9	10
3.	Emotionally?	1	2	3	4	5	6	7	8	9	10
4.	About their usual daily activities, such as schoolwork, job or housework?	1	2	3	4	5	6	7	8	9	10

Pt. No. ☐☐ ☐☐☐☐ ☐ * Seq. No. ☐ **Step No. ☐ Date ☐☐☐ ☐☐ ☐☐☐☐
mmm dd yyyy

II. Physical Functioning

A. HOW MUCH, if at all, has YOUR CHILD'S HEALTH interfered with his/her activities during the PAST 4 WEEKS?

(Please circle one number for each question)

HOW MUCH HAS YOUR CHILD'S HEALTH INTERFERED WITH…?	Not at all	A little bit	Moderately	Quite a bit	Extremely
1. The kinds or amounts of vigorous activities your child can do, like lifting heavy objects, running, or participating in strenuous sports?	1	2	3	4	5
2. The kinds or amounts of moderate activities your child can do, like moving a table, carrying groceries, or moderately active sports like bowling?	1	2	3	4	5
3. Walking uphill or climbing a few flights of stairs?	1	2	3	4	5
4. Walking one block?	1	2	3	4	5
5. Bending, lifting or stooping?	1	2	3	4	5
6. Eating, dressing, bathing or using the toilet?	1	2	3	4	5

B. Please comment on any other problems, if you wish [70]:

_____

Pt. No. [ ][ ] [ ][ ][ ][ ] [ ] * Seq. No. [ ] **Step No. [ ] Date [ ][ ][ ] [ ][ ] [ ][ ][ ][ ]
mmm dd yyyy

III. Psychological Well-Being

These statements are about behavior problems many children have. As you read each sentence, decide which phrase best describes your child's behavior over the past 3 months, then circle the number that goes with the answer you choose.

Thinking about your child, DURING THE PAST 3 MONTHS...

(Please circle one number for each question)

		Often True	Some-times True	Not True
1.	My child has sudden changes in mood or feelings	1	2	3
2.	My child feels or complains that no one loves him/her ..	1	2	3
3.	My child is rather high strung, tense, and nervous	1	2	3
4.	My child cheats or tells lies	1	2	3
5.	My child is too fearful or anxious	1	2	3
6.	My child argues too much	1	2	3
7.	My child has difficulty concentrating, cannot pay attention for long	1	2	3
8.	My child is easily confused, seems to be in a fog	1	2	3
9.	My child bullies or is cruel or mean to others	1	2	3
10.	My child is disobedient at home	1	2	3
11.	My child is disobedient at school	1	2	3
12.	My child does not seem to feel sorry after he/she misbehaves	1	2	3
13.	My child has trouble getting along with other children	1	2	3

Pt. No. [ ][ ] [ ][ ][ ][ ] [ ] * Seq. No. [ ] **Step No. [ ] Date [ ][ ][ ] [ ][ ] [ ][ ][ ][ ]
mmm dd yyyy

III. Psychological Well-Being (cont.'d)

Thinking about your child, DURING THE PAST 3 MONTHS...

(Please circle one number for each question)

	Often True	Some-times True	Not True
14. My child has trouble getting along with teachers	1	2	3
15. My child is impulsive, or acts without thinking	1	2	3
16. My child feels worthless or inferior	1	2	3
17. My child is not liked by other children	1	2	3
18. My child has a lot of difficulty getting his/her mind off certain thoughts (has obsessions)	1	2	3
19. My child is restless or overly active, cannot sit still	1	2	3
20. My child is stubborn, sullen or irritable	1	2	3
21. My child has a very strong temper and loses it easily ...	1	2	3
22. My child is unhappy, sad or depressed	1	2	3
23. My child is withdrawn, does not get involved with others	1	2	3
24. My child feels others are out to get him/her	1	2	3
25. My child hangs around with kids who get into trouble	1	2	3
26. My child is secretive, keeps things to himself/herself	1	2	3
27. My child worries too much	1	2	3
28. My child is too dependent on others	1	2	3

Pt. No. ☐☐ ☐☐☐☐ ☐ * Seq. No. ☐ **Step No. ☐ Date ☐☐☐ ☐☐ ☐☐☐☐
mmm dd yyyy

IV. Social and Role Functioning

A. Thinking about you/your child, during the past 4 weeks, how many days ….

(Place an "X" or "✓" on the line next to your answer)

1. Did you/your child stay in bed (most or all of the day) due to any illness or injury?

0 ____ (1)	1-2 ____ (2)	3-5 ____ (3)	6-10 ____ (4)	11-15 ____ (5)	>16 ____ (6)

2. Did illness or injury keep you/your child from school?
(If during a vacation period, refer to the last month school was open.)

Not In School ____ (-1)	0 ____ (1)	1-2 ____ (2)	3-5 ____ (3)	6-10 ____ (4)	11-15 ____ (5)	>16 ____ (6)

B. Check only one for each question:

1. What grade is you/your child in now (or will be in, if between grades)? **(Check One)**

4th grade	16	☐
5th grade	17	☐
6th Grade	18	☐
7th Grade	19	☐
8th Grade	20	☐
9th Grade	21	☐
10th Grade	22	☐
11th Grade	23	☐
12th Grade	24	☐
1st Year In College	25	☐
2nd Year In College	26	☐
3rd Year In College	27	☐
4th Year In College	28	☐
Not in school	99	☐

Pt. No. ☐☐ ☐☐☐☐ ☐ * Seq. No. ☐ **Step No. ☐ Date ☐☐☐ ☐☐ ☐☐☐☐
mmm dd yyyy

(Check One)

2. Have you/your child ever repeated a grade for any reason? Yes ☐ 1 No ☐ 2

3. In general, are you/your child limited in school attendance because of his/her health? …….. Yes ☐ 1 No ☐ 2

4. In general, are you/your child limited in the kind or amount of other activities because of his/her health? …… Yes ☐ 1 No ☐ 2

5. In general, have you/your child participated in school sports? Yes ☐ 1 No ☐ 2

6. Does you/your child go to a special class or get special help in school because of a disability or health problem? ……..…… Yes ☐ 1 No ☐ 2
   If No, go to question 7.
   If Yes, complete 'a.'

(Check One)

a. What type of special help do you/your child receive? …
   1 - Reading ☐
   2 - Learning disability ☐
   3 - Speech or Language ☐
   4 - Physical Therapy/ Occupational Therapy ☐
   5 - More than one of above ☐
   9 - Other, specify ☐

   If Other, specify [30]: _____

7. Are you/your child receiving home schooling? …….. Yes ☐ 1 No ☐ 2

Pt. No. ☐☐ ☐☐☐☐ ☐ * Seq. No. ☐ **Step No. ☐ Date ☐☐☐ ☐☐ ☐☐☐☐
mmm dd yyyy

V. Health Care Utilization *(Place an "X" or "✓" on the line next to your answer)*

A. DURING THE PAST 4 WEEKS...

1. HOW MANY NIGHTS did you/your child stay in a hospital?

0 ____	1-2 ____	3-5 ____	6-10 ____	11-20 ____	>20 ____
(1)	(2)	(3)	(4)	(5)	(6)

2. HOW MANY VISITS did you/your child make to a clinic, office or emergency room to see a doctor, nurse or other specialist?

0 ____	1-2 ____	3-5 ____	6-10 ____	11-20 ____	>20 ____
(1)	(2)	(3)	(4)	(5)	(6)

3. HOW MANY TIMES were you/your child visited by a nurse or other health care provider at your home?

0 ____	1-2 ____	3-5 ____	6-10 ____	11-20 ____	>20 ____
(1)	(2)	(3)	(4)	(5)	(6)

4. HOW MANY TIMES did you call a clinic, physician, nurse, or other health care provider for a medical consultation over the telephone about yourself/your child?

0 ____	1-2 ____	3-5 ____	6-10 ____	11-20 ____	>20 ____
(1)	(2)	(3)	(4)	(5)	(6)

Pt. No. ☐☐ ☐☐☐☐ ☐ * Seq. No. ☐ Step No. ☐ Date ☐☐☐ ☐☐ ☐☐☐☐
mmm dd yyyy

B. Please check only one box for each question:

(Check One)

DURING THE PAST 4 WEEKS, did illness or injury make it necessary for you/your child to use any medicine, other than vitamins, that a doctor prescribed? ..... Yes ☐ 1 No ☐ 2

If No, go to "C".

If Yes, which of the following prescription medications did you/your child use?

Was it necessary for you/your child to use...

1. Prescription pain medicine? ..... Yes ☐ 1 No ☐ 2
2. Prescription antibiotics? ..... Yes ☐ 1 No ☐ 2
3. Prescription cold medicine? ..... Yes ☐ 1 No ☐ 2
4. Prescription medicine for wheezing? ..... Yes ☐ 1 No ☐ 2
5. Prescription topical cream? ..... Yes ☐ 1 No ☐ 2
6. Prescription anti-diarrhea medicine? ..... Yes ☐ 1 No ☐ 2

C. "The following are a list of alternative treatments that you may have taken/provided for your child. These are treatments other than traditional medicines. Since the last clinic visit, has you/your child had or taken any of the following?"

a. Taking any over the counter herbs? ..... Yes ☐ 1 No ☐ 2
b. Taking any over the counter vitamins? ..... Yes ☐ 1 No ☐ 2
c. Had any acupuncture treatments? ..... Yes ☐ 1 No ☐ 2
d. Taken any yoga? ..... Yes ☐ 1 No ☐ 2
e. Used aromatherapy? ..... Yes ☐ 1 No ☐ 2
f. Practiced any specific form of spiritual activity? ..... Yes ☐ 1 No ☐ 2
g. Used chiropractic care? ..... Yes ☐ 1 No ☐ 2
h. Used any massage therapy? ..... Yes ☐ 1 No ☐ 2

Pt. No. [ ][ ] [ ][ ][ ][ ] [ ] * Seq. No. [ ] **Step No. [ ] Date [ ][ ][ ] [ ][ ] [ ][ ][ ][ ]
mmm dd yyyy

VI. Symptoms

The following questions ask about SYMPTOMS OR FEELINGS you/your child might have had during the past 4 weeks. Please answer HOW DISTRESSING the following symptoms have been for you/your child DURING THE PAST 4 WEEKS.
HOW MUCH WAS YOU/YOUR CHILD DISTRESSED BY THIS SYMPTOM OR FEELING?
(Please circle one answer for each question)

	Not at all	Very Mildly	Mildly	Moderately	Very Much	Extremely
1. Physical or bodily pain?	1	2	3	4	5	6
2. Coughing, wheezing?	1	2	3	4	5	6
3. Nausea, vomiting, abdominal/stomach pain?	1	2	3	4	5	6
4. Diarrhea	1	2	3	4	5	6
5. Rash, itching, or other skin problems?	1	2	3	4	5	6
6. Fatigue, weakness?	1	2	3	4	5	6
7. Feeling dizzy or lightheaded?	1	2	3	4	5	6
8. Fever, night sweats, shaking, chills?	1	2	3	4	5	6
9. Loss of appetite?	1	2	3	4	5	6
10. Trouble sleeping?	1	2	3	4	5	6
11. Eye trouble, problem with vision?	1	2	3	4	5	6
12. Headache?	1	2	3	4	5	6
13. Dry or painful mouth, trouble swallowing?	1	2	3	4	5	6
14. Chest pain or tightness?	1	2	3	4	5	6
15. Difficulty breathing or catching breath?	1	2	3	4	5	6
16. Runny nose, sinus trouble?	1	2	3	4	5	6
17. Muscle aches, joint bone pain?	1	2	3	4	5	6
18. Pain, numbness, or tingling in hands or feet?	1	2	3	4	5	6
19. Earaches?	1	2	3	4	5	6
20. Overall discomfort?	1	2	3	4	5	6

THANK YOU VERY MUCH FOR YOUR TIME.
Your efforts will be very valuable in evaluating new therapies.

Language: [E] English