TLC Trial Form TX1.05

formerly Form RX2

Review of Medications and Physical Exam
Treatment Day 7

Center ID:	____ - ____
Study ID:	T____ ____ ____ ____ - ____
Visit Code:	T ____ ____
Date of visit	____ ____/____ ____/____ ____

INSTRUCTIONS: This form is to be filled out at Treatment Day 7 of each round of treatment.

1. *Treatment round*

( )$_1$ *First* *T1*
( )$_2$ *Second* *T5*
( )$_3$ *Third* *T9*

CAREGIVER INTERVIEW

The following questions should be asked directly of the adult accompanying the child at Treatment Day 7 of each round of treatment.

2. Did you have any problems giving <*insert child's name*> the medicine?

( )$_0$ No ( )$_1$ Yes

3. About how many **doses** of medicine do you think <*insert child's name*> missed this past week?

____ ____ doses

4. Has <*insert child's name*> moved since the last clinic visit?

( )$_0$ No ( )$_1$ Yes

5. Except for work related to the TLC Study, has your home undergone any remodelling or repairs, been scraped for lead, or developed any structural problems since the last clinic visit?

( )$_0$ No ( )$_1$ Yes, specify _____

6. Is this child currently taking any prescription medicine?

( )$_0$ No ( )$_1$ Yes, specify _____

7. Has this child required inpatient hospitalization for any reason since her/his last TLC visit? Include **any** inpatient hospitalization, even if thought to be unrelated to TLC drug.

( )$_0$ No ( )$_1$ Yes, specify _____

If YES: Fill out TLC Form ADE

REVIEW OF MEDICINE DIARY

8. Did you bring <*insert child's name*> medicine diary with you today?

( )$_0$ No ( )$_1$ Yes

*IF YES: Record number of missed **doses** from diary____ ____*

9. Did the caregiver note any illnesses on TLC form MEDDIARY since the last TLC visit?

( )$_0$ No ( )$_1$ Yes, specify _____

IF YES:

a. In the opinion of the TLC clinician, was this illness associated with TLC drug?

( )$_0$ No ( )$_1$ Yes

Center ID:	____ - ____
Study ID:	T____ ____ ____ ____ - ____
Visit Code:	T ____ ____
Date of visit	____ ____/____ ____/____ ____

PHYSICAL MEASUREMENTS

10. **Length/Height**

a. **Method** ( )$_1$ Standing ( )$_2$ Supine

b. **Length or height** ____ ____ ____ . ____ cm ( )$_1$ Unable to obtain

c. **Concerns** ( )$_0$ No problems

( )$_1$ Interference from hair or non-removable hair ornaments

( )$_2$ Child would/could not stay still

( )$_3$ Other, specify: _____

11. **Weight**

a. **Diaper** ( )$_1$ With ( )$_2$ Without ( )$_3$ Not applicable

b. **Clothing** ( )$_1$ Underwear only ( )$_2$ Light clothing ( )$_3$ Heavy clothing

c. **Shoes** ( )$_1$ With ( )$_2$ Without

d. **Weight** ____ ____ . ____ ____ kg --*OR*-- ____ ____ lb ____ ____ oz ( )$_1$ Unable to obtain

e. **Concerns** ( )$_0$ No problems

( )$_1$ Child would/could not stay still

( )$_2$ Other, specify: _____

12. **Blood pressure**

a. **Method** ( )$_1$ Seated ( )$_2$ Supine ( )$_3$ Standing ( )$_4$ Other

b. **Reading 1** ____ ____ ____ / ____ ____ ____ ( )$_1$ Unable to obtain

c. **Concerns** ( )$_0$ No problems

( )$_1$ Child was crying during BP measurement

( )$_2$ Child would/could not stay still

( )$_3$ Other, specify: _____

d. **Reading 2** ____ ____ ____ / ____ ____ ____ ( )$_1$ Unable to obtain

e. **Concerns** ( )$_0$ No problems

( )$_1$ Child was crying during BP measurement

( )$_2$ Child would/could not stay still

( )$_3$ Other, specify: _____

Center ID:	____ - ____
Study ID:	T____ ____ ____ ____ - ____
Visit Code:	T ____ ____
Date of visit	____ ____/____ ____/____ ____

REVIEW OF SYMPTOMS

		ABSENT	MILD	MODERATE	SEVERE	Associated with drug?
13.	**Nausea**	( )$_0$	( )$_1$	( )$_2$	( )$_3$	( )$_1$
14.	**Vomiting**	( )$_0$	( )$_1$	( )$_2$	( )$_3$	( )$_1$
15.	**Diarrhea**	( )$_0$	( )$_1$	( )$_2$	( )$_3$	( )$_1$
16.	**Abdominal pain**	( )$_0$	( )$_1$	( )$_2$	( )$_3$	( )$_1$
17.	**Change in sleeping habits**	( )$_0$	( )$_1$	( )$_2$	( )$_3$	( )$_1$
18.	**Irritability**	( )$_0$	( )$_1$	( )$_2$	( )$_3$	( )$_1$
19.	**Rashes**	( )$_0$	( )$_1$	( )$_2$	( )$_3$	( )$_1$
20.	**Change in eating habits**	( )$_0$	( )$_1$	( )$_2$	( )$_3$	( )$_1$
21.	**Ear ache or ear infection**	( )$_0$	( )$_1$	( )$_2$	( )$_3$	( )$_1$
22.	**Other**	( )$_0$	( )$_1$	( )$_2$	( )$_3$	( )$_1$

If OTHER, specify: _____

PHYSICAL EXAM

23.	**Eyes**	( )$_1$ Normal	( )$_2$ Abnormal, specify _____	( )$_3$ Not Done
24.	**ENT**	( )$_1$ Normal	( )$_2$ Abnormal, specify _____	( )$_3$ Not Done
25.	**Neck**	( )$_1$ Normal	( )$_2$ Abnormal, specify _____	( )$_3$ Not Done
26.	**Lungs**	( )$_1$ Normal	( )$_2$ Abnormal, specify _____	( )$_3$ Not Done
27.	**Heart**	( )$_1$ Normal	( )$_2$ Abnormal, specify _____	( )$_3$ Not Done
28.	**Abdomen**	( )$_1$ Normal	( )$_2$ Abnormal, specify _____	( )$_3$ Not Done
29.	**Liver**	( )$_1$ Normal	( )$_2$ Abnormal, specify _____	( )$_3$ Not Done
30.	**Lymph Nodes**	( )$_1$ Normal	( )$_2$ Abnormal, specify _____	( )$_3$ Not Done
31.	**Extremities**	( )$_1$ Normal	( )$_2$ Abnormal, specify _____	( )$_3$ Not Done
32.	**Skin**	( )$_1$ Normal	( )$_2$ Abnormal, specify _____	( )$_3$ Not Done

Center ID:	____ - ____
Study ID:	T___ ___ ___ ___ - ___
Visit Code:	T ___ ___
Date of visit	___ ___/___ ___/___ ___

33. **Genitalia** ( )$_1$ Normal ( )$_2$ Abnormal, specify _____ ( )$_3$ Not Done

34. **Neurological** ( )$_1$ Normal ( )$_2$ Abnormal, specify _____ ( )$_3$ Not Done

35. **Other** ( )$_1$ Normal ( )$_2$ Abnormal, specify _____ ( )$_3$ Not Done

REVIEW BY TLC CLINICIAN

36. In the opinion of the TLC clinician, is this child on active drug or placebo?

( )$_1$ Active ( )$_2$ Placebo ( )$_3$ No opinion

37. **TLC Clinician** _____ ___ - ___ ___ ___ ___
Signature *TLC Code*

CDC BLOOD SAMPLES

38. **PbB**

Place barcode label from CDC
PbB
sample in this box

ADMINISTRATIVE MATTERS

39. **TLC Staff** _____ ___ - ___ ___ ___ ___
Signature *TLC Code*

COMMENTS