

TLC Trial Form VISIT2.04 Pre-Randomization Visit V2 or V2A

Center ID:	_____ - _____
Screening ID:	S _____ - _____
Visit Code:	V 2 _____
Date of Visit	_____/_____/_____

INSTRUCTIONS: This form is used for both Pre-Randomization Visits V2 and V2A. The first section of this form is to be administered to the parent or legal guardian of a potential subject at the beginning of the visit. Before beginning the interview, confirm that you are speaking to the parent or legal guardian of the subject.

PARENT/GUARDIAN INTERVIEW

1. Have you or <insert child's name> moved since <insert date of H1>?
()₀ No ()₁ Yes
2. Except for work related to the TLC Study, has your home undergone any remodelling or repair work, been scraped for lead, or developed any structural problems (e.g., roof leak) since <insert date of H1>?
()₀ No ()₁ Yes

The following questions need only be asked at Visit V2.

3. About how many days do you think <insert child's name> missed getting a vitamin pill?

4. Did you bring your vitamin bottle with you today?
()₀ No ()₁ Yes
IF YES: Count tablets and record number remaining _____
5. Did you bring your vitamin diary with you today?
()₀ No ()₁ Yes
IF YES: Record number of missed vitamins from diary _____

URINALYSIS RESULTS

Perform urinalysis only if unable to obtain at Visit

V1. If negative or trace, enter "0".

6. **Proteinuria** _____ + ()₁ unable to obtain ()₂ not required
7. **Glucosuria** _____ + ()₁ unable to obtain ()₂ not required

BRIEF PHYSICAL EXAM

8. **Child's date of birth** _____/_____/_____ mm/dd/yy
9. **Illness since V1** ()₀ No ()₁ Yes, specify _____

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10. **Length/Height**

- a. **Method** ₁ Standing ₂ Supine
- b. **Measurement 1** _____ . _____ cm ₁ Unable to obtain
- c. **Measurement 2** _____ . _____ cm ₁ Unable to obtain

If the first two height measurements differ by more than 0.5 cm, obtain a third height measurement.

- d. **Measurement 3** _____ . _____ cm ₁ Unable to obtain
- e. **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 readings**

- a. **Method** ₁ Seated ₂ Supine
- 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: _____

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REVIEW OF ELIGIBILITY

13. Have there been any changes in housing requiring a repeat Home Assessment?

()₀ No ()₁ Yes

14. Does the child have a current illness requiring deferral of possible chelation?

()₀ No ()₁ Yes

*If you have answered "Yes" to either of the above questions, this child's enrollment in the TLC Trial must be **DEFERRED**.*

15. Will this child's age at randomization (in approximately 1 week) be less than 12 months or greater than or equal to 33 months?

()₀ No ()₁ Yes

16. Is the BSA less than 0.357 m² or greater than 0.713 m²?

()₀ No ()₁ Yes

17. Is there a recent illness sufficient to preclude enrollment in the TLC Trial?

()₀ No ()₁ Yes

18. In the best judgment of the TLC physician, is this family **unable** to comply with the **medication** requirements of the TLC Trial?

()₀ No ()₁ Yes

*If you answered "Yes" to any of the above questions, this child is **NOT ELIGIBLE** for the TLC Trial.*

19. **TLC Clinician**

Signature

_____-_____
TLC Code

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CDC BLOOD SAMPLES

20. **PbB**

Place barcode label from CDC
PbB
sample in this box

21. **Ferritin**

Place barcode label from CDC
FERRITIN
sample in this box

Draw blood for CDC ferritin if V1 ferritin was less than 12 OR child required iron supplementation on the basis of V1 local lab results.

ADMINISTRATIVE MATTERS

22. **TLC Staff** _____ ____ - ____
Signature *TLC Code*

23. **Eligibility status** ()₁ Eligible ()₂ Not eligible, specify: _____
 ()₃ Defer, specify: _____

COMMENTS