

TLC Trial Form RANDO.04 Randomization

Center ID:	_____ - _____
Screening ID:	S _____ - _____
Date of randomization phone call	____/____/____

INSTRUCTIONS: Record the child's date of birth and height and weight as obtained at Pre-Enrollment Clinic Visit V2 or V2A before calling the Data Coordinating Center at 1-800-833-4784. The Data Coordinating Center will confirm the child's eligibility based on age, body surface area, and PbB. If the child is eligible, DCC staff will report the BSA, BSA class, treatment regimen and provisionally assign Study Drug Bottle number(s) and Study ID.

ELIGIBILITY INFORMATION *Please have the following information ready when you call the DCC:*

- Date of birth** _____ / _____ / _____ mm/dd/yy
- Date of most recent blood draw for CDC PbB** _____ / _____ / _____ mm/dd/yy
- Date of expected T0** _____ / _____ / _____ mm/dd/yy
- Length/Height** _____ . _____ cm
- Weight** _____ . _____ kg --OR-- _____ lbs _____ oz

If this child is not eligible for the TLC Trial, skip to FINAL OUTCOME.

TREATMENT REGIMEN

- Body surface area** 0 . _____
- BSA class**
()_A 0.357 - 0.428
()_B 0.429 - 0.499
()_C 0.500 - 0.523
()_D 0.524 - 0.618
()_E 0.619 - 0.642
()_F 0.643 - 0.713
- Days 1 - 7** _____ - _____ - _____
- Days 8 - 26** _____ - _____
- Study drug bottle number** _____
_____ *A second bottle will be required for children in BSA class F.*
- Study ID number** T _____ - _____

FINAL OUTCOME

*If this child is not eligible for enrollment in the TLC Trial, please complete this section and return this form to the DCC. Otherwise, complete and return this form when T0 is successfully completed **OR** more than 14 days have elapsed since the most recent CDC PbB.*

- Outcome** ()₁ Enrolled ()₂ Not enrolled

If enrolled:
13. **Date of T0** _____ / _____ / _____ mm/dd/yy

ADMINISTRATIVE MATTERS

- TLC Staff** _____
Signature _____ *TLC Code* _____

COMMENTS