EDC Infant Off-Study Form

FLOURISH Study

1. Infant/Child/Adolescent Visit
2. Date of completion of this form \_\_\_\_\_\_\_\_\_\_\_\_\_\_; Time of completion \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
3. Please code the primary reason the participant is being taken off the study:
4. Participant stated she will be moving out of the study area or unable to stay in study area
5. Participant lost to follow-up/ unable to locate
6. Participant lost to follow-up, contacted but did not come to study clinic
7. Child/Adolescent changed mind and withdrew consent
8. Father of the infant/child/adolescent refused to participate and therefore participant withdrew consent
9. Other family member refused the study and therefore participant withdrew consent
10. Infant/child/adolescent found to be HIV-infected \*
11. Infant/child/adolescent Death (complete the Infant Death Report Form)
12. Completion of protocol required period of time for observation (see Study Protocol for definition of “Completion” (skip to end of form)
13. Adolescent is incarcerated
14. Enrolled erroneously – did not meet eligibility criteria prior to consent
15. Did not meet eligibility criteria, after consent obtained
16. 18-year old – Contacted but could not come into the study clinic for re-consenting
17. 18-year old – Unable to contact
18. Other

Please specify \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*\* If “g” is chosen above, this will not count against the accrual/ recruitment cap*

4. Comment \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_