EDC Spec Form

Adolescent TB Study

Off Study

May 2, 2023

1. **2100A: Enrollment Visit** (for all participants)

**NOTE to DMC:** If any of the following conditions are met (both incorporating CRF responses and lab testing), the participant will require a clinic referral and remain on study for the follow up visit. For example, for an adolescent who has completed 2100A and the quantiferon result testing CRF is complete, the adolescent should remain *on study* if any of the following conditions are met:

* 1) Positive TB symptom screen: Q2,4,5,6, yes; or
* 2) Contact with household member with TB: Q4, no; or
* 3) Positive HIV testing: Q4, 6, no; or
* 4) Positive or indeterminate quantiferon test: Q1, 1 or 2. This lab result may take up to 1-2 weeks. The team will enter this result as 2100A.1.
	+ **Note to DMC:** If the result is indeterminate, the participant will return for an unscheduled visit for the following: 1) PRN lab requisition form for the quantiferon test; 2) quantiferon result testing CRF; 3) referral CRF. If the repeat lab result is positive, the participant will remain *on study*. If the repeat lab result is negative, and does not meet other referral criteria, the participant will go *off study* from the TB study, but remain on FLOURISH.

**NOTE to DMC:** For an adolescent who has completed 2100A and the quantiferon result testing CRF is complete, the adolescent should go *off study* from the TB study, but remain on FLOURISH if the following conditions exist:

* Negative TB symptom screen: Q2,4,5,6, no; or
* Contact with household member with TB: Q4, yes; or
* Negative HIV testing; Q3 negative, indeterminant or do not know; or Q4, 6 no; or
* Negative quantiferon test, Q1, 0. This lab result may take up to 1-2 weeks. The team will enter this result as 2100A.1.
1. **2200A: Follow up visit** (for participants who met referral criteria)

**Note to DMC:** All participants who complete the follow up visit will complete the engagement and referral outcomes CRFs. Clinician notes will be uploaded if available. Up to 5 participants are eligible for an interview per protocol. These participants will additionally complete the interview, transcription, and translation CRFs.

**Note to DMC:** Once the follow up visit is complete, all participants will go *off study* from the TB study, but remain on the FLOURISH study.