Adolescent TB Study

EDC Spec From for **2200A** (2-month TB study visit for FLOURISH participants)

**Note to clinic team:** All participants referred to government health clinic for further evaluation are eligible for follow-up visit. Review reason for referral prior to visit. All participants will complete CRF 1-3 and undergo chart abstraction. Complete CRF #4-6 only for 5 participants undergoing the interview.

1. CRF 1: Engagement
* Question 1: Is the participant interested in participating in the interview? □0= no □1= yes □2= not eligible (interview target reached)
	+ If yes or not eligible, proceed to CRF 2.
	+ If no, proceed to question 2.
	+ Note to DMC: programming for maximum of 5 interviews per protocol
* Question 2: Provide reason for not undergoing the interview: □0= Not able to physically come to clinic □1= Not interested in participating □2= Other
	+ Question 3: If other, specify: (free text)
1. CRF 2: Referral Outcomes Form
	* Question 1: Did participant go to a referral clinic for TB evaluation? □0= no □1= yes
		+ If yes, proceed to Q4
		+ If no, proceed to Q2. Require off-study form. Allow for comments.
	* Question 2: Add reason for not going to a referral clinic: □0=temporarily out of study area □1=participant does not have transport fares □2=unable to attend due to school, exams or tests □3 =participant/caregiver has work/home emergency issues □4=participant/caregiver cannot be released from work □5=participant is in isolation due to COVID-19 or another infection □6=participant/caregiver is not well □7= other
		+ Question 3: if other, specify
	* Question 4: If yes, which clinic did you go to? □1=Bontleng □2= Julia Molefe □3= Phase 2 □4= BH2 □5= Nkoyaphiri □6= Mogoditshane □7= Lesirane □8= Old Naledi □9= BH3 □10= GWest □11= BH1 □12= Sebele □13= Other
		+ Question 5: If other, specify.
	* Question 6: Were diagnostic studies performed at the clinic visit? □0= no □1= yes □2= unable to determine
		+ If yes, proceed to Q7
		+ If no or unable to determine, proceed to Q11
	* Question 7: What diagnostic studies were performed? □1=Sputum sample □2= Chest Xray □3= Gene Xpert □4= TST/Mantoux □5= COVID-19 test □6= other
		+ **Note to DMC**: allow for multiple answers to Q7.
		+ Question 8: If other, specify (free text)
	* Question 9: Were any of the diagnostic studies positive? □0= no □1= yes □2= pending □3= unable to determine
		+ If yes, proceed to Q10
		+ If no, pending, or unable to determine, proceed to Q11
* Question 10: Specify test and test result: (free text)
	+ Question 11: Was TB treatment started? □0= no □1= yes
		- If yes, require off-study form. Allow for comments.
		- If no, proceed to Q10.
	+ Question 12: Was TB preventative therapy started? □0= no □1= yes
		- Require off-study form regardless of answer to Q12. Allow for comments.
1. CRF 3: Clinician notes

**Note to clinic team**: if the participant agrees and is eligible for the interview, proceed to CRF 4-6.

**Note to DMC:** if the answer to Q1 is “no”, answer to Q9 is “yes”, or once CRF complete, generate off study form.

1. CRF 4: Interview Form
	* Question 1: Date and time of study visit: (insert date, time)
	* Question 2: Location of the interview: □0= FLOURISH clinic □1= BHP site □2= participant home □3= other
		+ Question 3: If other, specify (other)
	* Question 4: Was caregiver present for the interview? □0= no □1= yes
	* Question 5: Duration of interview: (insert # of minutes)
	* Question 6: *Upload audio recording as mp3 file*
* Question 7: In what language was the interview performed? □0= Setswana □1= English □2= Both
1. CRF 5: Translation
* Question 1: Date translation completed: (DD/MM/YY)
* Question 2: Name of staff who performed translation: (drop down with list of study staff: Gosego, Sam, Martha, Boi, Gao, Pearl, Lebo, Fanta)
	+ Question 3: *Upload final translation document*
1. CRF 6: Transcription
* Question 1: Date transcription completed: (DD/MM/YY)
	+ Question 2: Name of staff who performed transcription: (drop down with list of study staff: Gosego, Sam, Martha, Boi, Gao, Pearl, Lebo, Fanta)
	+ Question 3: *Upload final transcription document*