**INFANT/CHILDREN/ADOLESCENTS TB CRFs in the FLOURISH Study**

**I. TB Screening CRF**

Note to DMC: to be asked at Quarterly Call Visits to all children (on each dashboard)

***Note to Clinic staff****:*

*A) Ask about recent symptoms. If symptoms resolved, unlikely to be TB.*

1. Does your child currently have any cough? □Yes □No
   1. If Yes to Q1, proceed to Q2
   2. If “No” to Q1, skip to Q3
2. How long has this cough lasted? □< 2 weeks □ 2 weeks
3. Does your child currently have a fever? □Yes □No
   1. If Yes to Q3, proceed to Q4
   2. If “No” to Q3, skip to Q5
4. How long has this fever lasted? □< 2 weeks □ 2 weeks
5. Is your child currently experiencing night sweats? (Night sweats is defined as waking up with your bed clothing soaked – enough to require the bed clothing to be changed) □Yes □No
   1. If Yes to Q5, proceed to Q6
   2. If “No” to Q5, skip to Q7
6. How long have the night sweats lasted? □< 2 weeks □ 2 weeks
7. Since we last spoke with you, has your child have any weight loss (or no weight gain for a child who is less than 12 years of age)? □Yes □No
   1. If Yes to Q7, proceed to Q8
   2. If “No” to Q7, skip to Q9
8. How long has the weight loss (or no weight gain) lasted? □< 2 weeks □ 2 weeks

**Q9 is only for children 12 Years of age:**

1. Does your child have fatigue or reduced playfulness that has lasted 2 weeks? □Yes □No
2. Were any symptoms (cough, fever, night sweats, weight loss, or fatigue) present when you last spoke with FLOURISH staff? □Yes□ No □Do not recall

Note to DMC: include this question on follow up quarterly call

1. Since the last time you spoke with FLOURISH staff, has someone in your household been diagnosed with TB? □Yes □No
2. Since the last time you spoke with FLOURISH staff, has your child been evaluated in a clinic for TB? □Yes □No
   1. If “Yes” to Q12, proceed to Q13
   2. If no to Q12, end of CRF.
3. Was your child referred by our FLOURISH clinic team? □Yes □No
   1. If “Yes” to Q13, proceed to TB referral outcomes CRF.
   2. If “No” to Q13 (self-referral), proceed to Q14.
4. What was the date of the clinic visit? (DD/MM/YYYY)
   1. Note to DMC: If date of clinic visit is in the last 30 days, do not trigger 2 week follow up phone call or TB referral CRF.
5. What diagnostic tests were performed for TB? □=Chest Xray □= Sputum sample □= Stool sample □= Urine test (LAM) □= Skin test (TST/Mantoux) □Blood test (quantiferon) □= none □= other
6. If “Other”, specify test and result (free text)

**Note to DMC:** If a diagnostic test (any other than “none”) is checked on Q15, then require a response corresponding test type result (example: If “Chest Xray” was selected above, then Q17 “Chest Xray Result” is required. If the response to Q15 is “none,” proceed to **Q24**

**Note to DMC: allow multiple answers to Q15**

1. Chest Xray Results: □ positive □ negative □ pending □ not received
2. Sputum sample Results: □ normal □ abnormal □ pending □ not received
3. Stool Sample Results: □ positive □ negative □ pending □ not received
4. Urine Test Results: □ positive □ negative □ pending □ not received
5. Skin Test Results: □ positive □ negative □ pending □ not received
6. Blood Test Results: □ positive □ negative □ pending □ not received
7. Other Result: □ positive □ negative □ pending □ not received

Note to DMC: If results in Q17-23 are pending, make this CRF available to provide results in the next quarterly call

1. Was your child diagnosed with TB? □Yes □No □Awaiting results □Other (please specify:\_\_\_\_\_\_\_(free text))

a. If “Yes” to Q24, proceed to Q25

b. If “No” to Q24, proceed to Q26

c. If “Awaiting results” or “Other,” CRF complete

1. Was your child started on TB treatment (consists of four or more drugs taken over several months)? □Yes □No □Other (please specify:\_\_\_\_\_\_\_(free text))

a. End of CRF

1. Was your child started on TB preventative therapy (such as isoniazid or rifapentine/isoniazid for several months)? □Yes □No □Other (please specify:\_\_\_\_\_\_\_(free text))

a. End of CRF

**II. TB Referral CRF**

**Note to DMC:** this CRF is for participants referred to a clinic based on “TB Referral Guidelines” criteria

1. Was a TB referral made? □Yes □No
   1. If yes, continue to Q2
   2. If no, add reason: □Declined referral □Participant no longer has symptoms □Participant already evaluated for TB in last month
2. Date of referral: (DD/MM/YYYY)
3. Reason for referral: □Cough □Fever □Night sweats □Weight loss □Fatigue □Household Contact with TB □Persistent symptoms □Other
4. If other, specify: (free text)
5. Clinic names:  □Bontleng □Julia Molefe □Phase2 □BH2 □Nkoyaphiri □Mogoditshane □Lesirane □Old Naledi □BH3 □GWest □BH1 □Sebele □Other
6. If other, specify: (free text)
7. Is the participant able to come to FLOURISH clinic for referral? □Yes □No

a) If yes to Q7, instruct participant to come to clinic for referral note.

b) If no to Q7, refer participant to clinic over the phone for further evaluation.

**III. TB Referral Outcomes CRF**

**Note to DMC**: this CRF is for participants who completed the “TB referral CRF,” to be completed at the next quarterly call.

1. Did participant go to clinic for TB evaluation? □Yes □No □Other

1. If Yes to Q1, proceed to Q2
2. If “No” to Q1, skip to Q10

2. Clinic name for referral: □Bontleng □Julia Molefe □Phase2 □BH2 □Nkoyaphiri □Mogoditshane □Lesirane □Old Naledi □BH3 □GWest □BH1 □Sebele □Other

3. If other, specify: (free text)

4. What diagnostic tests were performed for TB (select all that apply) □=Chest Xray □= Sputum sample □= Stool sample □= Urine test (LAM) □=Skin test (TST/Mantoux) □= Blood test (quantiferon) □= none □= other

1. Question 5: if other, specify test and result (free text)
2. **Note to DMC:** if anything other than “none” is checked on question 4, then require a response to the corresponding diagnostic test under question 6. (for example, if ‘Chest X-ray’ is a response to Q4, then Q6a Chest Xray results is required. If “none,” proceed to question 7
3. **Note to DMC:** allow multiple answers for Q4

6. Results:

1. Chest Xray Results: □ positive □ negative □ pending □ not received
2. Sputum sample Results: □ normal □ abnormal □ pending □ not received
3. Stool sample Results: □ positive □ negative □ pending □ not received
4. Urine test Results: □ positive □ negative □ pending □ not received
5. Skin Test Results: □ positive □ negative □ pending □ not received
6. Blood Test Results: □ positive □ negative □ pending □ not received
7. Other Result: □ positive □ negative □ pending □ not received

7. Was your child diagnosed with TB? □Yes □No □Awaiting results □Other(please specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_(free text)

a. If “Yes” to Q7, proceed to Q8

b. If “No” to Q7, proceed to Q9

c. If “Awaiting results” or “Other,” CRF complete

8. Was your child started on TB treatment (consists of four or more drugs taken over several months)? □Yes □No □Other (please specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_(free text)

a. End of CRF

9. Was your child started on TB preventative therapy (such as isoniazid or rifapentine/isoniazid for several months)? □Yes □No □Other(please specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_(free text)

a. End of CRF

10. Reasons not able to go to TB clinic for evaluation (select all that apply):

□=temporarily out of study area

□=participant does not have transport fares

□=unable to attend due to school, exams or tests

□=participant/caregiver has work/home emergency issues

□=participant/caregiver cannot be released from work

□=participant is in isolation due to COVID-19 or another infection

□=participant/caregiver is not well

□= other(please specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_(free text)