**FLOURISH Study – EDC Design Requirements and Forms**

Visits for caregivers will occur at all visits listed below and for infants only beginning at delivery:

1. **Caregiver Eligibility**
	1. For all women:
		1. Must be 18 years of age or older.
		2. Legal guardian of child to be enrolled.
		3. Must be Botswana citizen (Omang or Omang Receipt).
		4. Able to provide informed consent.
		5. Must consent to allow HIV testing and counseling of child.
		6. Must be willing to remain in study area with child for five years .
		7. Must not be incarcerated during any period of study, including at enrollment.
	2. For selected caregivers/biological mothers
		1. For caregivers of female children who will be 12 years or older any time prior to 30-Jun-2025 must be willing to consent for the female child to undergo pregnancy testing.
		2. For biological mothers of children who require screening for Cohort C (newly recruited from school health education talks), must be alive, willing to undergo HIV-testing, and test negative for HIV.
		3. For women recruited in pregnancy must be willing to undergo HIV testing and counseling if not known to be living with HIV.
	3. For pregnant women:
		1. Pregnant women must be 16 - 30 weeks gestation with a singleton pregnancy. Singleton vs. multi-gestation pregnancy will be determined by ultrasound on “Ultrasound Initial Form” which may occur on the same day as Enrollment or on a day AFTER initial enrollment and consent.
		2. Women recruited in pregnancy must have the intent to breastfeed their infant.
		3. After enrollment into the study, mother must deliver liveborn infant. If stillbirth or no liveborn infant, failure to achieve the liveborn criteria should result in the mother being ineligible to progress in the study. Failure to meet this criteria does not count against accrual goal.
		4. Infant must be HIV-uninfected if born to an HIV-infected mother. Test will be performed at delivery but results will not be available until 3 business days after test is performed. If infant is positive, mother-infant pair will be placed off study.

**Note to Coulson**: For purposes of accrual, women enrolled in pregnancy who are lost to follow-up before delivery will be taken off study and will not count against the goal of accruing 100 pregnant WLHIV and 100 pregnant women without HIV (for Cohort A)

* 1. Determination of HIV Status of Pregnant Women and Biological Mothers of HUU screened for Cohort C
		1. If mother has evidence of HIV positive status either by showing a positive testing result and/or showing IDCC records that demonstrate that she is taking ARVs, this will be sufficient evidence that she is HIV positive.
		2. If mother has no evidence of HIV status or HIV testing will be performed.

**Note to Coulson**: Need to capture source of HIV status, either IDCC record or positive HIV test, or prescribed ARV medications, vs. study initiated testing and result

1. **Child/Adolescent Eligibility**
	1. All children/adolescents
		1. Must be ≤ 17 years old.
		2. Provision of assent if age and developmentally appropriate.
		3. Child/adolescent cannot be HIV positive at time of enrollment.
		4. Child/adolescent cannot be incarcerated at enrollment or during the study.
	2. For selected children/adolescents
		1. CHEU ≥ 16 years must have been told about their mother’s HIV status at time of enrollment.
		2. Children ≥ 13 years old must be willing to consent to continued study participation if they reach 18 years of age while on study.
		3. Children and adolescents providing written informed assent for study enrollment must assent to HIV testing & counseling.
		4. Female children ≥ 12 years old must assent to pregnancy testing at enrollment and any other in person study visit.
		5. Female adolescent cannot be pregnant at time of enrollment

**Note to Coulson**: At every study visit, in-person or by phone, the caregiver of a child/adolescent who is HEU must be asked if disclosure has occurred if there is no prior documentation of disclosure. Child/adolescent dashboard should contain a **‘Yes’/’No’ designation of disclosure status,** with a ‘Not Applicable’ option for children/adolescents who are HUU.

1. **Required Forms**
	1. **Consent**
		1. Five consents and two assents for FLOURISH study.
			1. Pre-FLOURISH Consents/Assents for newly enrolled children/adolescents (only applicable for Cohort C HUU Caregiver-Child pairs)
				1. Adult Pre-FLOURISH consent
				2. Parental Consent for Child/Adolescent Pre-FLOURISH
				3. Child/Adolescent Assent for Pre-FLOURISH

**Note to Coulson**: After Pre-FLOURISH consent, HUU wait in pool to be matched with HEU w/ same age and BMI – Will also receive quarterly calls (vital forms)

* + - 1. Consents/Assents for FLOURISH Participation
				1. Adult participation consent
				2. Parental consent for child/adolescent participation
				3. Child/adolescent assent for participation
				4. Consent for continuing adolescent participants at age 18
	1. **Cohort C Caregivers of CYHUU Pre-FLOURISH with No Prior Participation in MCH BHP studies (Figure 1) after Pre-FLOURISH Consent Signed**
		1. Question 1: Are you the biological mother of the child: □ 0=No □1=Yes
			1. If No = ineligible
			2. If Yes, continue to Q2
		2. Question 2: What is the DOB of your child (DD/MM/YYYY)
			1. DOB must be between 1-May-2005 and 1-Nov-2012
			2. If DOB does not fall between 1-May-2005 and 1-Nov-2012 = ineligible
		3. Question 3: Do you have documentation of your HIV Status? □ 0=No □1=Yes
			1. If Yes, continue to Q4
			2. If No, require HIV rapid testing and Counseling CRF (Tshilo Dikotla ‘Rapid Test Result’ form)
		4. Question4: HIV Test Result: □ 0=Negative □1=Positive □2=Indeterminate.
			1. If positive = ineligible but collect date of test.
				1. Trigger an ‘Off Study’ form.
		5. Question 5: Date of test (DD/MM/YYYY)
			1. If negative and date of test is after DOB of child = eligible for study
			2. If indeterminate OR if test date for negative test is before DOB of the child, require HIV rapid testing and counseling CRF

**Note to Coulson**: Q5, if sufficiently recent test (within 3 months) result shows negative, do not require HIV Rapid Test CRF.

* 1. **Cohort C HUU Child/Adolescent Pre-FLOURISH with No Prior Participation in MCH BHP studies after Pre-FLOURISH Assent/Parental Consent Signed**
		1. Question 1: What is your DOB? (DD/MM/YYYY)
			1. Compare against mother’s reported child DOB
			2. DOB must be between 1-May-2005 and 1-Nov-2012
			3. If DOB does not fall between 1-May-2005 and 1-Nov-2012 = ineligible.
		2. Question 2: Is there documentation of the child’s HIV status □ 0=No □1=Yes
			1. If Yes, continue to Q2
			2. If No, continue to Q4
		3. Question 2: HIV Test Result: □ 0=Negative □1=Positive □2=Indeterminate.
			1. If positive = ineligible but collect date of test
		4. Question 3: Date of test (DD/MM/YYYY)
			1. If negative and date of test is within 3 month of screening visit, child is eligible. Otherwise, if test date greater than 3 month of screening visit, child will require rapid HIV testing CRF
			2. If indeterminate, child will require rapid HIV testing CRF
		5. Question 4: Perform Rapid HIV testing and counselling CRF, use Tshilo Dikotla ‘Rapid Test Result’ form
			1. If test is negative = eligible for study
			2. If test result is positive = ineligible

**Note to Coulson:** Needed in this form. There is a separate Rapid Test CRF. Can response here be put into Rapid Test CRF Data table?

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* + 1. Question 4: Weight (kg)
			1. Range: Min=15kg to Max= 140kg
		2. Question 5: Height (cm)
			1. Range: Min = 40cm to Max= 210cm
			2. EDC to calculate BMI (**Formula: Weight (kg)/Height (m2)** )
		3. Question 6: Sex: □0=Male □1=Female
		4. Question 7: Does the caregiver know the gestational age of the child? Y/N
			1. If ‘Yes’ go to Q8
			2. If ‘No’ go to Q10
		5. Question 8: What is the Gestational Age of the child/adolescent?
			1. Response is a numeric two-digit value
			2. Add range value of 24 to 42 weeks
		6. Question 9: Was the child/adolescent premature when born?: □1=Yes □0=No □2=Unknown
			1. Insert Instruction: Preterm birth is a birth that occurs before 37 weeks gestation. You may have to ask the mother if this child was born earlier than she was told to expect the child, right at the same time, or after.
		7. Question 10: Was your child breastfed? □ 0=No □1=Yes □ 2=Unknown
			1. If ‘Yes’ continue to Q11
			2. If ‘No’ or ‘Unknown’, form is complete
		8. Question 11: Approximately how many months did this child breastfeed, including periods where the child was breast feeding and taking formula and solid foods together?
			1. Response is numeric two-digit value
			2. Add range value of 1 to 30



* 1. **Maternal Antenatal Enrollment Form (Figure 1) for Pregnant Women**– Use ‘Maternal Antenatal Enrollment Form’ for Tshilo Dikotla with the following changes:
		1. For Question 4 - under ‘GA by LMP at enrolment:’ Eligibility should be changed from >16 and <36 weeks GA, to >16 and ≤30 week GA
		2. For Question 6 – ask the question but do not make ineligible if answer is Yes.
		3. For Question 7 – Update to say ‘intent to’ instead of ‘willing to’
		4. Delete Question 8

Update form to have the following questions in this order:

* + 1. New Question 8: Have you tested for HIV before or during this pregnancy? □ No □ Yes
			1. If ‘No’ HIV test is required at Q12
		2. Q9: What is your current HIV status? □Positive □ Negative □ Indeterminate □ Never tested for HIV □Unknown □ Don't want to answer
		3. Q10: Date of HIV Test: \_\_\_\_\_\_ (DD/MM/YYYY)
			1. If Q9 is ‘Negative’ and results not within 3 months (Q10), Q12 is required

**Validation for Question 9 & 10:** If response to Q9 is ‘negative’, and the date of test (Q10) is greater than 3 months prior, require rapid HIV test for participant to confirm negative HIV status

* + 1. Q11: (Interviewer) If HIV+ve, do records show that participant is taking, is prescribed, or will be prescribed ARVs (if newly diagnosed) during pregnancy? □Yes □ No □ Not applicable
			1. Add note: *If found POS by RAPID TEST. Then answer YES*
		2. Q12: Was a rapid test processed? □Yes □ No □ Not applicable
			1. Add note: *Remember, rapid test is for NEG, UNTESTED, UNKNOWN or never done HIV test, old HIV test results and Don't want to answer*
		3. What is the rapid test result? □None □ Positive □ Negative □ Indeterminate
		4. For Question 11 (formerly Q15) – Remove comment ‘can take them OFF STUDY at birth visit if they were not on therapy for at least 4 weeks’
	1. **Enrollment Rapid HIV Testing and Counselling for** pregnant women who’s test date is greater than 3 months (90 days).
	2. **Enrollment Ultrasound for Pregnant Women** Use Tshilo Dikotla ‘Maternal Ultrasound Initial’ form

**Note to Coulson:** GA by LMP at ultrasound date will be calculated by using the Antenatal Enrollment form Q4. Please replicate EDC logic from Tshilo Dikotla that relies on the following formula:

$$\left[GA by LMP at Ultrasound Initial Date\right]=40- \left[\frac{\left(EDD by LMP\right)-(Ultrasound Initial Date)}{7}\right]$$

* + 1. For “GA confirmed” after Q9, please add days. Then calculate GA at consent using the weeks and days to determine eligibility.
	1. **Caregiver Locator** - Same as Tshilo Dikotla “Maternal Locator” form and please use same edit logic.

**Note to Coulson**: Caregiver Locator will be used prior to enrollment/consent for previously BHP participants, in order to be able to call the participants for recruitment. This will not be the case for Tshilo Dikotla participants, as recruitment will happen out of the Tshilo Dikotla EDC. For adolescents in the Mashi 06 protocol (HUU), locator will be needed to recruit into Cohort C Pre-FLOURISH Screening. It will also be used after consent for new to BHP participants and to update previous BHP participants information, to contact for follow-up visits

* 1. **Caregiver Enrollment Information for infant/children/adolescents previously enrolled in BHP study**
		1. Question 1 – ‘Is this caregiver the person previously enrolled in a BHP study’ □ 0=No □1=Yes
			1. If ‘yes’, and original record is for biological mother living with HIV – enrollment criteria met.
			2. If ‘yes’, and original record is for biological mother without HIV, ask:
				1. Add Question ‘What is your current HIV status?’ □ 0=Negative □1=Positive □2=Indeterminate.
				2. Add Question ‘Do you know your last HIV test date?” □ 0=No □1=Yes; If No, stop. If yes, go to c.
				3. Require test date
				4. Is this date estimated □ 0=No □1=Yes

**Note to Coulson**: This above information will not drive any eligibility criteria, it is for characterization of cohort only.

* + - 1. If ‘No’ to Question 1, ask the following questions:
				1. Sex □ 0=Male □1=Female
				2. Relationship to child: □ Father □ Grandmother □ Grandfather □ Aunt □ Uncle □ Sister □ Brother □ Guardian □ Other

If other, require text explanation

* 1. **Enrollment Socio-demographics for all Caregivers**. Use Tshilo Dikotla ‘Maternal Demographics’ form Version 2.0
		1. Delete Questions 15 through 22

Add new Question 15: Are you currently living in the same household as child who is also participating in the FLOURISH study? □ No □Yes**Note to DMC**: Q16 below is only for woman enrolled in pregnancy

* + 1. Add a Question 15 (new question): Is there anyone else in the household who contributes to supporting the family expenses? If yes… provide options (Grandmother, Grandfather, sister, brother, aunt, uncle, friend, etc.
			1. If Q15 is “Yes” Q16 is required.
			2. If Q15 is “No”, skip Q16
		2. Add Question 16: Who in the household contributes to supporting the family expenses (select all that apply) □ Partner/husband □ Mother □ Father □ Sister □ Brother □ Aunt □ Uncle □Grandmother □ Grandfather

□ Mother-in-law or Father-in-law □ Friend □ Unsure □ Other, specify

* + 1. Add Question 17: “How many household members live in the your primary home/ compound? A household member is considered someone who spends more nights on average in your household than in any other household in the same community over the last 12 months”
			1. Numeric entry and add range of 1 to 25

Note to DMC: Q18 is only for mothers who consented into FACET sub-study

* + 1. Add Question 18: Where did this visit take place: □At BHP □ At participant home □ Other :\_\_\_\_\_\_\_\_\_\_\_(specify) (free text option)
	1. **Enrollment Medical History for all Caregivers**.. Use Tshilo Dikotla ‘Maternal Medical History’ form
		1. Replace any reference of ‘mother’ to ‘caregiver’
		2. Question 3: Should be stated ‘Does the caregiver have any chronic conditions?’
		3. Move Question 6 and 7 to follow right after Question 3, and only require if Question 3 is ‘Yes’.
		4. Update Question 4 to say ‘Has the caregiver ever been diagnosed with a WHO Stage III or IV illness?’
			1. For logic criteria under Question 4, update logic to say ‘HIV infected caregivers’
		5. Delete Questions 8, 9, 12, 13, 14, 16 through 19
		6. For Q10, Add additional medications to the options: (starting after vitamin D supplement): □Diabetic medications □Anti-asthmatic drugs □ Antidepressant drugs □ Anti-anxiety drugs □Anti-hepatitis medications □Heart disease medications □ 3TC □Truvada □Efavirenz □DTG □Atripla □Combivir (3TC, AZT) □Nevirapine □Aluvia □Abacavir □Tenofovir □TLD (TDF,3TC,DTG) □Raltegravir
		7. Update wording to Question 15: ‘How many people know that you are living with HIV?’
		8. Add new Question: Q11 Do you have any current illness?
			1. If “Yes” next questions are required (Q12-Q14)
		9. Q12: What are your current symptoms: □Cough □ Fever □Headache □ Vomiting □Diarrhea □Fatigue □ Congestion □ Enlarged Lymph nodes □ Other (please specify:\_\_\_\_\_\_\_\_\_(free text))
		10. Q13: When did the symptoms start: \_\_\_\_\_\_\_\_\_\_\_\_DD/MM/YYYY
		11. Q14: Have you been seen at a local clinic or have you been seen for consultation at a local clinic because of this illness? □Yes □ No □ Appointment Scheduled □ Will seek care
	2. **Enrollment Obstetrical History for all Caregivers ONLY for Biological Mothers.** Use Tshilo Dikotla ‘Maternal Obstetrical History’ form

**Note to Programming Team:** This CRF is only to be completed if the Caregiver is the Biological Mother of the child in the FLOURISH study = This CRF will only be asked for Caregivers who respond ‘Yes’ to Question 1 on the CRF titled “*Caregiver Enrollment Information for infant/children/adolescents previously enrolled in BHP study.”*

* + 1. Reword Question 3 to be: “How many pregnancies has the participant had (if participant is currently pregnant, please include in the count of pregnancies)
		2. Reword Question 7: “How many living children does that participant have?”
			1. Add Question #9: How many of the participants children died after 5 years of age

Include responses for #9 in validation calculations

* + - 1. Add new Question: Number of pregnancies less than 24 weeks.

(Note to DMC:

1; This question only applicable to participants who are currently pregnant.

Refer to the FLOURISH ‘UATlog\_MaternalOBHistory’ excel for validations (found in the EDC Spec Form Folder in Dropbox)

* 1. **Enrollment for Caregivers Living with HIV (CRF Name = HIV Viral Load and CD4).**
		1. Question 1: Is the caregiver’s last CD4 count known? □ 0=No □1=Yes
			1. If ‘Yes’ continue to Q2
			2. If ‘No’ continue to Q4
		2. Question 2: What is the caregiver’s CD4 count? (Value Range of 1 to 9999)
		3. Question 3: Date of CD4 count (DD/MM/YYYY)
		4. Question 4: Is the caregiver’s last viral load known? □ 0=No □1=Yes
			1. If ‘Yes’ continue to Q5
			2. If ‘No’ end
		5. Question 5: Was the viral load detectable? □ 0=No □1=Yes
		6. Question 6: Quantitative results of most recent Viral Load test (value range of 10 to 150,000; units of copies/ml, not log10 results)
		7. Question 7: HIV results quantifier? □< □ = □>
		8. Question 8: Date of last viral load test (DD/MM/YYYY)
	2. **Enrollment ARVs Pre-Pregnancy for Pregnant women living with HIV (CRF Name= ARVs History Pre-Pregnancy)** Use Tshilo Dikotla ‘Maternal ARV Lifetime History’
		1. Change any reference to ‘HAART’ to ‘ART’

**Note to Sara:** Weekly review of ‘Other specify’ or ‘’Not applicable’. To review if updates to table are needed.

* 1. **Enrollment ARVs During Pregnancy for Pregnant women living with HIV (CRF Name= ARVs During Pregnancy)** Use Tshilo Dikotla ‘Maternal ARV In this Preg’
		1. This form must be completed after ARVs History Pre-Pregnancy CRF (above)
		2. For question 3, Logic to be added: If Q8 on ARVs History Pre-Pregnancy is answered ‘Yes’, then Q3 on this form cannot be answered as ‘No’
	2. **Enrollment HIV Disclosure status for Caregivers living with HIV with children aged 10-15.9 - Version 3.0**

**Note to DMC:** CRF only required when child age calculated by [today] to be between 10 and 15.9 years of age. If the Caregiver has a child greater than 16 at enrollment, and consented (confirmed they disclosed their HIV status), this form is not required.

* + 1. Q1: Have you disclosed your HIV status to your child? ? □No □Yes
			1. If ‘Yes’ note on child’s dashboard and skip to Q4
			2. If ‘Yes’ this CRF at all follow-up visits is NOT required
			3. If ‘No’ continue to Q2 & Q3
		2. Q2: Do you plan on disclosing your HIV status to your child? □No □Yes
		3. Q3: What is the reason you have not disclosed your HIV status to your child? □ Fear of burdening the child □ Stigma □Fear of rejection □ Feeling child is immature □Does not want the child to worry about her mother. □Does not want to scare the child. □ Does not want the child to be hurt by reactions of others. □Does not feel the child needs to know □Does not know how to explain this to their child □Other
			1. If other, please type reason
		4. Q4: At what age did you disclose your HIV status to your child?\_\_\_\_\_\_\_(range 0-18)
		5. Q5: Who disclosed this information to your child □ Myself (Caregiver enrolled in the FLOURISH study) □ Child’s biological father □ Child’s Grandmother □ Child’s Grandfather □ Child’s Sibling □ Child’s Aunt □ Child’s Uncle □ Other (please specify:\_\_\_\_\_\_\_\_\_)
		6. Q6: How easy or difficult was it to disclose your HIV status to your child? Very Difficult Difficult Neutral Easy Very Easy Prefer not to answer
		7. Q7: What was the reaction of the child after disclosure? (select all that apply) Understanding Calm Sympathetic Angry Scared Unaccepting Loss of respect/undermine Prefer not to answer Other (please specify:\_\_\_\_\_\_\_\_\_)
		8. Q8: Did your child find out about your HIV status (disclosure) because you or another person you designated, intentionally told them? Yes No
			1. If “No” for Q8, continue to Q9
			2. If “Yes” for Q8, end of CRF
		9. Q9: If this disclosure was unintentional, please provide reasons why (select all that apply): Someone else disclosed without your approval Child found out about status from accidentally seeing documentation/records Child found out about status when they found ARV medications Child overheard conversation about your HIV status Someone else told my child without my knowledge or permission Other
			1. If “Other”, specify: \_\_\_\_\_\_\_\_\_\_\_\_(free text)

**Note to Clinic Team:** If caregiver has not yet disclosed their HIV status at the enrollment visit, please provide them with educational materials for aid when disclosing HIV status.

* 1. **Enrollment Substance Use Prior to Pregnancy for pregnant women Only** Use Tshilo Dikotla ‘Maternal Substance Use Prior to Pregnancy’ form
		1. Add validation to Q4
			1. If Q3 was answered ‘No’ Q4 will automatically answer ‘None’
			2. If Q3 was answered ‘No’ Q4 cannot answer anything other than ‘None’
			3. If Q3 was answered ‘Yes’ Q4 cannot be answered as ‘None’
		2. Add validation to Q6
			1. If Q5 was answered ‘No’ Q6 will automatically answer ‘None’
			2. If Q5 was answered ‘No’ Q6 cannot answer anything other than ‘None’
			3. If Q5 was answered ‘Yes’ Q6 cannot be answered as ‘None’
		3. Update Q7 to say ‘Has the participant ever used marijuana**/**weed prior to this pregnancy?’
		4. Add validation to Q8
			1. If Q7 was answered ‘No’ Q8 will automatically answer ‘None’
			2. If Q7 was answered ‘No’ Q8 cannot answer anything other than ‘None’
			3. If Q7 was answered ‘Yes’ Q8 cannot be answered as ‘None’
		5. Add Q9; Has the participant ever used Khat prior to this pregnancy? □ No □Yes
			1. If ‘Yes’ continue to Q10
		6. Add Q10: If yes, please indicate how much: □None □ Daily □ Once every few days □Weekly □ 2-3 times per month or less
			1. Add validation to Q10
				1. If Q7 was answered ‘No’ Q8 will automatically answer ‘None’
				2. If Q7 was answered ‘No’ Q8 cannot answer anything other than ‘None’
				3. If Q7 was answered ‘Yes’ Q8 cannot be answered as ‘None’
		7. The original Q9 (‘Please list any other illicit substances...’) will be changed to Q11.
	2. **Enrollment History of TB for Pregnant Women Only**
		1. Question 1: Do you have a prior history of TB infection? TB infection, known as latent TB, is defined as persons who are infected by the bacterium, *M. tuberculosis*, but have no TB symptoms. TB infection is diagnosed with a positive tuberculin skin test (TST) or IGRA lab test. □ 0=No □1=Yes □2=Unknown □3=Prefer not to answer
		2. Question 2: Do you have a prior history of a TB contact? TB contact is defined as close contact with someone diagnosed \
		3. Question 3: Do you have a prior history of taking isoniazid for TB preventative therapy (TPT)? □ 0=No □1=Yes □2=Unknown □3=Prefer not to answer
			1. If ‘Yes’, continue to Q4
			2. If ‘No’ ‘Unknown’ or ‘Prefer not to answer’, continue to Q5
		4. Question 4: Did you complete your TB preventative therapy (TPT)? □ 0=No □1=Yes □2=Unknown □3=Prefer not to answer
		5. Question 5: Do you have a prior history of TB disease? TB disease, known as active TB, is defined as persons who are infected by the bacterium, *M. tuberculosis*, with TB symptoms or positive laboratory findings, such as Gene Xpert or sputum culture. □ 0=No □1=Yes □2=Unknown □3=Prefer not to answer
			1. If ‘Yes’, continue to Q6
			2. If ‘No’ ‘Unknown’ or ‘Prefer not to answer’, continue to Q7
		6. Question 6: What type of TB were you diagnosed with? Pulmonary TB is disease in the lungs, whereas extra-pulmonary TB is disease outside the lungs (ex: lymph nodes, abdomen, bones, brain) □0=Pulmonary □1=Extra-pulmonary □2=Unknown □3=Prefer not to answer
			1. If ‘Extra-pulmonary’ was selected, continue to Q6
			2. If ‘Pulmonary’, ‘Unknown’ or ‘Prefer not to answer’, Skip to Q8
		7. Question 7: Where was the location of your extra-pulmonary TB? □0=lymph nodes □1=abdomen □2=bones □3=brain □4=unknown
		8. Question 8: Do you have a prior history of taking TB treatment? TB treatment generally requires 4 drugs for 6 months or longer. □0=no □1=yes □2=Unknown □3=Prefer not to answer
			1. If ‘Yes’, continue to Q9
			2. If ‘No’ ‘Unknown’ or ‘Prefer not to answer’, skip to Q11
		9. Question 9: How many drugs did you take for TB treatment? □0=4 drugs □1=More than 4 drugs □2=Unknown □3=Prefer not to answer
		10. Question 10: Did you take any intravenous (IV) medications during TB treatment? □0=no □1=yes □2=Unknown □3=Prefer not to answer
		11. Question 11: Did you complete TB treatment? □0=no □1=yes □2=Unknown □3=Prefer not to answer
	3. **Enrollment Screen for TB at routine health encounters** (enrollment, delivery, 2 months postpartum)
		1. Question 1: *(Enrollment Specific):* Were you screened for TB at a routine healthcare encounter with the four screening questions (cough, fever, weight loss, night sweats) since conception? □0=no □1=yes □2=Unknown □3=Prefer not to answer
			+ 1. If yes, continue to Q2
				2. If no/unknown/prefer not to answer, CRF complete
		2. Question 2: Where were you screened? □0=antenatal visit □1=IDCC □2=postpartum visit □3=hospital □4=other
		3. Question 3: Did you screen positive for the TB symptom screen? □0=no □1=yes □2=Unknown □3=Prefer not to answer
		4. Question 4: Were you referred for TB diagnostic evaluation? □0=no □1=yes □2=Unknown □3=Prefer not to answer
	4. **Enrollment Clinical Measurements for all Caregivers**. Use Tshilo Dikotla ‘Maternal Clinical Measurements One’ form
		1. Replace any reference of ‘mother’ to ‘caregiver’
		2. Add new Q1: Is this Caregiver pregnant? □Yes □No □Not Applicable
			1. If “Yes” Q7 & Q8 (waist and hip circumference) is not required.
		3. Add new question before Q3 (Weight): Is the mother’s weight available? □Yes □No
			1. If “No” Q3/Weight should NOT be required.
		4. Add Ranges for Height (Question 3)
			1. Min= 130cm to Max= 210cm
		5. Add Ranges for Weight (Question 4)
			1. Min=40kg to Max=140 kg
		6. Add Question 7: Caregiver Waist Circumference.
			1. For logic criteria, only measure waist circumference for caregivers who are not pregnant
			2. Add range value of: 50cm to 420cm for all three measurements
				1. First measurement: \_\_ \_\_ . \_\_ cm
				2. Second measurement: \_\_ \_\_ . \_\_ cm

(If first and second measurements differ by < 1 cm, **SKIP** third measurement.)

* + - * 1. Third measurement: \_\_ \_\_ . \_\_ cm
		1. Add Question 8: Caregiver Hip Circumference.
			1. For logic criteria, only measure hip circumference for caregiver who are not pregnant
			2. Add range value of: 50cm to 420cm for all three measurements
				1. First measurement: \_\_ \_\_ . \_\_ cm
				2. Second measurement: \_\_ \_\_ . \_\_ cm

(If first and second measurements differ by < 1 cm, **SKIP** third measurement.)

* + - * 1. Third measurement: \_\_ \_\_ . \_\_ cm
		1. Add Question 9: Were you able to obtain all clinical measurements at this visit? □Yes □No
			1. If “No” EDC to allow the form to save without all responses inputted (i.e. allow for missing values)
	1. **Enrollment PHQ-9 for Non-pregnant Caregivers**

Use PDF in Dropbox titled ‘PHQ-9 Depression - Caregivers. Add questions to EDC form.

* + 1. When this form is saved, require referral if score is ≥ 5 points using the scoring criteria listed below OR require referral if response to Question 9 is anything other than ‘Not at all’.
		2. When this form is saved, if score is X to X, give the participant a Depression Handout



* 1. **PHQ-9 Referral Form for Caregivers**
		1. Q1: Date of referral (DD/MM/YYYY)
		2. Q2: Referred to: Drop down options: Community Social Worker, Hospital-based Social Worker, A&E, Psychologist, Psychiatrist, other
		3. Q3: If other, describe
	2. **Enrollment Edinburgh Questionnaire for Pregnant Caregivers**

Use PDF in Dropbox titled ‘Edinburgh Depression - Pregnant Women’. Add questions to EDC Form:

* + 1. When this form is saved, require referral if score is ≥ 10 points using the scoring criteria listed below, OR require referral if response to Question 10 is anything other than ‘Never’.
		2. When this form is saved, if score is X to X give the participant a Depression Handout



* 1. **Edinburgh Referral Form for Caregivers**
		1. Q1: Date of referral (DD/MM/YYYY)
		2. Q2: Referred to: Drop down options: Community Social Worker, Hospital-based Social Worker, A&E, Psychologist, Psychiatrist, other
		3. Q3: If other, describe
	2. **Enrollment GAD-7 Questionnaire for All Caregivers**

Use PDF in Dropbox titled ‘GAD-7 Anxiety. Add questions to EDC Form:

* + 1. When this form is saved, require referral if score is ≥ 10 points using the scoring criteria listed below:
		2. When this form is saved, if score is ≥5 to ≤9, give the participant an Anxiety Handout



* 1. **GAD-7 Referral Form for Caregivers**
		1. Q1: Date of referral (DD/MM/YYYY)
		2. Q2: Referred to: Drop down options: Community Social Worker, Hospital-based Social Worker, A&E, Psychologist, Psychiatrist, other
		3. Q3: If other, describe
	2. **Birth Visit Birth Form for Women who Enrolled While Pregnant** Use Tshilo Dikotla ‘Add Delivery Maternal’ form
		1. Add Question 20: How was the infant being fed immediately after delivery? □Breastfeed Only □Formula feeding only □Both breastfeeding and formula feeding □Medical complications: Infant did not feed
	3. **Birth Visit Medical History for all Caregivers** Use FLOURISH Quarterly call Medical History form
	4. **Birth Visit Maternal HIV Interim Hx for WLHIV** Use Tshilo Dikotla ‘Maternal HIV Interim Hx’ form
	5. **Birth Visit HIV Testing and Counselling for** pregnant women who’s are not living with HIV
		1. If negative test date is greater than 3 months (90 days) require rapid HIV testing
	6. **Birth Visit Maternal Substance Use During Pregnancy** Use the FLOURISH Enrollment Substance Use Prior to Pregnancy for pregnant women’ form
		1. Replace all wording of ‘Prior to’ to be changed to ‘During’
	7. **Birth Visit Maternal ARV Use during Pregnancy** Use FLOURISH ‘Enrollment Maternal ARV Use During Pregnancy’ form
	8. **Birth Visit Maternal Interim IDCC Data for WLHIV** Use Tshilo Dikotla ‘Maternal Interim IDCC Data’ form

Infant/Children/Adolescents:

* 1. **Birth Visit ‘Infant Birth Data’ for Infants born to women consenting in pregnancy** Use Tshilo Dikotla ‘Infant Birth Data’ form

**Note to Team:** This form must be completed within 72 hours / 3 days of the delivery

* + 1. Add Question before Q3: Is the infant’s birth weight available: Y/N
		2. Add Question before Q4: Is the infant’s length at birth available: Y/N
		3. Add Question before Q5: Is the infant’s head circumference at birth available? Y/N
			1. All the added questions to default to ‘Yes’
		4. Add question before congenital anomalies (new Q10): What is the infant’s determined gestational age: \_\_\_\_\_\_\_\_(in weeks)
			1. Add range for Q10 of 22 to 43
		5. Q11 Should not be driven by any of the questions above
	1. **Birth Visit ‘Infant Birth Exam’ for infants born to women consenting in pregnancy** Use Tshilo Dikotla ‘Infant Birth Exam’ form
	2. **Birth Visit ‘Infant Congenital Anomalies’** Use Tshilo Dikotla ‘Congenital Anomalies Infant’ Form and all related congenital anomaly forms
		1. For this form, Infant Birth Data Q11 must be answered ‘Yes’

**Note to Coulson**: Use the same congenital anomalies form starting at the Birth Data

* 1. **Birth Visit ‘Birth Feeding and Vaccinations’ for women consenting in pregnancy** Use Tshilo Dikotla ‘Birth Feeding Vaccination Infant’
		1. Add Q4: When did you begin breastfeeding your infant?: DD/MM/YYYY
			1. Q4 required only if either ‘Breastfeeding only’ or ‘Both breastfeeding and formula feeding’ was a response to Q3
		2. Add Q4a: Is this date estimated? □ Yes □ No
		3. Add Q5: When did you begin feeding your infant formula? DD/MM/YYYY
			1. Q5 required only if either ‘Formula feeding only’ or ‘Both breastfeeding and formula feeding’ was a response to Q3
		4. Add Q5a: Is this date estimated? □ Yes □ No
	2. **Birth Visit Infant ARV Exposure for Infants born to women who are living with HIV and consenting in pregnancy** Use Tshilo Dikotla ‘Infant Birth Record ARV’
	3. **Birth Visit Screen for TB at routine health encounters**
		1. Question 1: (*Delivery Specific)*: Were you screened for TB at a routine healthcare encounter with the four screening questions (, fever, weight loss, night sweats) between enrollment to delivery? □0=no □1=yes □2=Unknown □3=Prefer not to answer
			1. If yes, continue to Q2
			2. If no/unknown/prefer not to answer, CRF complete
		2. Question 2: Where were you screened? □0=antenatal visit □1=IDCC □2=postpartum visit □3=hospital □4=other
		3. Question 3: Did you screen positive for the TB symptom screen? □0=no □1=yes □2=Unknown □3=Prefer not to answer
		4. Question 4: Were you referred for TB diagnostic evaluation? □0=no □1=yes □2=Unknown □3=Prefer not to answer
	4. **Rapid HIV Testing and Counselling** Use Tshilo Dikotla Rapid Test Result’ form

First step in Enrollment, right after Consent and Assent.

* + 1. For infants < 18 months of age, ELISA
		2. For infants/children >18 months Rapid HIV Test
			1. If child tests positive, go to Child Off-Study form
	1. **Enrollment Immunization History for all Infant/Children/Adolescents** Use Tshilo Dikotla ‘Infant FollowUp Immunizations’ form
		1. Reorder the questions:
			1. Q1 ‘Please record all vaccinations received by this infant/child/adolescent’à Received vaccine table

**Note to Coulson:** Populate all information/immunization from any Tshilo Dikotla child on study and off study. For Tshilo Dikotla children off study, allow for immunizations to be added on the CRF. For on-study Tshilo Dikotla participants, real-time immunization records should be populated.

* + - * 1. Add ‘HPV vaccine’ to Received Vaccines table

Add validation that the child must be >12 years of age for this vaccine to be selected.

* + 1. Q2: ‘Is this infant/child/adolescent missing any vaccinations?’ □ Yes □No □Unknown
			1. Q3: Missing vaccine table
		2. Delete Question #3
	1. **Enrollment Socio-demographic for all Infant/Children/Adolescent – Version 3.0** Use the Maternal Socio-demographic form
		1. Delete Q3,Q4, Q7 through Q13/Q14.
		2. Add new Question #7 Is the Infant/Child/Adolescent currently living with the caregiver who is also participating in the FLOURISH study? □ No □Yes
			1. Compare against Caregiver Socio-demographic Q15 answer – must both have same answer
				1. Add validation for same answer required
		3. Add question #8: Which of the following people would be considered the child’s primary caretaker: □Biological Mother □Caregiver □ Biological Father □ Grandmother □ Grandfather □ Aunt □ Uncle □ Sister □ Brother □ Guardian □ Other
		4. Add Question #9: Who provides the second most caretaking responsibilities of the child enrolled in FLOURISH: □Biological Mother □Caregiver □ Biological Father □ Grandmother □ Grandfather □ Aunt □ Uncle □ Sister □ Brother □ Guardian □ Other
		5. Reword Q15: “At this child’s primary home/compound where do you get most of the drinking water?”
		6. Reword Q16: “Is there electricity at the child’s primary home/compound?”
		7. Reword Q17: “Is there a refrigerator being used in the child’s primary home/compound?”
		8. Reword Q18: “What is the primary method of cooking in the child’s primary home/compound?”
		9. Reword Q19: “Which of the following types of toilet facilities do you most often use at the child’s primary home/compound?”

Add new questions after Q19:

* + 1. Added Q: Is the house the child lives in currently painted on the outside or inside? □Yes □No □Unknown, Caregiver does not live with child
		2. Added Q: Is there any peeling, chipping or cracking paint in your home? □Yes □No □Do not know
		3. Added Q: When was the house you live in now built? □ Before 1980 □ 1980-1990 □ 1991-2000 □ 2001-2010 □ 2011-2019 □After 2019 □Do not know
		4. Added Q: Does the child currently live close to a busy road? □Yes □No □Unknown, Caregiver does not live with child
		5. Added Q: Since this child was born, have you ever lived next to a busy road? □Yes □No □Unknown, Caregiver does not live with child
		6. Reword Q21: “How many household members live in the child’s primary home/ compound? *A household member is considered someone who spends more nights on average in your household than in any other household in the same community over the last 12 months*”
			1. Numeric entry and add range of 1 to 25
		7. Add Question 22: Of the people who live in this household, how many are older than 18?
			1. Add range of 1 to 25
		8. Add Question 23: Is the infant/child/adolescent attending school? □ Yes □ No
			1. If ‘Yes’ continue to Q24 & 25 and **Enrollment Academic Performance for Children/Adolescents** CRF is required
			2. If ‘No’ skip to Q26 if applicable
		9. Add Question 24: What level/class of school is the child currently in?”: □ Preschool □ Standard 1 □ Standard 2 □ Standard 3 □ Standard 4 □ Standard 5 □ Standard 6 □ Standard 7 □ Form 1 □ Form 2 □ Form 3 □ Form 4 □ Form 5 □ Tertiary/University □ Other
			- 1. Allow free text for ‘Other’
			1. Use the following logic to determine the required field and skip logic for the **Academic Performance** CRF:
				1. If ‘No Schooling’ end of form
				2. If ‘Preschool’ is selected, skip to Q15
				3. If Standard 1 through Standard 7 was selected, questions Q2-Q7 are required. Then skip to Q15
				4. If Form 1 through Form 3 was selected, Q2-Q5, Q8, and Q9 are required. Then skip to Q15
				5. If Form 4 or Form 5 was selected, Q2-Q4, and Q10-Q14 are required. Then skip to Q15
		10. Add Question 25: What type of school does this child attend □ Public/Government □ Private □ Boarding School Public/Government □ Boarding School Private
			1. If “Boarding School Public/Government” OR “Boarding School Private” , Q26 is required. If any other answers are selected, skip to Q28
		11. Q26: How many months of the year does your child stay at boarding school? \_\_\_\_\_\_\_\_\_\_\_(range: 1-12)
		12. *Only ask this next question at follow-up/Quarterly calls* - Add Question 27: Is this adolescent currenting working in return for cash? □ Yes □ No
			1. Q26 only to be asked for children/adolescents who are ≥18 years
			2. If ‘Yes’ **Enrollment Working Status for Adolescents** CRF is required.

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* 1. **Enrollment Clinical Measurements for all Infant/Children/Adolescents** Use Tshilo Dikotla ‘Maternal Clinical Measurements One’ form
		1. Replace any reference of ‘mother’ to ‘infant/child/adolescent’
		2. Add new Q1, only to be asked to Female Adolescents who are ≥ 12 years of age : Q1: Is the participant pregnant? □ Yes □ No □ Not Applicable
			1. If Q1 is ‘Yes’, Q7 and Q8 (waist and hip circumference) are **not** required.

**Note to DMC:** If female adolescent is 18 years or older, this question must be asked directly to the adolescent participant

* + 1. **For Question 4, add range value of 50kg to 200kg**
			1. Q4 should only be asked for children/adolescents ≥ 4 Years Old
		2. **For Question 5, add range value of 40cm to 210cm**
			1. Q4 should only be asked for children/adolescents ≥ 4 Years Old
		3. Add Question 7: Infant/Child/Adolescent Waist Circumference.
			1. Add range value of: 15cm to 200cm for all 3 measurements
				1. First measurement: \_\_ \_\_ . \_\_ cm
				2. Second measurement: \_\_ \_\_ . \_\_ cm

(If first and second measurements differ by < 1 cm, **SKIP** third measurement.)

* + - * 1. Third measurement: \_\_ \_\_ . \_\_ cm
		1. Add Question 8: Infant/Child/Adolescent Hip Circumference.
			1. Add range value of: 15cm to 420cm for all 3 measurements
				1. First measurement: \_\_ \_\_ . \_\_ cm
				2. Second measurement: \_\_ \_\_ . \_\_ cm

(If first and second measurements differ by < 1 cm, **SKIP** third measurement.)

* + - * 1. Third measurement: \_\_ \_\_ . \_\_ cm
	1. **Enrollment Previous Hospitalizations Forms for all Infant/Children/Adolescents**
		1. Q1: Has your infant/child/adolescent been hospitalized after birth □ Yes □ No
			1. If Q1 is “Yes” continue to Q2. If Q1 is “No”, end of form
		2. Q2: How many times has your infant/child/adolescent been hospitalized?
			1. Value range must be at least 1

**Inline Table**: Hospital, Reason, and approximate date of admission. Allow for multiple entries but must equal the amount of previous hospitalizations response in Q2.

* + 1. Q3: What is the name of the hospital? □ Princess Marina □SLH □ DRMH □Thamaga Primary Hospital □ SDA □BLH □ Athlone □ Other
			1. Allow free text for ‘Other’
		2. Q4: What was the reason for hospitalization (multiple option answer): □Pneumonia □ Tuberculosis □Bronchiolitis □ Laryngotracheobronchitis / Croup □ Acute diarrheal disease □ Persistent diarrheal disease □ Meningitis □ Malaria □ Measles □Trauma □ Febrile seizure □ Malnutrition □ Anemia □Surgical reason (free text) □Other (free text)
			1. Allow free text options for “Surgical Reason” and “other”
		3. Q5: What is the approximate date of hospitalization: (DD/MM/YYY)
		4. Q6: Is it possible to extract/image the records from this hospitalization? □ Yes □ No

**Note to DMC:** If ‘Yes’ for Q6, activate the clinician notes CRF form

* 1. **Enrollment Food Security Questionnaire for Children/Adolescents ≥ 4 Years Old**
		1. Q1: Who will answer the Food Security Questionnaire: □ Caregiver □ Child/Adolescent

Instructions for study staff administering survey: Please state for participant “I’m going to read you several statements that people have made about their food situation. For these statements, please tell me whether the statement was often true, sometimes true, or never true for (you/your household) in the last 12 months—that is, since last (name of current month).”

1. Q2: “The food that (I/we) bought just didn’t last, and (I/we) didn’t have money to get more.” □ Often True □ Sometimes True □ Never True □I don’t know or Refused to answer
2. Q3: “(I/we) couldn’t afford to eat balanced meals.” □ Often True □ Sometimes True □ Never True □I don’t know or Refused to answer
3. Q4: In the last 12 months, since last (name of current month), did (you/you or other adults in your household) ever cut the size of your meals or skip meals because there wasn't enough money for food? □=1 Yes □=0 No □=2 I don’t know
	* + 1. If ‘No’ or ‘I don’t know’ continue to Q5
4. Q5: How often did this happen? □ Almost every month □ Some months but not every month □ Only 1 or 2 months □ I don’t know
5. Q6: In the last 12 months, did you ever eat less than you felt you should because there wasn't enough money for food? □=1 Yes □=0 No □=2 I don’t know
6. Q7: In the last 12 months, were you every hungry but didn't eat because there wasn't enough money for food? □=1 Yes □=0 No □=2 I don’t know
	1. **Enrollment Medical History for Children/Adolescents ≥ 4 Years Old** Use Tshilo Dikotla ‘Maternal Medical History’
		1. Delete Questions 1 and 2
		2. Update Question 3: Should be stated ‘ Does the child/adolescent have any chronic conditions?’ □Yes □ No
		3. List of Chronic Illnesses for options: □ Asthma, □ Headache (includes migraines, tension headaches) □ Anemia □ Cardiac murmur □Seizure disorder or other epilepsy □Diabetes □High blood pressure □High cholesterol □Depression □Systemic lupus □Juvenile rheumatoid arthritis □Nephrotic syndrome □Renal insufficiency □Nephrolithiasis (kidney stones) □Cancer (Solid tumor) □Cancer (Leukemia, lymphoma related) □Cardiac arrhythmia □Thyroid disorder □Inflammatory bowel disease (Crohn’s, ulcerative colitis)
		4. Delete Question 4, 8 through 20
		5. Add new Question Q5: Does your child have any current illness? □Yes □ No
			1. If “Yes” Q6, Q7, & Q8 are required
			2. If “No” end of CRF
		6. Q6: What are your child’s current symptoms (allow for multiple selection): □Cough □ Fever □Headache □ Vomiting □Diarrhea □Fatigue □ Congestion □ Enlarged Lymph nodes □ Other (please specify:\_\_\_\_\_\_\_\_\_(free text))
		7. Q7: When did the symptoms start: \_\_\_\_\_\_\_\_\_\_\_\_DD/MM/YYYY
		8. Q8: Has your child been seen at a local clinic or have you been seen for consultation at a local clinic because of this illness? □Yes □ No □ Appointment Scheduled □ Will seek care
		9. Q9: Is your child currently taking any medications □Yes □ No
			1. If “Yes” Q10 & Q11 required
			2. If “No” skip to ‘Outpatient Visit Question’ Section
		10. Q10: What medications does your child currently take (allow for multiple selection): □ Inhaler/Albuterol □Antibiotics □ Anti-anxiety drugs □ Anti-asthmatic drugs □ Antidepressant drugs □ Cholesterol medications □ Diabetic medications □ Heart disease medications □ Hypertensive medications □ Pain killers □ None □ Other, Specify □ TB Treatment □ TPT (TB preventive therapy) □ Traditional medications □ Vitamin D supplement □ PEP
		11. Q11: How long has your child been taking these medications: □Less than 1 week □>1 week to 2 weeks □>2 weeks to 1 month □> 1 month- 6 months □> 6 months

**Note to DMC:** Is it possible to pre-populate Q10 and Q11 at the next child’s visit/call ONLY if Q11 response is >1 – 6 months or > 6 months?

**Outpatient Visit Question Section:**

* + 1. Q1: Since the last you spoke to FLOURISH staff, has your child had an outpatient clinic visit? Yes No Unknown
			1. If “No” or “Unknown” end of CRF
			2. If “Yes” continue
		2. Q2: How many outpatient clinic visits has your child had? 1 2 3 4 5 or more
		3. Q3: What type of care did you seek for your child: New illness Growth Check Immunizations Mental health Unknown Other (specify:\_\_\_\_\_\_\_(free text))
			1. Q4 is required for all responses
			2. All other responses, Q4 required, then skip to Q6
			3. If “New Illness” is selected, Q5 is required
		4. Q4: Approximate date of when you’re child attended the outpatient care visit:\_\_\_\_\_\_\_\_ DD/MM/YYYY
		5. Q5 **\*Only required if “New illness” response in Q3\*** What symptoms did you child present with (select all that apply) : Cough Fever Vomiting Diarrhea Headache Fatigue Congestion Enlarged Lymph nodes Unknown Other (specify:\_\_\_\_\_\_\_\_\_(free text))
		6. Q6: Did you receive a new diagnosis? Yes No Unknown
			1. If “Yes” Q7 is required
		7. Q7: What was your child’s diagnosis: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (free text)
		8. Q8: Did the healthcare worker prescribe any medications for your child? Yes No Unknown
			1. If “Yes” Q9 is required
		9. Q9: What type of medications did your child receive: Antibiotic Paracetamol Bufen Multivitamin Ferrous Sulfate Unknown Other\_\_\_\_\_\_\_\_(free text)
		10. Q10: Did your child’s symptoms resolve? Yes No Unknown
			1. If “Yes”, Q11 is required
			2. If “No” ---- refer child to clinic
		11. Q11: What is the approximate date your child’s symptoms resolve: \_\_\_\_\_\_\_\_\_ DD/MM/YYYY
	1. **Enrollment Academic Performance for Children/Adolescents who are attending school**

**Note to DMC:** Use Question 24 on **Socio-demographic for all Infant/Children/Adolescent** CRF to display a statement noting the level/class of school the child is currently in.(And Pre-fill Q1 – Display the answer to Q1 on the sociodemographic form. )

 Also use Q24 on Socio-demographic CRF to use the skip logic for this form .

Question 1: ‘What level/class of school is the child currently in?”: [Pre-fill using Q24 from Socio-demographic form]

**Instructions:** If participant states the level of school is not correct, return to Socio-demographic form to update the class level.

* + 1. Question 2: What are your marks in Mathematics? □ A □B □C □D □E □U □Not taking subject □ I do not know right know
		2. Question 3 What are your marks in Science? □ A □B □C □D □E □U □Not taking subject □ I do not know right know
		3. Question 4: What are your marks in Setswana? □ A □B □C □D □E □U □Not taking subject □ I do not know right know
		4. Question 5: What are your marks in English? □ A □B □C □D □E □U □Not taking subject □ I do not know right know
		5. Question 6: What are your marks in Physical Education? □ A □B □C □D □E □U □Not taking subject □ I do not know right know
		6. Question 7 What are your marks in Cultural Studies? □ A □B □C □D □E □U □Not taking subject □ I do not know right know
		7. Question 8: What are your marks in Social Studies? □ A □B □C □D □E □U □Not taking subject □ I do not know right know
		8. Question 9: What are your marks in Agriculture? □ A □B □C □D □E □U □Not taking subject □ I do not know right know
		9. Question 10: What are your marks in Single Science? □ A □B □C □D □E □U □Not taking subject □ I do not know right know
		10. Question 11 What are your marks in Biology? □ A □B □C □D □E □U □Not taking subject □ I do not know right know
		11. Question 12: What are your marks in Chemistry? □ A □B □C □D □E □U □Not taking subject □ I do not know right know
		12. Question 13: What are your marks in Physics ? □ A □B □C □D □E □U □Not taking subject □ I do not know right know
		13. Question 14: What are your marks in Double Science? □ A □B □C □D □E □U □Not taking subject □ I do not know right know
		14. Question 15: What is your overall performance in your last examination? ‘ □ A □B □C □D □E □U □ Not applicable □ I do not know right know
		15. Question 16: How many days a week do you attend in-person classes □ 1 □2 □3 □4 □5 □None □ I do not know right know
	1. **Enrollment Physical Activity for Children/Adolescents ≥ 4 Years old**

Please say the following to the participant: ‘We are interested in finding out about the kinds of physical activities that people do as part of their everyday lives. The questions will ask you about the time you spent being physically active in the last 7 days. Please answer each question even if you do not consider yourself to be an active person. Please think about the activities you do at work, as part of your house and yard work, to get from place to place, and in your spare time for recreation, exercise or sport.’

Prompt for Q1 & Q2: Think about all the **vigorous** activities that you did in the **last 7 days**. **Vigorous** physical activities refer to activities that take hard physical effort and make you breathe much harder than normal. Think *only* about those physical activities that you did for at least 10 minutes at a time.

1. Q1: During the last 7 days, on how many days did you do vigorous physical activities like heavy lifting (carrying firewood, large buckets of water), digging, chopping firewood, fast bicycling, sports (football, track field, etc.), or other activities where you are breathing hard and exerting yourself?
	1. □ Days per week:\_\_\_\_\_\_\_\_\_
		1. Value cannot exceed 7
	2. □ No vigorous physical activity
		1. If ‘No vigorous physical activity’ skip to Q3
2. Q2: How much time did you usually spend doing vigorous physical activities on one of those days?
	1. □ Hours per day :\_\_\_\_\_\_\_\_\_
		1. Value cannot exceed 24
	2. □ Minutes per day:\_\_\_\_\_\_\_\_\_
		1. Value cannot exceed 60. If value of minutes is 60, convert to hours
	3. □ Don’t know/not sure

Prompt for Q3 and Q4: Think about all the moderate activities that you did in the last 7 days. Moderate activities refer to activities that take moderate physical effort and make you breathe somewhat harder than normal. Think only about those physical activities that you did for at least 10 minutes at a time.

1. Q3: During the last 7 days, on how many days did you do moderate physical activities like carrying light loads, bicycling at a regular/leisurely pace, or sports such as doubles tennis, badminton, or shotput? Do not include walking.
	1. □ Days per week:\_\_\_\_\_\_\_\_\_
		1. Value cannot exceed 7
	2. □ No moderate physical activity
		1. If ‘No moderate physical activity’ skip to Q5
2. Q4: How much time did you usually spend doing moderate physical activities on one of those days?
	1. □ Hours per day :\_\_\_\_\_\_\_\_\_
		1. Value cannot exceed 24
	2. □ Minutes per day:\_\_\_\_\_\_\_\_\_
		1. Value cannot exceed 60. If value of minutes is 60, convert to hours
	3. □ Don’t know/not sure

Prompt for Q5 & Q6: Think about the time you spent **walking** in the **last 7 days**. This includes at work and at home, walking to travel from place to place, and any other walking that you have done solely for recreation, sport, exercise, or leisure.

1. Q5: During the last 7 days, on how many days did you walk for at least 10 minutes at a time?
	1. Days per week:\_\_\_\_\_\_\_\_\_
		1. Value cannot exceed 7
	2. □ No walking
		1. If ‘No walking’ skip to Q7
2. Q6: How much time did you usually spend walking on one of those days?
	1. □ Hours per day :\_\_\_\_\_\_\_\_\_
		1. Value cannot exceed 24
	2. □ Minutes per day:\_\_\_\_\_\_\_\_\_
		1. Value cannot exceed 60. If value of minutes is 60, convert to hours
	3. □ Don’t know/not sure

Prompt for Q7: The last question is about the time you spent **sitting** on weekdays during the **last 7 days**. Include time spent at work, at home, while doing course work and during leisure time. This may include time spent sitting at a desk, visiting/texting friends, reading, or sitting or lying down to watch television.

1. Q7: During the last 7 days, how much time did you spend sitting on a week day?
	1. □ Hours per day :\_\_\_\_\_\_\_\_\_
		1. Value cannot exceed 24
	2. □ Minutes per day:\_\_\_\_\_\_\_\_\_
		1. Value cannot exceed 60. If value of minutes is 60, convert to hours
	3. □ Don’t know/not sure
	4. **Enrollment Tanner Staging for Children/Adolescents ≥ 7 Years Old**

**Note to DMC:** Enrollment Tanner Staging CRF only to appear for children/adolescents whose age is 7 or older at time of enrollment visit.

* + 1. Q1 Was a tanner stage assessment performed □ No □ Yes
			1. If ‘Yes’ skip to Q3
			2. If ‘No’ continue to Q2 and then end form
		2. Q2: Why was tanner staging not performed?
			1. Allow free text answer option
		3. Q3: Indicate participant gender: □ Male □ Female
			1. If ‘Female’ Q4 through Q6 are required
			2. If ‘Male’ skip to Q9 through Q11, and are required
		4. Q4: What was the tanner stage for female breast: □1 □2 □3 □4 □5
		5. Q5: What was the tanner stage for pubic hair: □1 □2 □3 □4 □5
		6. Q6: is the date of menarche available? □ No □Yes □Not reached menarche
			1. If ‘Yes’ continue to Q7 and Q8
			2. If ‘No’ or ‘Not reached menarche’, end of form
		7. Q7: Indicate the date of menarche: (DD/MM/YYYY)
		8. Q8: Is this date estimated □ 0=No □1=Yes
		9. Q9: What is the tanner stage for male genitalia: □1 □2 □3 □4 □5
		10. Q10: What is the tanner stage for pubic hair: □1 □2 □3 □4 □5
		11. Q11: Was the testicular volume measured? □ No □Yes
			1. If ‘Yes’ continue to Q12 and Q13 (both required)
			2. If ‘No’ end of form and leave blank fields for Q12 & Q13
		12. Q12: Indicate the testicular volume of right testicle:
			1. Range to be 1 to 25 ccs
		13. Q13: Indicate the testicular volume of left testicle:
			1. Range to be 1 to 25 ccs
	1. **Enrollment Pregnancy Testing for Female Adolescents ≥ 12 Years Old**
		1. Q1: What is the result of the pregnancy test: □ Positive □ Negative
			1. If ‘Positive’, child/adolescent must go off study
	2. **Enrollment PHQ-9 Questionnaire for Adolescents ≥ 12 Years Old**

Use PDF in Dropbox titled ‘form\_phq9\_adolescent Highlighted’ Add questions to EDC form.

**DMC to Add at top of CRF:** Over the last 2 weeks, how often have you been bothered by any of the following problems?

* + 1. When this form is saved, require referral if score is ≥ 10 points using the scoring criteria listed below OR require referral if response to Question 9 is anything other than ‘Not At All’ OR require referral if response to Question 12 or Question 13 is ‘yes’.
		2. When this form is saved, if score is X to X, give the participant a Depression Handout

 

* 1. **PHQ-9 Referral Form for Adolescents**
		1. Q1: Date of referral (DD/MM/YYYY)
		2. Q2: Referred to: Drop down options: Community Social Worker, Hospital-based Social Worker, A&E, Psychologist, Psychiatrist, other
		3. Q3: If other, describe
	2. **Enrollment GAD-7 Questionnaire for Adolescents ≥ 12 Years Old** Use Enrollment GAD-7 Questionnaire for Caregivers
		1. When this form is saved, require referral if score is ≥ 10 points using the scoring criteria listed below:
		2. When this form is saved, if score is ≥5 to ≤9, give the participant an Anxiety Handout



* 1. **GAD-7 Referral Form for Adolescents**
		1. Q1: Date of referral (DD/MM/YYYY)
		2. Q2: Referred to: Drop down options: Community Social Worker, Hospital-based Social Worker, A&E, Psychologist, Psychiatrist, other
		3. Q3: If other, describe

**2-MONTH CALL:**

**2-Month Post-Partum Visit – ONLY For Pregnant WLHIV who are Co-Enrolled In TB Study**

* 1. **Screen for TB at routine health encounters** (enrollment, delivery, 2 months postpartum)
		1. Question 1: *2 months postpartum:* Were you screened for TB at a routine healthcare encounter with the four screening questions (cough, fever, weight loss, night sweats) between delivery and 2 months postpartum? □0=no □1=yes □2=Unknown □3=Prefer not to answer
			1. If yes, continue to Q2
			2. If no/unknown/prefer not to answer, CRF complete
		2. Question 2: Where were you screened? □0=antenatal visit □1=IDCC □2=postpartum visit □3=hospital □4=other
		3. Question 3: Did you screen positive for the TB symptom screen? □0=no □1=yes □2=Unknown □3=Prefer not to answer
		4. Question 4: Were you referred for TB diagnostic evaluation? □0=no □1=yes □2=Unknown □3=Prefer not to answer
	2. **2-Month Visit Screen for TB screen for women CRF (**per Botswana guidelines):
		1. **Cough Questions**: Question 1: Do you currently have a cough? □0=no □1=yes □2=Unknown □3=Prefer not to answer
			+ 1. If yes, continue to Q2
				2. If no/unknown/prefer not to answer, continue to Q3
		2. Question 2: What is the duration of your cough? □0=< 1 week □1=1-2 weeks □2=>2 weeks□3=Prefer not to answer
		3. Question 3: Did you have a cough more than 2 weeks ago, including during pregnancy or shortly after delivery? □0=no □1=yes □2=Unknown □3=Prefer not to answer
			+ 1. If yes, enter timing of cough: [Month/Year]; continue to Q4
				2. If no/unknown/prefer not to answer, continue to Q5
		4. Question 4: What was the duration of that cough? □0=< 1 week □1=1-2 weeks □2=>2 weeks□3=Prefer not to answer
		5. **Fever Questions**: Question 5: Do you currently have a fever? □0=no □1=yes □2=Unknown □3=Prefer not to answer
		6. Question 6: Did you have a fever other than right now during pregnancy to 2 months postpartum? □0=no □1=yes □2=Unknown □3=Prefer not to answer
			+ 1. If yes, enter timing of fever: [Month/Year]; continue to Q7
				2. If no/unknown/prefer not to answer, continue to Q7
		7. **Night sweats:** Question 7: Do you currently have night sweats? A patient is considered to have night sweats if they have had more than two nights of waking up with their night clothing drenched due to sweating with a need to change the night clothing. □0=no □1=yes □2=Unknown □3=Prefer not to answer
		8. Question 8: Did you have night sweats at any time during pregnancy to 2 months postpartum? □0=no □1=yes □2=Unknown □3=Prefer not to answer
			+ 1. If yes, enter timing of night sweats: [Month/Year]; continue to Q9
				2. If no/unknown/prefer not to answer, continue to Q9
		9. **Weight loss:** Question 9: Do you currently have any unexplained weight loss? □0=no □1=yes □2=Unknown □3=Prefer not to answer
		10. Question 10: Did you have any unexplained weight loss during pregnancy to 2 months postpartum? □0=no □1=yes □2=Unknown □3=Prefer not to answer
			+ 1. If yes, enter timing of weight loss: [Month/Year]; continue to Q11
				2. If no/unknown/prefer not to answer, continue to Q11
		11. **Cough up blood:**  Question 11: Have you coughed up blood in the last 2 weeks? □0=no □1=yes □2=Unknown □3=Prefer not to answer
		12. Question 12: Did you cough up blood at a time other than right now during pregnancy to 2 months postpartum? □0=no □1=yes □2=Unknown □3=Prefer not to answer
			+ 1. If yes, enter timing of coughing up blood: [Month/Year]; continue to Q13
				2. If no/unknown/prefer not to answer, continue to Q13
		13. **Enlarged lymph nodes:** Question 13: Do you currently have enlarged lymph nodes? □0=no □1=yes □2=Unknown □3=Prefer not to answer
		14. Question 14: Did you have enlarged lymph nodes during pregnancy to 2 months postpartum? □0=no □1=yes □2=Unknown □3=Prefer not to answer
			+ 1. If yes, enter timing of enlarged lymph nodes: [Month/Year]; continue to Q15
				2. If no/unknown/prefer not to answer, continue to Q15
		15. **Unexplained fatigue:** Question 15: Do you currently have unexplained fatigue? □0=no □1=yes □2=Unknown □3=Prefer not to answer
		16. Question 16: Did you have unexplained fatigue during pregnancy to 2 months postpartum? □0=no □1=yes □2=Unknown □3=Prefer not to answer
			+ 1. If yes, enter timing of unexplained fatigue: [Month/Year]; continue to Q17
				2. If no/unknown/prefer not to answer, continue to Q17
		17. **COVID-19:** Question 17: You reported having symptoms of [cough] [fever] today and/or during pregnancy to 2 months postpartum. When you experienced these symptoms, were you tested for COVID-19? □0=no □1=yes □2=Unknown □3=Prefer not to answer
			+ 1. If yes, did you receive the result(s)? □0=no □1=yes □2=Unknown □3=Prefer not to answer; continue to Q18
				2. If no/unknown/prefer not to answer, continue to Q19
		18. Question 18: If yes, what were the results? □0=negative □1=positive □2=Unknown □3=Prefer not to answer □4=indeterminant
		19. **TB referral:** Question 19: Were you referred to a TB clinic during pregnancy to 2 months postpartum? □0=no□1=yes □2=Unknown □3=Prefer not to answer
	3. **Presence of TB symptoms in household members CRF at 2 month postpartum visit**
		1. Question 1: Has any member of your household been diagnosed with tuberculosis in the last 12 months? □0=No □1=Yes □2=unknown □3=Prefer not to answer
			+ 1. If ‘Yes’, continue to Q2
				2. If ‘No’ ‘Unknown’ or ‘Prefer not to answer’, skip to Q3
		2. Question 2: Please indicate the relationship of this individual or individuals to you. □0=Partner □1=Child □2=Mother □3=Father □4=Sibling □5=Other
			+ 1. If other, require text explanation:
				2. Continue to Q11.
		3. Question 3: Has any member of your household had cough for two weeks or more in the last 12 months? □0=No □1=Yes □2=unknown □3=Prefer not to answer
			+ 1. If ‘Yes’, continue to Q4
				2. If ‘No’ ‘Unknown’ or ‘Prefer not to answer’, skip to Q5
		4. Question 4: Please indicate the relationship of this individual or individuals to you □0=Partner □1=Child □2=Mother □3=Father □4=Sibling □5=Other
			+ 1. If other, require text explanation:
		5. Question 5: Has any member of your household had unexplained fever concerning for tuberculosis in the last 12 months? □0=No □1=Yes □2=unknown □3=Prefer not to answer
			+ 1. If ‘Yes’, continue to Q6
				2. If ‘No’ ‘Unknown’ or ‘Prefer not to answer’, skip to Q7
		6. Question 6: Please indicate the relationship of this individual or individuals to you. □0=Partner □1=Child □2=Mother □3=Father □4=Sibling □5=Other
			+ 1. If other, require text explanation:
		7. Question 7: Has any member of your household had night sweats in the last 12 months? □0=No □1=Yes □2=unknown □3=Prefer not to answer
			+ 1. If ‘Yes’, continue to Q8
				2. If ‘No’ ‘Unknown’ or ‘Prefer not to answer’, skip to Q9
		8. Question 8: Please indicate the relationship of this individual or individuals to you. □0=Partner □1=Child □2=Mother □3=Father □4=Sibling □5=Other
			+ 1. If other, require text explanation:
		9. Question 9: Has any member of your household had unexplained weight loss in the last 12 months? □0=No □1=Yes □2=unknown □3=Prefer not to answer
			+ 1. If ‘Yes’, continue to Q10
				2. If ‘No’ ‘Unknown’ or ‘Prefer not to answer’, skip to Q11
		10. Question 10: Please indicate the relationship of this individual or individuals to you. □0=Partner □1=Child □2=Mother □3=Father □4=Sibling □5=Other
			+ 1. If other, require text explanation:
		11. Question 11: Were you referred to a TB clinic during pregnancy to 2 months

**QUARTERLY CALLS:**

**Note to DMC:** All questions to be pre-populated with previous responses from previous visit – for the Socio-demographic CRF.

**Note to Clinic Team**: Use the pre-populated responses on the socio-demographic CRF to guide conversation on phone call and make any changes necessary in the CRF.

* 1. **Quarterly Phone Call Socio-demographics** **for all Caregivers** Use FLOURISH ‘Enrollment Socio-Demographics for all Caregivers’ form
		1. Default all SES questions from enrollment/previous visit form to be pre-selected. Clinic team can confirm answer is same or different and ability to change the answer.
			1. To pre fill: Q8-Q14
		2. Add Question 27 (Question only to be asked to the adolescent): Are you currently pregnant □Yes □No □Prefer not to answer

**Q27 is only for female adolescents who are 18 years of age or older\*\***

* 1. **Quarterly Phone Call Medical History for all Caregivers** Use FLOURISH ‘Enrollment Medical History for all Caregivers’

**DMC add Question:** Since the last visit

* 1. **Quarterly Phone Call Maternal ARV Post-Partum Update for WLHIV who enrolled in Pregnancy.** Use Tshilo Dikotla ‘Maternal ARV Post Maternal’ CRF
		1. Change any reference to ‘HAART’ to ‘ART’
	2. **Quarterly Phone Call HIV Testing and Counselling for women who enrolled in pregnancy not living with HIV.**
		1. If negative test date is greater than 3 months (90 days) require rapid HIV testing
	3. **Quarterly Phone Call Maternal Interim IDCC Data for WLHIV** Use FLOURISH ‘Birth Visit Maternal Interim IDCC Data’ form
		1. This CRF will be required for any caregiver who is WLHIV
	4. **Quarterly Phone Call HIV Disclosure status for Caregivers living with HIV with children aged 10-17.9** Use FLOURISH ‘ Enrollment HIV Disclosure status’ form

**Not to DMC:** CRF only required if previous visit indicates Caregiver has not disclosed their HIV status (Q1 = No). CRF only required when child age calculated by [today] to be between 10 and 17.9 years of age.

**Note to Clinic Team:** If caregiver has not yet disclosed their HIV status at the enrollment visit, please provide them with educational materials for aid when disclosing HIV status.

* 1. **Quarterly call ONLY occurring at 6months postpartum (2002) for women enroll in pregnancy: To appear at subsequent visit if missed 2002 Quarterly Call visit: Breastfeeding Questionnaire**. Use spec forms in dropbox folder “EDC Spec forms-CRFs, titled “Breastfeeding CRF\_FLOURISH\_Reformated”
	2. **Quarterly Phone Call Socio-demographics** **for all Infant/Children/Adolescents** Use FLOURISH ‘Enrollment Socio-demographic for all Children’ form
		1. Default all SES questions from enrollment/previous visit form to be pre-selected. Clinic team can confirm answer is same or different and ability to change the answer.
			1. To Prefill all questions from Enrollment/previous visit
		2. Add Question: Is this adolescent currenting working in return for cash? □ Yes □ No
			1. Q25 only to be asked for children/adolescents who are >18years
			2. If ‘Yes’ **Quarterly Phone Call Working Status for Adolescents** CRF is required.
	3. **Quarterly Phone Call Immunization History for all Infant/Children/Adolescent** Use FLOURISH ‘Enrollment Immunization History for all Children’ form
		1. Stem Question at the top to state ‘Since the last scheduled visit, have you received any additional immunizations?
	4. **Quarterly Phone Call Medical History for all Infant/Children/Adolescents** Use FLOURISH ‘Enrollment Medical History for Children/Adolescents ≥ 4 Years Old’
		1. Stem Question at top of form to state ‘Since the last scheduled visit, has any of your following Medical history changed?
		2. Add Question 6: What is the current HIV status of this infant/child/adolescent: □ Negative □ Positive □ Unknown
			1. If unknown, clinic team to schedule HTC PRN
		3. Add Question 7: Is this participant pregnant?
			1. This question is only asked for female adolescents who are ≥12 years of age
		4. Q8: Date of LMP: \_\_\_\_\_\_\_\_\_\_ (DD/MM/YYYY)
		5. Q9: Is the date estimated? □ Yes □ No
		6. Q10: What is the result of the pregnancy test: □ Positive □ Negative
			1. If ‘Positive’, child/adolescent **CAN REMAIN ON STUDY**
	5. **Quarterly Phone Call Birth Data ONLY for infants who were enrolled in pregnancy and missed the Birth visit** Use FLOURISH ‘Enrollment Birth Data CRF”
	6. **Quarterly Phone Call Hospitalizations Forms for all Infant/Children/Adolescents**
		1. Q1: Has your infant/child/adolescent been hospitalized since the last FLOURISH Visit □ Yes □ No
			1. If Q1 is “Yes” continue to Q2. If Q1 is “No”, end of form
		2. Q2: How many times has your infant/child/adolescent been hospitalized?
			1. Value range must be at least 1

**Inline Table**: Hospital, Reason, and approximate date of admission. Allow for multiple entries but must equal the amount of previous hospitalizations response in Q2.

* + 1. Q3: What is the name of the hospital? □ Princess Marina □SLH □ DRMH □Thamaga Primary Hospital □ SDA □BLH □ Athlone □ Other
			1. Allow free text for ‘Other’
		2. Q4: What was the reason for hospitalization (multiple option answer): □Pneumonia □ Tuberculosis □Bronchiolitis □ Laryngotracheobronchitis / Croup □ Acute diarrheal disease □ Persistent diarrheal disease □ Meningitis □ Malaria □ Measles □Trauma □ Febrile seizure □ Malnutrition □ Anemia □Surgical reason (free text) □Other (free text)
			1. Allow free text options for “Surgical Reason” and “other”
		3. Q5: What is the approximate date of hospitalization: (DD/MM/YYY)
	1. **Quarterly Phone Call Infant Feeding Form for Infants in Cohort A:** Use CRF word document saved in Dropbox
	2. **Quarterly Call: Pregnancy Question & Testing for Female Adolescents ≥ 12 Years Old**
		1. Q1: Has the child reached menarche since the last scheduled visit?
			1. If “Yes” Q2 (and the remaining questions on the CRF) is required and pre-fill responses from Q1 & Q2 for future CRFs.
				1. **If Enrollment or Follow-up Tanner Staging CRF indicated child has reached menarche, please pre-fill Q1 & Q2.**
			2. If “No” end of CRF
		2. Q2: Start date of start date of menarche: \_\_\_\_\_\_\_\_DD/MM/YYYY
		3. Q4: Is this date estimated □ 0=No □1=Yes
		4. *Q5: For the Adolescent:* Have you experienced pregnancy since the last contact with FLOURISH staff? □ Yes □ No
			1. If ‘Yes’ continue to Q6
			2. If ‘No’ skip to Q8
		5. Q6: Date of LMP: \_\_\_\_\_\_\_\_\_\_ (DD/MM/YYYY)
		6. Q7: Is the date estimated? □ Yes □ No
		7. Q8: Was the Pregnancy test done? □Yes. □ No □None
		8. Q9: Date of the Pregnancy Test
		9. Q10: What is the result of the pregnancy test: □ Positive □ Negative
			1. If ‘Positive’, child/adolescent **CAN REMAIN ON STUDY**
	3. **Quarterly Phone Call Working Status for Adolescents ≥ 18 years**
		1. Q1: Do you get paid at your current job □ Yes □ No
		2. Q2: What type of work do you do? □ Construction □ Retail □ Domestic □ Security □ Hospitality □ Tirelo Sechaba (volunteers) □ Other
			1. If other allow free text.
	4. **Quarterly Phone Call Academic Performance for Children/Adolescents Who Are Attending School**

**Note to DMC:** Use Question 24 on **Quarterly** **Socio-demographic for all Infant/Children/Adolescent** CRF to display a statement noting the level/class of school the child is currently in.(And Pre-fill Q1 – Display the answer to Q1 on the sociodemographic form. ) **Allow for edits.**

Also use Q24 on Socio-demographic CRF to use the skip logic for this form .

* + 1. Question 1: ‘What level/class of school is the child currently in?”: [Pre-fill using Q24 from Socio-demographic form] **Instructions:** If participant states the level of school is not correct, return to Socio-demographic form to update the class level.

**Add Question**: Since the last scheduled visit in (**date of last scheduled visit**), has any of your subject marks or overall performance in your last examination changed? ? □ Yes □ No

* + 1. If Yes, answer required class questions (Q2-Q14) and Q15 & 16 is required

If ‘No’ skip to Q16.

* + 1. Question 2: What are your marks in Mathematics? □ A □B □C □D □E □U □Not taking subject □ I do not know right know
		2. Question 3 What are your marks in Science? □ A □B □C □D □E □U □Not taking subject □ I do not know right know
		3. Question 4: What are your marks in Setswana? □ A □B □C □D □E □U □Not taking subject □ I do not know right know
		4. Question 5: What are your marks in English? □ A □B □C □D □E □U □Not taking subject □ I do not know right know
		5. Question 6: What are your marks in Physical Education? □ A □B □C □D □E □U □Not taking subject □ I do not know right know
		6. Question 7 What are your marks in Cultural Studies? □ A □B □C □D □E □U □Not taking subject □ I do not know right know
		7. Question 8: What are your marks in Social Studies? □ A □B □C □D □E □U □Not taking subject □ I do not know right know
		8. Question 9: What are your marks in Agriculture? □ A □B □C □D □E □U □Not taking subject □ I do not know right know
		9. Question 10: What are your marks in Single Science? □ A □B □C □D □E □U □Not taking subject □ I do not know right know
		10. Question 11 What are your marks in Biology? □ A □B □C □D □E □U □Not taking subject □ I do not know right know
		11. Question 12: What are your marks in Chemistry? □ A □B □C □D □E □U □Not taking subject □ I do not know right know
		12. Question 13: What are your marks in Physics ? □ A □B □C □D □E □U □Not taking subject □ I do not know right know
		13. Question 14: What are your marks in Double Science? □ A □B □C □D □E □U □Not taking subject □ I do not know right know
		14. Question 15: What is your overall performance in your last examination? ‘ □ A □B □C □D □E □U □ Not applicable □ I do not know right know
		15. Question 16: How many days a week do you attend in-person classes □ 1 □2 □3 □4 □5 □None □ I do not know right know

**ANNUAL CALLS (Every 4th quarterly call):**

* 1. **Relationship Father Involvement CRF for biological mothers living with HIV.** Use the specifications outlined in the dropbox folder EDC Spec Forms – CRF, document titled “Relationship Father Involvement CRF”

**Follow-up Visits (In-Person):**

* 1. **Follow-up Vital Status Form for all Caregivers**
	2. **Follow-up Socio-demographics** **for all Caregivers** Use FLOURISH ‘Enrollment Socio-Demographics for all Caregivers’ form
		1. Stem Question at top of form to state ‘Since the last time you spoke to a FLOURISH study member, has any of your following Socio-demographic information changed?
	3. **Follow-up Medical History for all Caregivers** Use FLOURISH ‘Enrollment Medical History for all Caregivers’
		1. Stem Question at top of form to state ‘Since the last time you spoke to a FLOURISH study member, has any of your following Medical history changed?
	4. **Follow-up HIV Viral Load and CD4 for Caregivers Living with HIV** Use FLOURISH ‘Enrollment HIV Viral Load and CD4’ form
	5. **Follow-up Maternal Interim IDCC Data for WLHIV** Use FLOURISH ‘Birth Visit Maternal Interim IDCC Data’ form

* 1. **Follow-up Clinical Measurements for all Caregivers** Use ‘FLOURISH Clinical Measurements for all Caregivers’ form
		1. Question 3, 4, 5, 7 and 8 logic criteria, only ask these questions for caregivers in Cohort A and C
	2. **Follow-up Edinburgh Questionnaire for Pregnant Caregivers in Cohort A**

Use FLOURISH ‘Enrollment Edinburgh Questionnaire for Pregnant Caregivers’

* + 1. When this form is saved, require referral if score is ≥ 10 points using the scoring criteria listed below, OR require referral if response to Question 10 is anything other than ‘Never’.
		2. When this form is saved, if score is X to X give the participant a Depression Handout



* 1. **Follow-up Edinburgh Referral Form for Caregivers**
		1. Q1: Date of referral (DD/MM/YYYY)
		2. Q2: Referred to: Drop down options: Community Social Worker, Hospital-based Social Worker, A&E, Psychologist, Psychiatrist, other
		3. Q3: If other, describe
	2. **Follow-up PHQ-9 for Non-pregnant Caregivers in Cohort B**

Use PDF in Dropbox titled ‘ phq-9’. Add questions to EDC form.

* + 1. When this form is saved, require referral if score is ≥ 5 points using the scoring criteria listed below OR require referral if response to Question 9 is anything other than ‘Not at all’.
		2. When this form is saved, if score is X to X, give the participant a Depression Handout



* 1. **PHQ-9 Referral Form for Caregivers**
		1. Q1: Date of referral (DD/MM/YYYY)
		2. Q2: Referred to: Drop down options: Community Social Worker, Hospital-based Social Worker, A&E, Psychologist, Psychiatrist, other
		3. Q3: If other, describe
	2. **Follow up GAD-7 Questionnaire for Caregivers in Cohort B**

Use PDF in Dropbox titled ‘GAD-7\_English’. Add questions to EDC Form:

* + 1. When this form is saved, require referral if score is ≥ 10 points using the scoring criteria listed below:
		2. When this form is saved, if score is ≥5 to ≤9, give the participant an Anxiety Handout



* 1. **GAD-7 Referral Form for Caregivers**
		1. Q1: Date of referral (DD/MM/YYYY)
		2. Q2: Referred to: Drop down options: Community Social Worker, Hospital-based Social Worker, A&E, Psychologist, Psychiatrist, other
		3. Q3: If other, describe
	2. **Follow-up Vital Status Form for all Infants/Children/Adolescents**
	3. **Follow-up Rapid HIV Testing and Counseling for all Infants/Children/Adolescents**
	4. **Follow-Up Immunization History for all Infants/Children/Adolescents** Use FLOURISH ‘Enrollment Immunization History for all Children’ form
		1. Stem Question at the top to state ‘Since the last time you spoke to a FLOURISH study member, have you received any additional immunizations?
	5. **Follow-Up Medical History for all Infants/Children/Adolescents** Use FLOURISH ‘Enrollment Medical History for Children/Adolescents ≥ 4 Years Old’
		1. Stem Question at top of form to state ‘Since the last time you spoke to a FLOURISH study member, has any of your following Medical history changed?
	6. **Follow-up Hospitalizations Forms for all Infant/Children/Adolescents**
		1. Q1: Has your infant/child/adolescent been hospitalized since the last FLOURISH Visit □ Yes □ No
			1. If Q1 is “Yes” continue to Q2. If Q1 is “No”, end of form
		2. Q2: How many times has your infant/child/adolescent been hospitalized?
			1. Value range must be at least 1

**Inline Table**: Hospital, Reason, and approximate date of admission. Allow for multiple entries but must equal the amount of previous hospitalizations response in Q2.

* + 1. Q3: What is the name of the hospital? □ Princess Marina □SLH □ DRMH □Thamaga Primary Hospital □ SDA □BLH □ Athlone □ Other
			1. Allow free text for ‘Other’
		2. Q4: What was the reason for hospitalization (multiple option answer): □Pneumonia □ Tuberculosis □Bronchiolitis □ Laryngotracheobronchitis / Croup □ Acute diarrheal disease □ Persistent diarrheal disease □ Meningitis □ Malaria □ Measles □Trauma □ Febrile seizure □ Malnutrition □ Anemia □Surgical reason (free text) □Other (free text)
			1. Allow free text options for “Surgical Reason” and “other”
		3. Q5: What is the approximate date of hospitalization: (DD/MM/YYY)
	1. **Follow-Up INFORM Instrument for all Infants/Children/Adolescents** Guide clinicians to use REDCap if hospitalization within the past year.
		1. Using Q5 from “Follow-up Hospitalizations Forms for all Infant/Children/Adolescents” CRF, calculated date difference between TODAY and the Q5 to determine if the hospitalization occurred within 1 years
		2. If yes, please create a pop up/reminder for the clinic team to log into REDCap and complete the INFORM questionnaire: <https://redcap.bhp.org.bw/redcap_v10.8.4/index.php?pid=41>
	2. **Follow-up Socio-demographics** **for all Infants/Children/Adolescents** Use FLOURISH ‘Enrollment Socio-demographic for all Children’ form
		1. Stem Question at top of form to state ‘Since the last time you spoke to a FLOURISH study member, has any of your following Socio-demographic information changed?
	3. **Follow-up Clinical Measurements for all Infants/Children/Adolescents** Use Tshilo Dikotla ‘Maternal Clinical Measurements One’ form
		1. Question 4, 5, 7 and 8 logic criteria, only ask these questions for Children in Cohort B and C ( ≥ 6 years old)

**Note to DMC:** For Q1 (about pregnancy) If female adolescent is 18 years or older, this question must be asked directly to the adolescent participant, not to the caregiver

* 1. **Follow-up Food Frequency Questionnaire for all Infants/Children/Adolescents** Use FLOURISH ‘Enrollment Food Frequency Questionnaire for Children/Adolescents ≥ 4 Years Old’ form
	2. **Follow-up Food Frequency Questionnaire for Caregivers in Cohort C** Use FLOURISH ‘Enrollment Food Frequency Questionnaire for all Caregivers’ Form
	3. **Follow-up Pregnancy Question & Testing for Female Adolescents ≥ 12 Years Old**
		1. Q1: Has the child reached menarche since the last scheduled visit?
			1. If “Yes” Q2 (and the remaining questions on the CRF) is required and pre-fill responses from Q1 & Q2 for future CRFs.
				1. If Enrollment or Follow-up Tanner Staging CRF indicated child has reached menarche, please pre-fill Q1 & Q2.
			2. If “No” end of CRF
		2. Q2: Start date of start date of menarche: \_\_\_\_\_\_\_\_DD/MM/YYYY
		3. Q4: Is this date estimated □ 0=No □1=Yes
		4. *Q5: For the Adolescent:* Have you experienced pregnancy since the last contact with FLOURISH staff? □ Yes □ No
			1. If ‘Yes’ continue to Q6
			2. If ‘No’ skip to Q8
		5. Q6: Date of LMP: \_\_\_\_\_\_\_\_\_\_ (DD/MM/YYYY)
		6. Q7: Is the date estimated? □ Yes □ No
		7. Q8: Was the Pregnancy test done? □Yes. □ No □None
		8. Q9: Date of the Pregnancy Test
		9. Q10: What is the result of the pregnancy test: □ Positive □ Negative
			1. If ‘Positive’, child/adolescent **CAN REMAIN ON STUDY**
	4. **Follow-up Anemia Testing (FBC) for all Infants/Children/Adolescents**
	5. **Follow-up Lead Levels for all Infants/Children/Adolescents**
	6. **Follow-up Repository Blood Specimens for Infants/Children/Adolescents who consented/assented for supplemental blood collection**
	7. **Follow-up Academic Performance for Children/Adolescents who are attending school**
		1. Question 1: What grade level are you in? □Standard 1 □Standard 2
		2. Question 1: What are your marks in Mathematics? □ A □B □C □D □F □Not taking subject
		3. Question 2: What are your marks in Reading? □ A □B □C □D □F □Not taking subject
	8. **Follow-up Physical Activity for Children/Adolescents in Cohort B & C (≥ 6 Years Old)** Use FLOURISH ‘Enrollment Physical Activity’ Form
	9. **Follow-up Tanner Staging for Children/Adolescents ≥ 7 Years Old**
	10. **Follow-up Child Neurodevelopment Testing BRIEF-2 for Children in Cohort B.**
		1. Use the instrument BRIEF-2 in Dropbox to code questions Multiple Tests- how to put in EDC
	11. **Follow-up Child Neurodevelopment Testing CBCL for Children in Cohort B.**
		1. Use the instrument CBCL in Dropbox to code questions Multiple Tests- how to put in EDC
	12. **Follow-up PHQ-9 Questionnaire for Adolescents ≥ 12 Years Old**

Use PDF in Dropbox titled ‘form\_phq9\_adolescent Highlighted’ Add questions to EDC form.

* + 1. When this form is saved, require referral if score is ≥ 5 points using the scoring criteria listed below OR require referral if response to Question 9 is anything other than ‘Not At All’ OR require referral if response to Question 12 or Question 13 is ‘yes’.
		2. When this form is saved, if score is X to X, give the participant a Depression Handout

 

* 1. **PHQ-9 Referral Form for Adolescents**
		1. Q1: Date of referral (DD/MM/YYYY)
		2. Q2: Referred to: Drop down options: Community Social Worker, Hospital-based Social Worker, A&E, Psychologist, Psychiatrist, other
		3. Q3: If other, describe
	2. **Follow-up GAD-7 Questionnaire for Adolescents ≥ 12 Years Old** Use Enrollment GAD-7 Questionnaire for Caregivers
		1. When this form is saved, require referral if score is ≥ 10 points using the scoring criteria listed below:
		2. When this form is saved, if score is ≥5 to ≤9, give the participant an Anxiety Handout



* 1. **GAD-7 Referral Form for Adolescents**
		1. Q1: Date of referral (DD/MM/YYYY)
		2. Q2: Referred to: Drop down options: Community Social Worker, Hospital-based Social Worker, A&E, Psychologist, Psychiatrist, other
		3. Q3: If other, describe
	2. **Follow-Up Fasting Glucose for Adolescents in Cohort C**
	3. **Follow-Up Fasting Insulin for Adolescents in Cohort C**
	4. **Follow-up Fasting Lipids for Adolescents in Cohort C**
	5. **Follow-up Pregnancy Testing for Female Adolescents ≥ 12 Years Old**
	6. **Follow-up Clinical Measurements for All Infant/Children/Adolescents**
		1. Add Question 9: Infant/Child/Adolescent Skin Folds Measurement at triceps (repeat 3 times)
			1. First measurement: \_\_ \_\_ . \_\_ mm
			2. Second measurement: \_\_ \_\_ . \_\_ mm
				1. (If first and second measurements differ by < 1 mm, **SKIP** third measurement.)
			3. Third measurement: \_\_ \_\_ . \_\_ mm

Question 9: Q9 only for children ≥ 2 months of age

* + - * 1. Add range of 1 to 45 mm for all 3 measurements
				2. All numbers must be above 1.0 and cannot be negative for all 3 measurement
1. Add Question 10: Infant/Child/Adolescent Skin Folds Measurement at subscapular (repeat 3 times)First measurement: \_\_ \_\_ . \_\_ mm
2. Second measurement: \_\_ \_\_ . \_\_ mm
	* + - 1. (If first and second measurements differ by < 1 mm, **SKIP** third measurement.)
3. Third measurement: \_\_ \_\_ . \_\_ mm

Question 10: Q10 only for children ≥ 2 months of age

* + - * 1. Add range of 1 to 45 mm for all 3 measurements
				2. All numbers must be above 1.0 and cannot be negative for all 3 measurements
		1. Add Question 11: Infant/Child/Adolescent Skin Folds Measurement at suprailiac crest (repeat 3 times)
1. First measurement: \_\_ \_\_ . \_\_ mm
2. Second measurement: \_\_ \_\_ . \_\_ mm
	* + - 1. (If first and second measurements differ by < 1 mm, **SKIP** third measurement.)
3. Third measurement: \_\_ \_\_ . \_\_ mm

Question 11: Q11 only for children ≥ 2 months of age

* + - * 1. Add range of 1 to 55 mm for all 3 measurements
				2. All numbers must be above 1.0 and cannot be negative for all 3 measurements
1. **Window Periods for Study Visits**

|  |  |  |
| --- | --- | --- |
| **Study Visit Name** | **Preferred Window** | **Allowable Window in EDC**  |
| Pre-FLOURISH Visita |  |  |
| Enrollment Visit | 0-2 |  |
| Birth Visitb |  |  |
| Quarterly Phone Calls |  |  |
| Follow-up Visit | 3-5 |  |
|  |  |  |
| a Cohort C HUU Child-Caregiver Pairs onlyb Women who enroll while Pregnant (Cohort A) only |