**Recruitment: Phone Call Contact Attempt for Enrollment CRF for Previous BHP Participants**

**Note to Coulson**:

1. Brackets should show data.
2. EDC will keep track of number of attempted calls to this person and display the number on the dashboard.
3. EDC will keep track of the BHP employee completing this CRF and generate productivity management reporting.
4. EDC will monitor call attempt as morning (before noon), afternoon (noon-4:30pm), and evening (after 4:30pm).
5. EDC to monitor how many times a call was attempted 🡪 to determine home visits
6. EDC to load Tshilo Dikotla eligible off study into locator log
7. Mechanism for indicating how many times a participant was contacted
8. EDC to only populate this CRF if there is an available phone number in the locator data
9. Mother Study Participant Identification (Mother PID) [subject identifier]
10. Previous Study Name [Mashi, Mma Bana, Tshipidi, Mpepu, Tshilo Dikotla]
11. Date of contact attempt: DD/MM/YYYY
12. Which phone number (s) was used for contact? [Cell phone] [Cell phone (alternate)] [Telephone] [Telephone (alternate)] [Work Contact Number] [Alternative contact person cell phone] [Alternative contact person telephone] [Responsible person cell phone] [Responsible person telephone]
13. Which number(s) were you successful in reaching? [Cell phone] [Cell phone (alternate)] [Telephone] [Telephone (alternate)] [Work Contact Number] [Alternative contact person cell phone] [Alternative contact person telephone] [Responsible person cell phone] [Responsible person telephone None
	1. Any number selected in Q4 but NOT selected in Q5, requires information on contact failure by contact type (Q6 through Q14).
	2. If any or all calls were successful (all selected in Q4 were also selected in Q5, continue to **Screening for Prior BHP Participants after Contact CRF**
14. Why was the contact to [**Cell phone]** unsuccessful? Phone rang, no response but voicemail left Phone rang no response and no option to leave voicemail Phone did not ring/number disconnected No longer the phone number of BHP participant
	1. If ‘No longer the phone number of BHP participant’ is selected for Q7, grey out the corresponding phone numbers in the locator data (on this form). To be added in the management report.
15. Why was the contact to [**Cell phone (alternate)]** unsuccessful? Phone rang, no response but voicemail left Phone rang no response and no option to leave voicemail Phone did not ring/number disconnected No longer the phone number of BHP participant
	1. If ‘No longer the phone number of BHP participant’ is selected for Q8, grey out the corresponding phone numbers in the locator data (on this form). To be added in the management report.
16. Why was the contact to **[Telephone]** unsuccessful? Phone rang, no response but voicemail left Phone rang no response and no option to leave voicemail Phone did not ring/number disconnected No longer the phone number of BHP participant
	1. If ‘No longer the phone number of BHP participant’ is selected for Q9, grey out the corresponding phone numbers in the locator data (on this form). To be added in the management report.
17. Why was the contact to **[Telephone (alternate)]** unsuccessful? Phone rang, no response but voicemail left Phone rang no response and no option to leave voicemail Phone did not ring/number disconnected No longer the phone number of BHP participant
	1. If ‘No longer the phone number of BHP participant’ is selected for Q10, grey out the corresponding phone numbers in the locator data (on this form). To be added in the management report.
18. Why was the contact to **[Work Contact Number]** unsuccessful? Phone rang, no response but voicemail left Phone rang no response and no option to leave voicemail Phone did not ring/number disconnected No longer the phone number of BHP participant
	1. If ‘No longer the phone number of BHP participant’ is selected for Q11, grey out the corresponding phone numbers in the locator data (on this form). To be added in the management report.
19. Why was the contact to **[Alternative contact person cell phone]** unsuccessful? Phone rang, no response but voicemail left Phone rang no response and no option to leave voicemail Phone did not ring/number disconnected No longer the phone number of BHP participant
	1. If ‘No longer the phone number of BHP participant’ is selected for Q12, grey out the corresponding phone numbers in the locator data (on this form). To be added in the management report.
20. Why was the contact to **[Alternative contact person telephone]** unsuccessful? Phone rang, no response but voicemail left Phone rang no response and no option to leave voicemail Phone did not ring/number disconnected No longer the phone number of BHP participant
	1. If ‘No longer the phone number of BHP participant’ is selected for Q13, grey out the corresponding phone numbers in the locator data (on this form). To be added in the management report.
21. Why was the contact to **[Responsible person cell phone]** unsuccessful? Phone rang, no response but voicemail left Phone rang no response and no option to leave voicemail Phone did not ring/number disconnected No longer the phone number of BHP participant
	1. If ‘No longer the phone number of BHP participant’ is selected for Q14, grey out the corresponding phone numbers in the locator data (on this form). To be added in the management report.
22. Why was the contact to **[Responsible person telephone]** unsuccessful? Phone rang, no response but voicemail left Phone rang no response and no option to leave voicemail Phone did not ring/number disconnected No longer the phone number of BHP participant
	1. If ‘No longer the phone number of BHP participant’ is selected for Q15, grey out the corresponding phone numbers in the locator data (on this form). To be added in the management report.
23. Is the participant willing to schedule an appointment: Yes No Still Thinking Not applicable

**Note to DMC**: Allow multiple answer options for Q16

1. What is the reason the participant is unwilling to schedule an appointment: None [Caregiver] Not interested in participating Busy during the suggested times Out of town during the suggested times Not available during the suggested times Caregiver Prefers not to say why unwilling. Caregiver is busy and does not want to participate Caregiver does not live in study area Caregiver is not willing to disclose status to their child Caregiver feels that child is not living with HIV and does not see a need to join the study Caregiver does not want to join another study Caregiver has work constraints Caregiver has fears of joining study/traveling during COVID Caregiver’s partner does not want/allow them to participate Caregiver has many other doctor appointments Caregiver fears stigmatization Child is busy and does not want to participate Child is not interested in joining study Child does not live in study area Child has fears of joining study/traveling during COVID Child has many other doctor appointments Caregiver fears stigmatization Child is late (has passed away) Biological mother is late (has passed away), and caregiver is unwilling Child is unwilling and prefers not to say why Other reason ...
	1. If ‘other’, allow for open text option (‘specify)
2. Appointment Date:
3. Is this appointment... None Firm appointment Possible appointment Estimated by RA
4. Appointment location: None At home At work By telephone At clinic Other location
	1. Other location, please specify ...
5. May we continue to contact the participant? Yes, we may continue to contact the participant. No, participant has asked NOT to be contacted again. No, the participant has asked not to be contacted about the FLOURISH study No, the participant has asked not to be contacted about any BHP study Not Applicable
6. Perform home visit. Not Applicable Decide to do home visit because the phone is never answered Participants prefers/requested a home visit Other reason ...
	1. Other reason, please specify ...
7. Is this the final contact attempt and no other calls or home visits will be made for this participant?  No – contact attempts with continue  Yes – this was the final attempt

**Note to DMC**: If ‘Yes’ to Q22, please note this participant as Unable to Reach in reports.

end of form. CRF to be used again for same participant in 1 week

**Recruitment: In Person Visit Contact Attempt for Enrollment CRF for Previous BHP Participants**

**Note to Coulson**:

1. Brackets should show data.
2. EDC will keep track of number of attempted calls to this person and display the number on the dashboard.
3. EDC will keep track of number of home visits to this person and display the number on the dashboard.
4. EDC will keep track of the BHP employee completing this CRF and generate productivity management reporting.
5. EDC will monitor call attempt as morning (before noon), afternoon (noon-4:30pm), and evening (after 4:30pm).
6. EDC to monitor how many times a call was attempted 🡪 to determine home visits
7. Mother Study Participant Identification (Mother PID) [subject identifier]
8. Previous Study Name [Mashi, Mma Bana, Tshipidi, Mpepu, Tshilo Dikotla]
9. Date of contact attempt: DD/MM/YYYY
10. Which location was used for contact? [Physical Address with detailed description (#7)] [Name and location of workplace (#14)] Contact person [Full physical address (#19)]
	1. If participant did not provide permission for in-person visit (#6, #13, #19) grey out the corresponding address on this form and future in person visit contact attempt forms.
11. Which location(s) were successful? [Physical Address with detailed description (#7)] [Name and location of workplace (#14)] Contact person [Full physical address (#19)] None
	1. Any location selected in Q4 but NOT selected in Q5, requires information on contact failure by location (Q6 through Q8).
	2. If any locations were successful, continue to **Screening for Prior BHP Participants after Contact CRF**
		1. If location successful but different from original location information on locator data, update locator data with new address/location
12. Why was the in-person visit to [Physical Address with detailed description (#7)] unsuccessful: No one was home Previous BHP participant no longer uses this location Other
	1. If ‘Other’ allow free text
	2. If ‘Previous BHP participant no longer uses this location’ was selected for Q6, grey out the address in the locator data (on the locator form). To be added in the management report.
13. Why was the in-person visit to [Name and location of workplace (#14)] unsuccessful: No one was home Previous BHP participant no longer uses this location Other
	1. If ‘Other’ allow free text
	2. If ‘Previous BHP participant no longer uses this location’ was selected for Q7, grey out the address in the locator data (on the locator form). To be added in the management report.
14. Why was the in-person visit to Contact person [Full physical address (#19)] unsuccessful: No one was home Previous BHP participant no longer uses this location Other
	1. If ‘Other’ allow free text
	2. If ‘Previous BHP participant no longer uses this location’ was selected for Q8, grey out the address in the locator data (on the locator form). To be added in the management report.
15. Is the participant willing to schedule an appointment: Yes No Still Thinking Not applicable

**Note to DMC**: Allow multiple answer options for Q10

1. What is the reason the participant is unwilling to schedule an appointment: None [Caregiver] Not interested in participating Busy during the suggested times Out of town during the suggested times Not available during the suggested times [Caregiver] Prefers not to say why unwilling. Caregiver is busy and does not want to participate Caregiver does not live in study area Caregiver is not willing to disclose status to their child Caregiver feels that child is not living with HIV and does not see a need to join the study Caregiver does not want to join another study Caregiver has work constraints Caregiver has fears of joining study/traveling during COVID Caregiver’s partner does not want/allow them to participate Caregiver has many other doctor appointments Caregiver fears stigmatization Child is busy and does not want to participate Child is not interested in joining study Child does not live in study area Child has fears of joining study/traveling during COVID Child has many other doctor appointments Caregiver fears stigmatization Child is late (has passed away) Biological mother is late (has passed away), and caregiver is unwilling Child is unwilling and prefers not to say why Other reason ...
	1. If ‘other’, allow for open text option (‘specify)
2. Appointment Date:
3. Is this appointment... None Firm appointment Possible appointment Estimated by RA
4. Appointment location: None At home At work By telephone At clinic Other location
	1. Other location, please specify ...
5. May we continue to contact the participant? Yes, we may continue to contact the participant. No, participant has asked NOT to be contacted again. No, the participant has asked not to be contacted about the FLOURISH study No, the participant has asked not to be contacted about any BHP study Not Applicable
6. Perform home visit. Not Applicable Decide to do home visit because the phone is never answered Participants prefers/requested a home visit Other reason ...
	1. Other reason, please specify ...
7. Is this the final contact attempt and no other calls or home visits will be made for this participant?  No – contact attempts with continue  Yes – this was the final attempt

**Note to DMC**: If ‘Yes’ to Q16, please note this participant as Unable to Reach in reports.

**Screening: Screening for Prior BHP Participants after Contact**

1. Is the child from the previous study alive (Child PID) [subject identifier]? Yes No Unknown
	1. If ‘No’ or ‘Unknown’, previous participant is ineligible for FLOURISH. End of form
		1. Take participant off calling list and maintain a management report showing how many are ineligible for the study by ineligibility reason. This is the first ineligibility reason.
	2. If ‘Yes’ continue to Q2
2. Is the biological mother from the previous study alive? Yes No Unknown
	1. If ‘No’ or ‘Unknown’ continue to Q3
	2. If ‘Yes’ continue to **script**
3. Is there another caregiver (instead of the biological mother) within the household that would be interested consenting into the FLOURISH study? Yes No
	1. If ‘No’ previous participant is ineligible for FLOURISH. End of form.
		1. Take participant off calling list and maintain a management report showing how many are ineligible for the study by ineligibility reason. This instance is the second ineligible reason (see 10a).
	2. If ‘Yes’ continue Q4

**SCRIPT:** The RA will read the script saved in the Dropbox titled ‘Recruitment Script - Prior BHP Participant’ for the FLOURISH study. After script continue to Q5

1. Are you or another caregiver of this child interested in participating in the FLOURISH Study Yes I am interested Yes another caregiver is interested No Undecided
	1. If ‘No’ ineligible for study participation, continue to Q5
		1. Take participant off calling list and maintain a management report showing how many are ineligible for the study by ineligibility reason. This instance is the third ineligible reason.
	2. If ‘Yes’ provide Consent CRFs
		1. If ‘Yes’ to Q2 and ‘Yes I am interested’ to Q4, pull in data from previous study to FLOURISH EDC consent forms
	3. If Undecided, schedule contact with potential participant in 1 week and re-administer form
2. What is the reason the participant is unwilling to participate in the study: None [Caregiver] Not interested in participating Busy during the suggested times Out of town during the suggested times Not available during the suggested times [Caregiver] Prefers not to say why unwilling. Caregiver is busy and does not want to participate Caregiver does not live in study area Caregiver is not willing to disclose status to their child Caregiver feels that child is not living with HIV and does not see a need to join the study Caregiver does not want to join another study Caregiver has work constraints Caregiver has fears of joining study/traveling during COVID Caregiver’s partner does not want/allow them to participate Caregiver has many other doctor appointments Caregiver fears stigmatization Child is busy and does not want to participate Child is not interested in joining study Child does not live in study area Child has fears of joining study/traveling during COVID Child has many other doctor appointments Caregiver fears stigmatization Child is late (has passed away) Biological mother is late (has passed away), and caregiver is unwilling Child is unwilling and prefers not to say why Other reason ...
	1. If ‘other’, allow for open text option (‘specify)

**Eligibility on EDC Specification Form:**

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. **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