**CARE PrEP Study Exit Guide**

**Participants can exit the study for the following reasons**

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| **Scheduled exit of study** | Completing study visits through the 6M Post-natal Visit (V203); exit of a maternal participant at the Pregnancy Outcome Visit (201) due to a pregnancy loss; exit of a maternal participant upon an infant death in the post-natal study period. |
| **Investigator decision** | Country PI decides participant should not remain in study, i.e. participant is lost to follow-up, participant is unwilling to comply with study procedures, continuing participation presents a safety risk, etc. Participant can be exited in absentia if they cannot be contacted to complete a final visit/contact. |
| **Withdrawal of consent** | Maternal participant withdraws consent for herself and/or infant participant. **This means NO further contact should be made after confirming the withdraw, unless permitted by the participant.** |
| **Death** | Exit in absentia. If death of the maternal participant, any living infant participant may stay in the study with the consent of a legal guardian. If the death of an infant, maternal participant may exit as well if no further need for follow-up. |
| **Study terminated my sponsor or other reason for early study closure** | Study leadership will provide guidance in this unexpected circumstance. |

**For maternal participants who can be contacted (in person or by phone) at the time of her and/or her infant’s study exit, complete the following steps:**

1. Confirm participant’s willingness and ability to complete outlined exit procedures. As always, participants have the right to decline any study procedures. If any exit procedures are declined, document in chart notes and complete CRFs to the extent possible.
2. *If exited at a scheduled visit:* attempt to complete all study visit procedures for the visit the participant is in window to complete, to the extent possible, e.g. omit procedures that cannot be completed over a phone contact or per participant refusal.
3. *If exited at an interim visit:* complete study procedures prompting the interim visit. If in-person interim visit, perform a final HIV test for maternal participant, including HIV pre-and post-test counseling, if feasible.
4. Ask about any ongoing Medical Events/Conditions, Medications, SAEs, or Social Harms to get the most current information and record on the applicable CRF in REDCap.
   1. Provide any referrals for care as needed

*Note: No further follow-up by study staff for ongoing events is to occur post-study exit.*

1. Counsel the participant about the study exit, including:
   1. Thank the participant for their time and effort to participant in the study, reinforcing their valuable contribution to HIV prevention, especially among those who are pregnant.
   2. Remind them that this visit/contact ends their study participation.
2. Review and update information on the **Participant Locator Form**
3. Confirm permission to be contacted after the study. Ask if they are interested and give permission to be contacted by CARE PrEP to:
   1. Receive the study results once available (reinforce that this will happen at the end of the entire study).
   2. Ask them about any future studies that they (or their infant, as appliable) may be eligible for. Reinforce that CARE PrEP would not share contact information with another study without first asking the participant for permission.
   3. Record responses for each contact type on the **Permission to Contact Log.**
4. Remind them that they are free to contact the study team with questions about the study that were not answered or if they encounter any problems related to their participation.
5. Document the study exit in chart notes including a summary of any salient points about the exit reason or study exit counseling with the participant.
6. Complete the **Study Exit CRF** in REDCap

*Note: if a participant is being exited but medical record abstraction still needs to occur, the above steps can still be done including completion of the Study Exit CRF. The study exit date is the date of the last visit/contact with the participant. Data entry from records abstraction can occur after the Study Exit CRF is completed.*

**For participants who are cannot to be contacted at the time of study exit, exit the participant in absentia per the following steps:**

1. Complete the **Study Exit CRF** in absentia.
2. Document in chart notes the reason for exiting in absentia and details of any attempts to contact the participant before moving forward with exiting
3. Complete an entry on the **Permission to Contact Log** with ‘no’ for each question

*Note: Any enrolled participant who does not return to complete the 6-Month Post-natal Visit within the visit window should have study exit procedures completed in absentia after the visit window closes.*