**MTN-043/B-PROTECTED Study Exit Worksheet**

***Instructions****:* *Using the script for study exit visits as a guide, complete this worksheet for participants at their scheduled study exit visit, i.e. the Visit 8.0/SEV or early termination visit, if applicable.*

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| --- | --- | --- |
| **Mother PTID:** | **Infant PTID:** | **Visit Date:** |
| Does the mother participant have study product remaining in her possession?  ❒ No, per participant report, all product has been collected/returned  ❒ Yes🡪 describe plan for product collection (continue on back if needed):  ❒ Follow-up Completed: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| Is the mother participant currently pregnant?  ❒ No  ❒ Yes 🡪 confirm permission to contact participant upon pregnancy outcome and at the infant’s first birthday, if born alive, to obtain information about her pregnancy and her infant’s health. Document permission on early termination visit checklist *[sites to modify source as needed to be site-specific]*, and outline plan for follow-up here:  *Note: Contacts after study termination should be documented in the chart notes and on the Pregnancy Outcome CRF and One Year Infant Assessment CRF. Do not update any AE CRFs after participant termination.*  ❒ Follow-up Completed: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| Is the infant participant currently pending HIV-1 testing (i.e. tested negative and waiting for 4 to 6-week or 12-week post maternal seroconversion repeat testing?  ❒ No  ❒ Yes 🡪 Do not exit the infant until all HIV-1 testing is completed. | | |
| Does the mother and/or infant participant have any ongoing SAEs/EAEs, new grade 3 AEs, or any AEs that have increased in severity at the termination visit?  **Mother**  ❒ No  ❒ Yes🡪 describe plan for AE follow-up (continue on back if needed):  **Infant**  ❒ No  ❒ Yes🡪 describe plan for AE follow-up (continue on back if needed):  IoR approval or designee: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  ❒ Follow-up Completed: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| Plan for providing participant with study results:  OR:  ❒ Participant requests NOT to be contacted for study results dissemination  Record outcome on Permission to Contact Log [or site-specific form] | | |
| Is participant willing to be contacted about other future studies for which she or her infant may be eligible?  ❒ No  ❒ Yes  Record outcome on Permission to Contact Log [or site-specific form] | | |
| **Staff Signature and Date:** | | |

**Sample Script for B-PROTECTED Study Exit Visits**

Before we finish your visit today, I would like to take some time to sincerely thank you for taking part in this study. By taking part, you have made an important contribution to the fight against HIV/AIDS. In recognition of this contribution, I would like to present you with this certificate of completion which you can take with you today *[sites to modify as needed]*. I also would like to review a few more details with you:

* In order for us to share the results of the study with you, we need to be able to keep in touch with you. *[Tell the participant about any estimated timelines for results dissemination, if known].* Are you willing to give us your permission to do that? *[Record response on study exit worksheet]*
  + *[If permission is granted, explain that information recorded on the participant’s locator form would be used for this purpose and enter participant on future contact permission log.]*We ask you to please inform us if you move to a new home, change your phone number, or have any other new details that would help us keep in touch with you. *[Give contact card.]*
* We would like to be able to contact you in the future about other studies that you or your infant may be eligible for. Are you willing to give us your permission to do that? *[Record response on study exit worksheet; if permission is granted, explain that information recorded on the participant’s locator form would be used for this purpose and enter participant on future contact permission log.]*
* *If applicable, reinforce plans to determine pregnancy outcome.*
* *If applicable, reinforce plans for AE follow-up or any additional visits that are scheduled (for example, to provide any pending test results)*.
* Lastly, we would like to give you some information on places where you can go for different types of services now that you will not be coming here for regular study visits *[give referral sheet]:*
* For HIV counseling and testing
* For family planning and other reproductive health care
* For continued postnatal and/or well-baby care
* Other types of healthcare, as applicable
* Please feel free to contact us if you have any questions about the study that we have not answered today, or if you encounter any problems related to your participation in the study. Once again, we sincerely thank you for your contributions to the study and we look forward to sharing the results with you when they become available.