**MTN-042/DELIVER Infant Study Exit Worksheet**

***Instructions:*** *Using the script for infant study exit visits as a guide, complete this worksheet for infant participants at their scheduled study exit visit, i.e. the 12-month visit (or early termination visit, if applicable).*

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| --- | --- |
| **PTID:** | **Visit Date:** |
| **For HIV positive participants ONLY:** Refer for HIV-related care and treatment and continued care, as needed.Does participant have any pending HIV-related test results to be provided? ❒ No❒ Yes 🡪 describe plan to provide results once available:❒ Follow-up Completed: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Does participant have any ongoing SAEs/EAEs, new grade 3 AEs, or any AEs that have increased in severity at the termination visit? ❒ No❒ Yes 🡪 describe plan for AE follow-up (continue on back if needed):IoR approval or designee: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_❒ Follow-up Completed: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Plan for providing mother/guardian of participant with study results:OR: ❒ Mother/guardian requests NOT to be contacted for study results disseminationRecord outcome on Permission to Contact Log [or site-specific form] |
| Is the mother/guardian willing to be contacted about other future studies for which the participant (child) may be eligible?❒ No ❒ YesRecord outcome on Permission to Contact Log [or site-specific form] |
| **Staff Signature and Date:** |

**Sample Script for DELIVER Infant Study Exit Visits**

Before we finish your visit today, I would like to take some time to sincerely thank you for having your child take part in this study. By taking part, s/he has 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:

* Your infant’s participation in this study is now complete.
* 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 mother/guardian about any estimated timelines for results dissemination, if known]* Therefore, 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 your child 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 review the mother’s original entry on the permission to contact log and update as needed.* 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.]*
* *If applicable, reinforce plans for provision of any pending HIV test results, and referrals for continued HIV treatment, testing and care.*
* *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 and your infant can go for different types of services now that you will not be bringing your infant 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 infant’s 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.