**Study Exit Worksheet**

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| --- | --- |
| **Participant ID:** | **Termination Visit Date:** |
| Plan for providing participant with final study results | |
| Method by which participant wishes to be contacted when study results are available | |
| Does 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)  ❒ Completed \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | |
| Is participant currently pregnant?  ❒ No  ❒ Yes ⇒ describe plan for ascertaining pregnancy outcome (continue on back if needed). If enrolled in MTN-016, discuss plan for continued follow-up in MTN-016 (e.g. next scheduled visit). If not already enrolled, discuss potential enrollment in MTN-016.  IoR approval or designee: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  ❒ Completed: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | |
| For HIV positive participants ONLY: Are they enrolled in MTN-015?   No 🡪 Discuss potential enrollment into MTN-015 and plans for continued access to HIV-related care. Provide referrals and/or schedule MTN-015 enrollment as appropriate.   Yes 🡪 Discuss plan for continued follow-up in MTN-015 (e.g. next scheduled visit) | |
| Does participant have any ongoing SAEs/EAEs or any AEs at this visit?  ❒ No  ❒ Yes ⇒ describe plan for AE follow-up (continue on back if needed)  IoR approval or designee: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  ❒ Completed: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | |
| Is participant willing to be contacted about future studies for which she may be eligible?  ❒ No  ❒ Yes | |
| **Staff Signature and Date:** | |

**Sample Script for 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:

* Your appointment to receive your final exam and test results is scheduled for [date]. This appointment will take place [here at the clinic / other specify]. If you need to change this appointment for any reason, please contact us to let us know.
* Although your scheduled study visits have now been completed, the study is planned to be ongoing until the end of June this year. After that, we expect it will take about another 6 months to determine the results of the study.  At that time, we will also learn which participants received active or placebo study product.  In order for us to share the results of the study with you and tell you which ring you received, we need to be able to keep in touch with you. [Tell the participant about any future results events you have planned- a group event etc.] 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.]
* As you have heard, if the results of ASPIRE show that the ring is effective in preventing HIV, there will e a follow-on study called HOPE. All women who enrolled in ASPIRE will be invited to participate in HOPE. If you are eligible to participate, you would receive the active study product, there will be no placebo ring.
* We would like to be able to contact you in the future about other studies that you may be eligible for, such as HOPE. 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*.
* *If applicable, reinforce plans for follow-up HIV counseling and testing*.
* *If applicable, let the participant know about any services that will continue to be provided at the research clinic after ASPIRE (family planning, HIV testing etc)*.
* 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 other types of health care
* Other
* *If applicable, replace above bullet with a discussion of plans for ongoing participation in MTN-015 and/or MTN-016.*
* 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.

**Sample Future Study Contact Permission Log**

**Participants Willing to Be Contacted for Future Studies By Participant Name**

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| --- | --- | --- | --- |
| **No.** | **Name, address and phone** | **Date of Contact Approval** | **Method of Contact Preferred** |
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