**Study Exit Worksheet**

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| --- | --- |
| **PTID:** | **Visit Date:** |
| Plan for providing participant with final study results:  OR:  ❒ Participant requests NOT to be contacted for study results dissemination | |
| 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 within 5 business days (continue on back if needed):  ❒ Follow-up 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.  ❒ Follow-up 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)  ❒ Follow-up Completed: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | |
| Does participant have any ongoing SAEs/EAEs or any AEs that have increased in severity at this visit?  ❒ No  ❒ Yes ⇒ describe plan for AE follow-up (continue on back if needed):  IoR approval or designee: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  ❒ Follow-up Completed: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | |
| Did the participant provide permission to contact her for participation in MTN-032 Phase 2? *[For sites implementing MTN-032/AHA only]*  ❒ No  ❒ Yes | |
| Did the participant provide permission to contact her **male partner** for participation in MTN-032 Phase 2? *[For sites implementing MTN-032/AHA only]*  ❒ No  ❒ Yes | |
| Is participant willing to be contacted about other 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:

* Although your scheduled study visits have now been completed, the study is planned to be ongoing until the end of October 2018. After that, we expect it will take about another 6 months to determine the results of the study.   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 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.]
* [*For sites implementing MTN-032/AHA only*] As you may have heard, a qualitative study called AHA is taking place at this site. Some women who enrolled in HOPE and give permission to be contacted will be invited to participate in the second phase of AHA. If you agree to participate and are selected, you could be invited back to the clinic for a single interview or focus group discussion. Are you willing to give us your permission to contact you about AHA? [Record response on study exit worksheet and enter on future contact permission log]
* [*For sites implementing MTN-032/AHA only*] For the second part of AHA, we will also be conducting interviews and focus group discussions with male sexual partners of HOPE participants. Male participants in interviews and focus groups will be asked for their opinions about their partners’ participation in the HOPE study and use of the dapivirine vaginal ring. Men who participate in the second part of AHA will know that their partners participated in HOPE, whether their partners were acceptors of the vaginal ring, and that the ring is an HIV-prevention method. Are you willing to give us permission to contact any male sexual partner that you had during HOPE about AHA? [Record response on study exit worksheet; if permission is granted, complete the partner permission to contact form for one partner per participant only following the guidance on the form, and enter on future contact permission log.]
* We would like to be able to contact you in the future about other studies that you 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)*.
* *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 HOPE (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**

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| --- | --- | --- | --- | --- |
| **Participant Name** | **Permission to Contact for HOPE Results?** | **Permission to Contact for MTN-032/AHA** | **Permission to contact male partner(s) for MTN-032/AHA?** | **Permission to contact for other future studies?** |
|  | ❒ YES ❒ NO | ❒ YES ❒ NO | ❒ YES ❒ NO | ❒ YES ❒ NO |
|  | ❒ YES ❒ NO | ❒ YES ❒ NO | ❒ YES ❒ NO | ❒ YES ❒ NO |
|  | ❒ YES ❒ NO | ❒ YES ❒ NO | ❒ YES ❒ NO | ❒ YES ❒ NO |
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