PTID: \_\_ \_\_ \_\_- \_\_ \_\_ \_\_ \_\_ \_\_- \_\_ Visit Code: \_\_\_

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Visit Type: Period 1 Follow Up Phone Calls –Rectal Biopsy/Fluid Subset

**Instructions:** Enter staff initials next to each procedure completed. Do not initial procedures another staff member completed. If other staff members are not available to initial next to each procedure they completed themselves, initial, date and add a note on the checklist documenting who completed the procedure, e.g., “done by {staff initials}” or “done by nurse.” If a procedure listed on the checklist is not performed, enter “ND” for “not done” or “NA” for “not applicable” beside the item and record the reason why (if not self-explanatory); initial and date this entry.

|  |  |  |  |
| --- | --- | --- | --- |
| **Period 1 Phone Calls Checklist** | | | |
| **Procedure** | **48-72 Hours Post-Initiation Call** | **Two Week Post-Initiation Call** | **48-72 Hours Post-Period 1 End Visit Call** |
| Confirm participant identity and PTID. |  |  |  |
| Conduct an interval medical history with documentation of current medications |  |  |  |
| If required based on all available information, complete Adverse Event Log (DataFax) CRF |  |  |  |
| If site IoR/designee have any concerns regarding the participant’s continued use of study product based on information collected from the participant, consult the PSRT. |  |  |  |
| If indicated, schedule interim visit for follow-up of AEs |  |  |  |
| Provide instructions to report symptoms and/or request information or counseling, before next visit. |  |  |  |
| Remind participant of next visit, to bring unused tablets and/or applicators (if applicable), and to respond to daily SMS. |  |  |  |

Comments:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

PTID: \_\_ \_\_ \_\_- \_\_ \_\_ \_\_ \_\_ \_\_- \_\_ Visit Code: \_\_\_

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Visit Type: Period 2 Follow Up Phone Calls –Rectal Biopsy/Fluid Subset

**Instructions:** Enter staff initials next to each procedure completed. Do not initial procedures another staff member completed. If other staff members are not available to initial next to each procedure they completed themselves, initial, date and add a note on the checklist documenting who completed the procedure, e.g., “done by {staff initials}” or “done by nurse.” If a procedure listed on the checklist is not performed, enter “ND” for “not done” or “NA” for “not applicable” beside the item and record the reason why (if not self-explanatory); initial and date this entry.

|  |  |  |  |
| --- | --- | --- | --- |
| **Period 2 Phone Calls Checklist** | | | |
| **Procedure** | **48-72 Hours Post-Initiation Call** | **Two Week Post-Initiation Call** | **48-72 Hours Post-Period 2 End Visit Call** |
| Confirm participant identity and PTID. |  |  |  |
| Conduct an interval medical history with documentation of current medications |  |  |  |
| If required based on all available information, complete Adverse Event Log (DataFax) CRF |  |  |  |
| If site IoR/designee have any concerns regarding the participant’s continued use of study product based on information collected from the participant, consult the PSRT. |  |  |  |
| If indicated, schedule interim visit for follow-up of AEs |  |  |  |
| Provide instructions to report symptoms and/or request information or counseling, before next visit. |  |  |  |
| Remind participant of next visit, to bring unused tablets and/or applicators (if applicable), and to respond to daily SMS. |  |  |  |

Comments:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

PTID: \_\_ \_\_ \_\_- \_\_ \_\_ \_\_ \_\_ \_\_- \_\_ Visit Code: \_\_\_

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Visit Type: Period 3 Follow Up Phone Calls –Rectal Biopsy/Fluid Subset

**Instructions:** Enter staff initials next to each procedure completed. Do not initial procedures another staff member completed. If other staff members are not available to initial next to each procedure they completed themselves, initial, date and add a note on the checklist documenting who completed the procedure, e.g., “done by {staff initials}” or “done by nurse.” If a procedure listed on the checklist is not performed, enter “ND” for “not done” or “NA” for “not applicable” beside the item and record the reason why (if not self-explanatory); initial and date this entry.

|  |  |  |
| --- | --- | --- |
| **Period 3 Phone Calls Checklist** | | |
| **Procedure** | **48-72 Hours Post-Initiation Call** | **Two Week Post-Initiation Call** | |
| Confirm participant identity and PTID. |  |  | |
| Conduct an interval medical history with documentation of current medications |  |  | |
| If required based on all available information, complete Adverse Event Log (DataFax) CRF |  |  | |
| If site IoR/designee have any concerns regarding the participant’s continued use of study product based on information collected from the participant, consult the PSRT. |  |  | |
| If indicated, schedule interim visit for follow-up of AEs |  |  | |
| Provide instructions to report symptoms and/or request information or counseling, before next visit. |  |  | |
| Remind participant of next visit, to bring unused tablets and/or applicators, and to respond to daily SMS. |  |  | |

Comments:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_