|  |  |
| --- | --- |
| Study Number | **End of Trial** |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | | | | | | | | | | | | | | | | | | | |
| Did the woman complete the trial? *If Yes, please do not complete the rest of the form, just sign and date the form* | | | Yes | | | | | | | | | |  | | No | | | |  |
|  | | |  | | | | | | | | | | | | | | | | |
| Date of withdrawal | | | **D** | **D** | **/** | **M** | **O** | **N** | **/** | | | **Y** | | **Y** | | **Y** | | **Y** | |
|  | | | | | | | | | | | | | | | | | | | |
| Main reason for woman’s withdrawal (Select main reason)  N.B. The woman may choose not to give her reasons for, or answer any questions about her decision to withdraw; however if the woman is happy to offer this information, please record in the space below. | | | | | | | | | | | | | | | | | | | |
| Woman’s decision |  |  | | | | | | | | | | | | | | | | | |
| Protocol violation |  |  | | | | | | | | | | | | | | | | | |
| Lost to follow-up |  |  | | | | | | | | | | | | | | | | | |
| Trial stopped |  |  | | | | | | | | | | | | | | | | | |
| Adverse Event |  | Please specify the Adverse Event:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | | | | | | | | | | | | | |
| Other |  | Please specify Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | |
| Woman’s Trial Status  N.B. All women withdrawn from the trial should remain on-study for follow-up and sampling purposes, unless the woman has specifically requested to be completely withdrawn from the trial i.e. no follow-up | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | |  | **Woman** | | | | | | **Baby** | | |
| Withdrawn from intervention | | | | | | | | | |  |  | | | | | |  | | |
| Withdraw from follow-up | | | | | | | | | |  |  | | | | | |  | | |
| Withdraw from long-term possible future follow-up (within 25 years) | | | | | | | | | |  |  | | | | | |  | | |

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Name of person completing the form (print name):please note, your name must be on the trial delegation log |  | | | | | | | | | | |
| Signature of person completing the form: |  | | | | | | | | | | |
| Date Signed: | **D** | **D** | **/** | **M** | **O** | **N** | **/** | **Y** | **Y** | **Y** | **Y** |