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| INSTITUTION CODE\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | PARTICIPANT ID­­­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | FORM DATE*(MM/DD/YYYY)**\_\_ \_\_ / \_\_ \_\_ / \_\_ \_\_ \_\_ \_\_* |

**OFF STUDY FORM**

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| Date on Follow-up: \_\_ \_\_ / \_\_ \_\_ / \_\_ \_\_ \_\_ \_\_ Date Off Follow-up: \_\_ \_\_ / \_\_ \_\_ / \_\_ \_\_ \_\_ \_\_*(MM/DD/YYYY) (MM/DD/YYYY)* |
| Date off study: \_\_ \_\_ / \_\_ \_\_ / \_\_ \_\_ \_\_ \_\_ Date of Last Contact: \_\_ \_\_ / \_\_ \_\_ / \_\_ \_\_ \_\_ \_\_ *(MM/DD/YYYY) (MM/DD/YYYY)* |
| Date Last Study Agent Taken: \_\_ \_\_ / \_\_ \_\_ / \_\_ \_\_ \_\_ \_\_ *(MM/DD/YYYY)* |

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| Reason Off Study (Please mark only the primary reason. Reasons **other than the Completed Study** require explanation next to the response)* Completed Study \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* AE/SAE **(complete AE CRF & SAE form, if applicable) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**
* Lost to follow-up \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* Non-compliant participant \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* Concomitant medication \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* Medical contraindication \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* Withdraw consent \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* Death **(complete Death Report CRF & SAE form) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**
* Other \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
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