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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 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |