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| --- | --- | --- | --- | --- |
| **Participant Initials:** |  | **Visit Date:** |  | **Study Title:** |
| **Participant ID code:** |  | **DOB:** |  |
| **Documentation of Informed Consent** |
| Informed Consent Form (ICFs) reviewed with participant: □ Main Study ICF, Version/Date: □ Other ICF, Specify: Version/Date: □ Other ICF, Specify: Version/Date:  |
| How was the participant provided with the Informed Consent?  | □ e-mail □ In-person □ Both |
| Did the participant have adequate time to read and consider the Informed Consent?  |  □ Yes □ No *If not, please explain:* \_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_  |
| Were all the participant’s questions answered to their satisfaction?  |  □ Yes □ No *If not, please explain: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_* |
| Date Informed Consent was signed by the participant |  \_\_\_\_\_\_\_/\_\_\_\_\_\_\_/\_\_\_\_\_\_\_\_ *Month Day Year* |
| Was/were the ICF(s) signed prior to initiation of study procedures?  |  □ Yes □ No If not, please explain: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Was a copy of the signed ICF(s) provided to the study participant? |  □ Yes □ No*If not, please explain:*  \_\_\_\_\_\_\_\_\_\_ |
| Was the original ICF placed in the participant’s study file? |  □ Yes □ No If not, please explain: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Additional Notes: |
|  |
|  | *Signature of person obtaining consent* |  |  | *Date* |  |