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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* |  |