# SAMPLE INFORMED CONSENT PROCESS CHECKLIST

## Study Name

|  |  |
| --- | --- |
| **Site ID:** **Participant ID:**  | **Date (dd/mmm/yyyy):** **Study Visit:** Screening Visit |

| **Questions Regarding the Consent Process** | **Yes or No** |
| --- | --- |
| 1. Prior to signing the consent, was the study discussed with the participant? This is including, but not limited to, all potential risks, benefits, discomforts and participant responsibilities.
 | [ ]  Yes[ ]  No |
| 1. Did the participant read the entire Informed Consent Form (ICF) at his/her own pace?
 | [ ]  Yes[ ]  No |
| 1. Was the participant given the opportunity to ask questions?
 | [ ]  Yes[ ]  No |
| 1. Was the participant consent conducted prior to initiation of any study related procedures, including data collection or measurements?
 | [ ]  Yes[ ]  No |
| 1. Did the participant execute the ICF, HIPAA, and any other required consent documents?
 | [ ]  Yes[ ]  No |
| 1. Was the participant given a copy of the signed and dated ICF?
 | [ ]  Yes[ ]  No |
| 1. Was the consent process documented?
 | [ ]  Yes[ ]  No |

| ***The Participant was asked the following questions and provided these responses*** | **Yes or No** |
| --- | --- |
| 1. Can you withdraw from this research at any time?
 | [ ]  Yes[ ]  No |
| 1. If you participate in this research, are you guaranteed to receive the active [intervention]?
 | [ ]  Yes[ ]  No |
| 1. Protocol Specific question 1
 | [ ]  Yes[ ]  No |
| 1. Protocol Specific question 2
 | [ ]  Yes[ ]  No |
| 1. Protocol Specific question 3
 | [ ]  Yes[ ]  No |
| 1. Could you experience [known side effects]?
 | [ ]  Yes[ ]  No |
| 1. Should you tell the study staff if you have any planned vacations or time away from home scheduled in the next [Study period]?
 | [ ]  Yes[ ]  No |
| 1. How many visits will you need to complete?
 |       |
| 1. Did the participant provide correct answers to all questions 8 through 16*? (If Yes, skip Questions 17 and 18)*
 | [ ]  Yes[ ]  No |

| ***For all questions for which the Participant provided incorrect answers*** | **Yes or No** |
| --- | --- |
| 1. If the participant did not answer all questions correctly, did you review the ICF with the participant and ask again?
 | [ ]  Yes[ ]  No |
| 1. For all questions you reviewed again with the participant, did the participant demonstrate understanding?
 | [ ]  Yes[ ]  No |

Date and Time Informed Consent Form Signed and Effective:(dd/mmm/yyyy):       (00:00 – 23:59)

Completed by (Signature):

*Version\_November 2020*