Date Informed Consent Signed \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_\_ Time Informed Consent Signed \_\_\_\_\_\_\_

 MM DD YYYY

Informed Consent Version \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_\_ Obtained By: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 MM DD YYYY

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| --- | --- |
| 1. Did the subject sign the most recent version of the Informed Consent?
2. Initial if IFC was verified by a second person for completeness \_\_\_\_\_\_\_\_\_\_\_
3. The consent form is given to the subject at the initial meeting. The Subject is encouraged to take the ICF home to allow ample time to review. They can discuss their study participation with their PCP and family members. They are provided with contact information if they have any further questions. Date ICF was received initially \_\_\_\_\_\_\_\_\_( if different from date signed )
4. Study information was discussed fully and described to the subjects. Areas reviewed include: purpose/objectives, design, inclusion/exclusion criteria, requirements, risks and benefits of participation.
5. Patient read the consent was able to verbalize understanding of the general purpose of the trial along with risks and benefits of participation.
6. Patient appears to have the mental capacity to give informed consent, and has voluntarily agreed to participate. The decision was not made by the patient under coercion.

 1. The PI and/or Sub I was involved in the ICF process and was available to answer any questions.
2. The consent form was signed and a copy was given to the patient.
3. All of the above were completed prior to any study procedures being performed.

Reason for new IC Version: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | [ ]  Yes [ ]  No[ ]  Yes [ ]  No[ ]  Yes [ ]  No[ ]  Yes [ ]  No[ ]  Yes [ ]  No[ ]  Yes [ ]  No[ ]  Yes [ ]  No[ ]  Yes [ ]  No[ ]  Yes [ ]  No |