**Documentation of the Informed Consent Process Note**

**Protocol Title:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Subject Name:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ ICF Version:\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date of Consent:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Consent Discussion.** Mark if the following apply, if not marked, include in the comments below:

[ ]  Subject was alert, oriented and content of conversation seemed appropriate to confirm understanding.

[ ]  The subject read the consent form.

[ ]  The risks in the consent form were carefully explained to the subject.

[ ]  Pregnancy prevention was discussed with the subject.

[ ]  PI (or physician investigator, if applicable)met with the subject prior to any study procedures and discussed the study.

[ ]  Consent form reviewed page by page and discussed with the subject and time for discussion and questions was available. The subject was satisfied with answers received.

[ ]  Subject verbalized understanding of the ICF, study expectations and expressed a clear decision to voluntarily proceed with the study.

[ ]  Others were present for ICF discussion.

[ ]  If yes, subject gave permission for others to be present during consenting process.

[ ]  Subject voluntarily signed ICF prior to any study procedures being performed.

[ ] Costs of participation and potential additional costs were discussed with the subject.

[ ] Witness signed informed consent document.

[ ]  Copy of signed consent given to subject.

­­­­­­­­­­­­­­­ **Consent document reviewed for completeness and accuracy by Coordinator:**

[ ]  Labels placed on footer of each page.

[ ]  Subject signed, dated and timed for self.

[ ]  Subject marked any checkboxes throughout consent.

[ ]  PI signed, dated and timed for self.

[ ]  Coordinator signed, dated and timed for self.

 **Consent Documentation**:

[ ]  Original signed consent retained in the research file.

[ ]  Copy forwarded to medical records department.

**Comments** (if noted below, no need to generate a Note to File): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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**Printed Name of Consenter: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Signature:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_\_**