**CRSO Template:**

**Checklist for Documenting the Informed Consent Discussion**

Adapted from: UNC office of Clinical Trials, Informed Consent Process and HIPAA Authorization Documentation

Contributing Authors: UNC CTQA Program, SOM CRSO

**IRB Study #: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Participant Initials­­­­­­­­­­: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Study ID: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

*Please initial**next to “Yes” or “No” by each line as appropriate. If “No,” an explanation must be provided in the notes section below.*

|  |  |  |
| --- | --- | --- |
|  Yes |  No | A concise and focused presentation of the key information was provided. |
|  Yes |  No | The details of this research study were discussed, including an explanation of the required elements of the ICF. |
|  Yes |  No | It was emphasized that study participation is voluntary, that the participant’s clinical care would not be affected if study participation is declined, and that the participant may withdraw consent at any time. |
|  Yes |  No | The ICF was provided in the preferred language. |
|  Yes |  No | Ample time was provided for reading the consent document and questions were encouraged. |
|  Yes |  No | All questions and concerns were addressed to the satisfaction of the participant (or LAR). |
|  Yes |  No | The PI or Co-I was available for questions. |
|  Yes |  No | The participant (or LAR) reviewed the current IRB approved consent document(s) and agreed to participate. Specify ICF version and date/time signed below.  |
|  Yes |  No | A copy of the signed consent document was provided to the participant and/or LAR. |
|  Yes |  No | No procedures specifically related to the study were performed prior to the participant signing the consent document. |
|  Yes |  No | A copy of the signed consent document was placed in the participant’s research file. If a copy was also placed in the medical record, specify in Notes.  |
| [ ]  Main Study ICF, Version/Date: [ ]  Other ICF, Specify: \_\_ Version/Date: \_\_\_\_\_\_\_Time:­ ­­\_\_\_\_\_\_\_\_[ ]  Other ICF, Specify: \_\_ Version/Date: \_\_\_\_\_\_\_Time:­ ­­\_\_\_\_\_\_\_\_ |
| **Additional Notes­­­­­­:***Additional Notes may include,* * *People who were present during the consent discussion, such as the participant, an LAR, the person obtaining consent, relative(s), PI, study coordinator, interpreter, witness, etc.)*
* *any questions or concerns raised during the consent discussion*
* *use of a verbal consent process, LAR or the short form method*
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 \_\_\_\_\_\_\_ **Signature of Person Completing the Note Date Time**