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| The purpose of this worksheet is to provide support for IRB members or Designated Reviewers using the **CHECKLIST: Criteria for Approval and Additional Considerations** when reviewing research involving the short form of consent documentation. This worksheet is to be used. It does not need to be completed or retained. |
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| 1. Short Form of Consent Documentation (All must be “Yes”)
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| [ ]  Yes [ ]  No | The written consent document states that the elements of consent have been presented orally to the subject or the subject’s legally authorized representative. |
| [ ]  Yes [ ]  No | There is written summary of what is to be said to the subject or the legally authorized representative that embodies the required and appropriate additional elements in **Section 7: ELEMENTS OF CONSENT DISCLOSURE** in the **CHECKLIST: Criteria for Approval and Additional Considerations.** |
| [ ]  Yes [ ]  No | The consent document and short form are accurate and complete. |
| [ ]  Yes [ ]  No | An impartial witness is present during the entire consent discussion. |
| [ ]  Yes [ ]  No | For subjects who do not speak English the witness is conversant in both English and the language of the subject or the subject’s legally authorized representative. |
| [ ]  Yes [ ]  No | The subject or the subject’s legally authorized representative will sign and date the short form document.  |
| [ ]  Yes [ ]  No | When a subject or the subject's legally authorized representative is unable to read: An impartial witness will be present during the entire consent discussion and the consent document notes that the witness attests that the information in the consent document and any other information provided was accurately explained to, and apparently understood by, the subject or the subject's legally authorized representative, and that consent was freely given. |
| [ ]  Yes [ ]  No | The witness will sign and date the consent and the short form document.  |
| [ ]  Yes [ ]  No | The person obtaining consent will sign and date the consent document.  |
| [ ]  Yes [ ]  No | A copy of the signed and dated short form will be given to the subject or the subject’s legally authorized representative signing the document. |
| [ ]  Yes [ ]  No | A copy of the signed and dated consent document will be given to the subject or the subject’s legally authorized representative. |
| [ ]  Yes [ ]  No | If there is a signature line for a legally authorized representative or parent, the IRB has approved inclusion of adults unable to consent or children. |