

## WORKSHEET: Short Form

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This worksheet is used to determine whether non-exempt <Human Research> using a short form of consent documentation can be approved.

Ⓟ

All criteria in 1 must be met

### 1. Criteria for approval of a short form of consent documentation *45 CFR §46.117(b)(2) and 21 CFR §50.27(b)(2)*

- |     |                          |                                                                                                                                                  |
|-----|--------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------|
| 1.1 | <input type="checkbox"/> | The short form is written in language understandable to the subject or LAR (see Footnote 1)                                                      |
| 1.2 | <input type="checkbox"/> | The short form states that the required elements of informed consent have been presented orally to the subject or LAR                            |
| 1.3 | <input type="checkbox"/> | The summary embodies the required and appropriate additional elements in Section 4 of "WORKSHEET: Criteria for Approval (HRP-400)"               |
| 1.4 | <input type="checkbox"/> | The summary is accurate and complete                                                                                                             |
| 1.5 | <input type="checkbox"/> | There will be an <Impartial Witness> to the oral presentation who can converse in the language of the short form and the language of the summary |
| 1.6 | <input type="checkbox"/> | The subject or LAR will sign and date the short form                                                                                             |
| 1.7 | <input type="checkbox"/> | The person obtaining consent will sign and date the summary                                                                                      |
| 1.8 | <input type="checkbox"/> | The witness will sign and date the short form and the summary                                                                                    |
| 1.9 | <input type="checkbox"/> | The subject or LAR will be given signed and dated copies of the short form and the summary                                                       |

### 2. Additional considerations

- |     |                          |                                                                                                                                                                                      |
|-----|--------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 2.1 | <input type="checkbox"/> | Once a short form is used for a particular language, should the summary be translated into that language and future subjects have consent documented in writing using the long form? |
| 2.2 | <input type="checkbox"/> | Once a short form is used for a particular language, should the summary be translated into that language and provided to that subject?                                               |

### 3. Notes

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### 4. Footnotes

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| 4.1 | In general, the short form is a standard document translated into the subject or LAR's language and the summary is an untranslated long form consent document. |
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