The purpose of this worksheet is to provide support for IRB members or designated reviewers using the OIA-314 WORKSHEET: Criteria for Approval and Additional Considerations, or equivalent, when reviewing research involving the short form consent form documentation. This worksheet, or equivalent, is to be used. It does not need to be completed or retained.

### 1 Requirements for Written Short Form Consent Form Documentation

- [ ] The written short form consent form states that the elements of consent have been presented orally to the subject or the subject’s legally authorized representative (LAR).
- [ ] There is a written summary of what is to be said to the subject or the subject’s LAR that incorporates the required and appropriate additional consent elements in OIA-314B WORKSHEET: Requirements for Informed Consent, or equivalent.
- [ ] The consent document and summary are accurate and complete.

### 2 Requirements for Short Form Consent Form Process

- [ ] An impartial witness will be present during the entire consent discussion.
- [ ] For subjects who do not speak English, the witness is conversant in both English and the subject’s or the LAR’s language.

### 3 Requirements for Signature

- [ ] The subject or the subject’s LAR will sign and date the short form consent form.
- [ ] The witness will sign and date the short form consent form and the summary.
- [ ] The person obtaining consent will sign and date the summary.

If a subject or the subject’s LAR is unable to read: An impartial witness will be present during the entire consent discussion. The consent document witness signature line indicates that the witness was present for the entire consent discussion; 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 LAR; and that consent was freely given.

### 4 Requirements for Documentation to be Provided to Subjects

- [ ] A copy of the signed and dated summary will be given to the subject or the subject’s LAR.
- [ ] A copy of the signed and dated short form consent form will be given to the subject or the subject’s LAR.
- [ ] If there is a signature line for a subject’s LAR or parent, the IRB has approved inclusion of adults unable to consent, or children, respectively.

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1 The written summary may be a separately approved summary or the approved consent document in English.