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| **Regulatory Consent Process Requirement** | **How the Requirement was Met** |
| 1. *Provide the participant or legally authorized representative (LAR) with all of the required information about the study.*     1. *Provide a copy of the written consent document.*    2. *Have a consent discussion with the participant.* | The participant/LAR was provided with a copy of the consent document using the following method:   |  |  | | --- | --- | | * In-person * Email * Mail * Fax * Online * Other (describe): | Date the consent document was provided:  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Person who provided the consent document:  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |   A consent discussion with the participant/LAR occurred using the following method:   |  |  | | --- | --- | | * In-person * Telephone * Web conference * Other (describe): | Date the consent discussion occurred:  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | List the name and role of each individual involved in the consent discussion. Roles include participant, investigator, study team member, legally authorized representative, family member, impartial witness, interpreter, etc. *Note that an impartial witness must observe the consent process if a copy of the signed consent form cannot be physically given or transmitted to the study team.*  Name: Role: | | |  | | |  | | |  | | |  | | |  | | |  | | |

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| 1. *Give information in a language the participant understands.* | Language used for the consent process:  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  *Note that if a language other than English is used, a certified interpreter must be present for the consent discussion. Additionally, translated consent document must be used and approved by the IRB.* |
| 1. *Give the participant an opportunity to ask questions before providing consent?* | Did the participant/LAR have questions during the consent discussion?   * Yes * No |
| 1. *Give the participant enough time to consider being in the study.* | Did the participant/LAR request more time to consider participation after the consent discussion?   * Yes * No   If yes, describe the follow up that occurred: |
| 1. *Document that the participant’s consent was obtained before beginning study procedures.* | Date the participant/LAR signed the consent form:  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  How will proof of the participant/LAR signature be documented in the research record:   * An original signed consent document (signed in ink) is included in the research record. * An electronically signed copy of the consent document is included in the research record.   + What platform/method was used to obtain an electronic signature:   \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_   * A photocopy, photo, or fax of the signed document is included in the research record.   + Date the copy received by the study team:  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ * An original copy with the participant/LAR signature could not be obtained because of physical COVID-19 transmission concerns. Consent was obtained verbally and the participant kept the original signed consent document. The research record includes a written attestation by the investigator/designee and an impartial witness that the participant gave consent verbally. **ATTESTATIONS SECTION 7 REQUIRED BELOW.** |

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| 1. *Document that other persons involved in obtaining consent have signed the consent document.* | Name of the **person obtaining consent**:  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Did the **person obtaining consent** sign the same document as the participant/LAR, or a separate copy?   * Same document * Separate copy   Name of the **impartial witness:**   * Check here if n/a   \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Did the **impartial witness** sign the same document as the participant/LAR, or a separate copy?   * Same document * Separate copy * n/a   Name of the **interpreter:**   * Check here if n/a   \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Did the **interpreter** sign the same document as the participant/LAR, or a separate copy?   * Same document * Separate copy * n/a |

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| 1. *Documentation of attestations for impartial witness and person obtaining consent* | **ATTESTATIONS SECTION** required when an original copy with the participant/LAR signature could not be obtained because of physical COVID-19 transmission concerns. Consent was obtained verbally and the participant kept the original signed consent document. The research record includes a written attestation by the investigator/designee and an impartial witness that the participant gave consent verbally.   * Check here if n/a   **Witness attestation is documented using:**   * The COVID-19 Witness Signature & Attestation Page (downloaded from IRB website) * A separate memo signed by the witness   **Person obtaining consent attestation is documented using:**   * The COVID-19 Person Obtaining Consent Attestation Page (downloaded from IRB website) * A separate memo signed by the person obtaining consent |

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| 1. *Give a copy of the signed consent form to the participant.* | The participant/LAR was provided with a signed copy of the consent document using the following method:   |  |  | | --- | --- | | * A fully signed version was provided * In-person * Email * Mail * Fax * Online * Other (describe): * Participant/LAR kept their copy of the partially signed consent, due to COVID-19 transmission concerns. | Date the signed copy was provided:  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Person who provided the signed copy:  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | |

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| Other notes about the Consent Process and Documentation: |

**Person who completed this form:**

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Name Date

**Signature of investigator:**

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Signature Date