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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:

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| * 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:

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| * 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:

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| --- | --- |
| * 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:**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name Date

**Signature of investigator:**

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Signature Date