|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Consent Documentation** | | | | |
| ***Instructions****: The study team should complete this form in order to document the written informed consent process for any adult participant on COVID-19 isolation where the paper consent document with participant/LAR signature cannot be collected.* | | | | |
| **Consent Approval Date:** |  | **Consent Expiration Date:** |  |

**Research team member completing informed consent conversation with participant:**

(*only add people who are listed as “yes” to being involved in the consent process in myIRB*):

[insert name] [insert name] [insert name]

[insert name] [insert name] [insert name]

**Was the consent conversation held in person through direct communication with the patient/LAR?**

Yes  No

*(Please note: If direct communication with the patient in isolation is not feasible or safe, the PI/Designee should obtain the patient’s phone number & arrange a three-way call or video conference with the patient, an impartial witness (if the role of the witness cannot be undertaken by the nurse), and if desired and feasible, additional participants requested by the patient, e.g. next of kin.)*

**If no, was the consent conversation held via phone call or video conference with the participant and/or LAR?**

Phone call  Video conference  Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**If applicable, who was the impartial witness (***hospital staff, healthcare worker, nurse etc***.,** *who is independent of the trial and not related to the participant***) to the consent conversation?**

|  |
| --- |
| Print Name of Impartial Witness: |

*(Please note: The impartial witness will need to be present for the entire conversation and confirm that the patient has signed and dated the consent document in accordance with the University’s policy on consenting COVID-19 Patients.)*

**Was consent by an LAR needed?**  Yes  No

If yes, document the reason the participant was not capable of providing consent:

|  |
| --- |
|  |

**Confirm that the person is in fact the patient’s LAR and indicate below their relationship with the patient. If there is NO LAR or attorney-in-fact, the individuals listed below may sign in the order of priority below** (*mark who consented for the patient*):

|  |  |
| --- | --- |
| **Attorney-in-fact or legal guardian** (print name):  *must be willing to provide documentation if necessary* |  |
| **Spouse** (print name): |  |
| **Adult Child** (print name): |  |
| **Parent** (print name):  Mom  Dad |  |
| **Sibling** (print name):  Brother  Sister |  |
| **Relative by blood or marriage** (print name & relationship): |  |
|  | **Print name of LAR Relationship to Adult** |

**---------------------------------------------- *Modify this section based on your study’s details*---------------------------------------------------**

**Confirm that the following items were completed by checking off below:**

Patient and if applicable, their Legally Authorized Representative (LAR) was provided with a copy of the informed consent to review and sign. The original copy is retained with the PI/Designee obtaining consent.

The informed consent was reviewed in its entirety with the participant/LAR and the following major points were reinforced:

they may or may not receive any benefit from participating in this study and their participation is completely voluntary and they may quit at any time.

the potential risks for participating include the possibility for a [**Adjust per your study**-e.g., breach of confidentiality and the potential to elevate negative feelings]. Every effort will be made to keep their information confidential, minimize risk and provide them with services as needed.

Participation in this study includes [**insert high level summary here:** e.g., completion of surveys/questionnaires and leftover sample collection].

they will be offered a [insert amount paid] for participating OR they will not be compensated for participating.

they can take all the time needed to consider participation.

**---------------------------------------------------------------------------------------------------------------------------------------------------------------------**

**-----------------------------------*Modify this section based on the answerable items or remove if it does not apply*---------------------------------------**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **The participant/LAR provided consent permissions for the following optional study items:** | | | | |
| Permission for Future Use of Data | Yes  No | Permission to email | Yes  No |
| Permission to share data with other researchers | Yes  No | Permission to text | Yes  No |
| Permission to email PHI | Yes  No | Permission to video/audio record | Yes  No |
| Permission to text PHI | Yes  No | [other, insert any additional optional items] | Yes  No |

**------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------**

**Did the patient/LAR provide verbal confirmation that they are willing to participate in the trial and that they have signed and dated the informed consent document that is in their possession?**

Yes  No

***(Remove if not applicable)* Did the minor patient provide verbal confirmation that they are willing to participate in the trial and that they have signed and dated the assent document that is in their possession (as applicable per the study)?**

Yes  No—If no, provide reason:

Too young

Not mentally competent to provide assent

|  |
| --- |
| Other: |

**Patient/LAR was instructed to sign & date and retain the informed consent document that was just reviewed with them.**

**Did the impartial witness verbally confirm that the participant’s questions have been answered and that the patient is willing to participate in the trial?**

Yes  No

**Did the impartial witness sign & date the PI/Designee’s copy of the informed consent?**

Yes  No, if no because the impartial witness was not physically present, the impartial witness should document their witness of the consent discussion and provide an attestation statement to the research team. The attestation should confirm their witness to the consent conversation and patient’s agreement to participate. This documentation should be printed (signed & dated) and attached to the PI/Designee’s copy of the consent. Either the original version of the attestation with signature can be provided or a certified copy may be created.

**Additional Comments:**

**PI/Designee Attestation Statement:**

By signing below, I am confirming that all of the above information is correct and is an accurate account of the informed consent discussion. The consent was reviewed in its entirety with the patient/LAR, the patient/LAR verbally confirmed that they agree to participate in the trial and that an impartial witness witnessed the consent conversation.

|  |  |  |  |
| --- | --- | --- | --- |
| **PI/Designee Signature:** |  | | |
|  |  | | |
| **END Date & time of verbal consent conversation:** | **/ /** | **:** | am  pm |
|  | MM/DD/YYYY | HH:MM |  |

**A copy of the informed consent was provided to the participant via** (*check off which method was used*):

In-person on the date consent was obtained

Mail on: \_\_\_\_/\_\_\_\_/\_\_\_\_  email on: \_\_\_\_/\_\_\_\_/\_\_\_\_  other\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ on: \_\_\_\_/\_\_\_\_/\_\_\_\_