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| V**erbal Consent Documentation with Legally Authorized Representative (LAR) or Parent/Legal Guardian** | | | |
| ***Instructions***: *This document* *is for use only in studies with an IRB-approved waiver of documentation of consent (no written signature required) and is used to document the informed consent process for an LAR or Parent/Legal Guardian on behalf of a minor participant OR adult participant.* | | | |
| **Consent Approval Date:** |  | **Consent Expiration Date:** |  |

|  |  |
| --- | --- |
| **Participant’s Name (print):** |  |

**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] [insert name] [insert name]

**Was the participant/parent/legal guardian/or LAR approached in person in or over the phone?**

**Over video conference**, verbal consent obtained  **Over the phone**, verbal consent obtained

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| **Other:** |

**Was the participant a minor?**  Yes  No

If **Yes**, confirm that the person is in fact the minor’s parent or legal guardian.

**Participant is a minor; consent obtained from the following *confirmed* parent/legal guardian:**

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| --- | --- |
| **Mom** (print name): |  |
| **Dad** (print name): |  |
| **Other**-*must be legal guardian and willing to provide documentation if necessary* |  |
|  | **Print name of parent/legal guardian Relationship to child** |

**Was the participant an adult?**  Yes  No **Was consent by LAR needed?**  Yes  No

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

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Confirm that the person is in fact the patient’s LAR and indicate their relationship with the participant below. 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*):

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| --- | --- | --- |
| **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): | |  |
| **Brother or sister** (print name): | |  |
| **Relative by blood or marriage** (print name): | |  |
|  | **Print name of LAR Relationship to Adult** |

**--------------------------------------------------*Modify this section to fit your study* --------------------------------------------------**

**Documentation of consent conversation** *(check off to verify that each of the following items were completed)***:**

The informed consent was reviewed in its entirety with the participant/LAR/parent/legal guardian 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*---------------------------------**

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| **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 participant/LAR/Parent/ or Legal Guardian have any questions regarding the study or the consent document?**

Yes  No *(If yes, summarize below***):**

**Summary of conversation:**

**Minor Participants**

**Was the minor capable of providing verbal assent?**

No, too young [**Adjust per your study**-must be consistent with assent table in myIRB section 2.4]. Age: \_\_\_\_\_

No, not capable of assent. Reason:

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|  |

Yes

**If yes, did the minor provide assent to participant in the study?**

Yes, the minor *verbally agreed*.

No, the participant *declined participation* and they were thanked for their time and consideration.

**Did the participant’s parent/legal guardian provide consent for the minor to participate in the study?**

Yes, the parent/legal guardian *verbally agreed*.

No, the parent/legal guardian *declined participation* and they were thanked for their time and consideration.

**Adult Participants**

**Did the participant/LAR provide consent to participate in the study?**

Yes, the adult participant/LAR *verbally agreed*.

No, the participant/LAR *declined participation* and they were thanked for their time and consideration.

**By signing and dating 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, adequate time was given for participation consideration, and that the participant/LAR/parent/legal guardian (as applicable) confirmed their willingness to participate in the research study.**

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