**Documentation of Consent Process by Investigators**

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| **Guidance:**  Informed consent is a process and involves providing a potential subject with adequate information about the research to allow for an informed decision about the subject’s voluntary participation in a research study. Informed consent is a process. Documenting informed consent occurs after explaining the research, addressing any questions, and assessing participant comprehension.   * Documentation of informed consent requires the signature of informed consent by the research participant (or their legally authorized representative or parent(s), as applicable) unless a waiver of that signature has been approved by the IRB. * The forms here are two different suggested templates that can be used so that the person obtaining consent notates the following: current and IRB-approved informed consent forms were used, that he/she explained the research to the participant, ensured that the participant understood the research and that the participant freely agreed to enroll. * These forms should be utilized at the beginning of the study and throughout the study, when updates and revisions to the consent form(s) require re-consent. * The templates herein provide a framework for documenting the consent discussion and process with each potential study participant and should be customized to different studies as applicable. * Modify the form as needed/desired to add or remove any additional consent information, such as:   + If a legally authorized representative is present   + Information related to signatures as applicable |

***Suggested templates start on the next page.***

**Documentation of Consent Process Form**

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| **IRBNet # and Study Title:** |  |
| **Principal Investigator:** |  |
| **Participant ID #:** |  |
| **Consent Process Medium:** | (e.g., in-person, zoom, phone) |
| **Date and Time consent signed (if applicable):** |  |

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| **Yes** | **No** | **Consent Process Procedure** |
|  |  | The consent form is verified\* IRB approved and current.  \*Valid consent documents contain the UD IRB approval stamp at the top of each page. Use the current approved consent documents posted in IRBNet under “Board Documents”  Date of IRB approval: \_\_\_\_\_\_\_\_\_\_\_\_\_\_ Version (IRBNet #): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  |  | Informed consent for the study was discussed in detail with participant. |
|  |  | Participant was given adequate time to read the consent form and ask questions. |
|  |  | Informed consent process: the following questions were asked by the participant and/or LAR and the following answers were provided by the person obtaining consent (POC):  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  |  | Participant showed competency to decide whether they want to participate in the research. |
|  |  | Participant understands the purpose, risks, and benefits of the study. |
|  |  | Participant understands that participation is voluntary, and consent may be withdrawn. |
|  |  | Participant initialed their choice for all optional elements (if applicable). |
|  |  | Participant and the person obtaining consent both signed and dated the consent form. |
|  |  | Copy of the consent form was offered/provided to the participant. |
|  |  | Consent has been signed and dated prior to any study procedures being performed. |

*(If re-consenting)* Reason for re-consent: \_\_\_\_\_\_\_\_\_\_\_\_\_

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| Name of person obtaining consent (POC): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | |
| Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

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| **Participant Initials or Subject ID #** | **Consent Process Medium (e.g., in-person, zoom, phone)** | **Initial Consent or Re-consent?** | **Consent Form Version/ IRB Approval Date** | **Consent Form**  **IRB approval Expiration Date** | **Printed Name and Signature Recorded (Y/N)** | **Date Signed by Participant** | **Name of Person Obtaining Consent (POC)** | **Date signed by POC** | **Optional Element - Initialed? (Y/N)** | **Comments/Notes** |
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| **IRBNet # and Study Title:** |  |
| **Principal Investigator:** |  |

**Documentation of Consent Process Log**