**Informed Consent Cover Sheet**

This form should be attached to the first page of the consent and is meant to be used as a record of consent in order to determine how the consent process was conducted. This form should be filled out at the same time as the consent form tor retain an accurate record of events.

**Protocol:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Principal Investigator:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

🞏 The subject was referred to the study by the principal investigator and all protocol inclusion criteria exclusion criteria will be verified after consent.

🞏 The subject contacted the research site/personnel due to interest in participating in research study and has been deemed as pre-qualifying for the study based on the principal investigator’s initial assessment.

The Informed Consent Document was explained and questions were discussed in:

🞏 English 🞏 Spanish 🞏 Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

An interpreter 🞏 was used 🞏 was not used

If an interpreter was used, list name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

The Informed Consent discussion took place at \_\_\_\_\_\_AM/PM on,\_\_\_/\_\_\_\_/\_\_\_\_\_\_ and before any research procedures were performed.

The following type of consent was obtained using Good Clinical Practice Guidelines:

🞏 Biomedical 🞏 SocioBehavioral 🞏 Blood and Tissue 🞏 Parental 🞏 Assent 🞏 Other: \_\_\_\_\_\_\_\_\_\_

**The consent discussion included:**

🞏 subject 🞏 subject’s family 🞏 legally authorized representative (LAR) 🞏 impartial witness

In a brief statement, please explain why an LAR or an impartial witness was used: ­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

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**Mark all of the items discussed with the subject?**

🞏 Introduction, including voluntary nature of research

🞏 Study Purpose

🞏 Qualifications to participate

🞏 Design and duration

🞏 Risks and discomforts

🞏 Right of withdrawal

🞏 Benefits

🞏 New findings

🞏 Alternative Treatments

🞏 Confidentiality

🞏 Policy regarding research related injuries

🞏 Compensation

🞏 Problems or questions (contact information)

The subject/LAR verbalized understanding of the study, study procedures and their role? 🞏 Yes 🞏 No

🞏 After all questions were answered, adequate time was allowed to consider participation prior to any study related procedures.

🞏 Informed Consent or Assent was obtained voluntarily

🞏 The original signed and dated consent form is retained by the Principal Investigator

🞏 Signed copy of the consent form was provided to the subject

Printed name of person who obtained informed consent: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name(s) of other individuals present during informed consent process: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

HIPAA Authorization Form signed: 🞏 Yes 🞏 No 🞏 N/A

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

Printed name of person completing this form