**\Title of Study:** *<insert title of research study here>*

**Principal Investigator:**  *<insert name of PI>*

**Department:** *<insert PI’s department>*

**Phone Number:** *<insert phone number and 24-hour contact number>*

**Email Address:** *<insert Email address>*

**Study Contact Name:** *<insert name of contact>*

**Study Contact Telephone Number:** *<insert phone number and 24-hour contact number>*

**Study Contact Email:** *<insert Email address>*

**Sponsor:** *<insert Sponsor name if applicable>*

This Consent Form Addendum provides new information about your participation in the above referenced study.

The purpose of this Consent Form Addendum is to document your agreement to allow the research team to continue collecting data about you from your medical record. Except for the procedures for this study, all of the other information in the informed consent form you signed when you joined the study remains the same.

You have decided to discontinue participating in the research procedures involved in this study. You will no longer receive the investigational treatment or complete other procedures described in that i consent form. However, any data previously collected as part of your participation in the study will remain as part of the study records and cannot be removed.

The study doctor discussed with you an option to allow the study team to continue to collect data about you for this research study.

If you agree, the study team will review your medical record and collect information about your health status, treatments you are receiving, and any adverse events you may have experienced. The review will occur every so often until the study ends or unless you withdraw your consent. The study doctor will share this information with the sponsor of this study and may share the information with the FDA and with organizations overseeing this study such as the study monitors and the IRB.

There are risks to your confidentiality if you allow the study team collect information about you. The investigator will protect the information collected as described in the consent form you signed when you joined the study.

You will not benefit personally if you allow the research team to continue to collect information about you. However, the research done on the information the study team collects, may help others in the future.

Your information (both identifiable and de-identified) may be used to create products or to deliver services, including some that may be sold and/or make money for others. If this happens, there are no plans ***[or replace with plans when using identifiable information/samples****]* to tell you, or to pay you, or to give any compensation to you or your family.

You do not have to agree to allow the study team to continue collect information about you. If you decide not to agree to this data collection, you will not be penalized or lose any benefits that you are entitled to receive. If you agree to all this data collection and later change your mind, let the research team know. You will not be penalized or lose any benefits if you change your mind.

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at [Insert contact information for the research team.]

This research has been reviewed and approved by an Institutional Review Board (“IRB”). The Human Subject Research Office (HSRO)provides administrative support to the University of Miami’s IRBs.

Please call the HSRO at 305-243-3195if:

* The research team has not answered your questions, concerns, or complaints.
* You cannot reach the research team.
* You want to talk to someone besides the research team.
* You have questions about your rights as a research subject.
* You want to get information or provide input about this research.

**Documentation of Consent**

* *I have read this form and the research study has been explained to me.*
* *I have been given the chance to ask questions, and my questions have been answered. If I have more questions, I have been told who to call.*
* *I agree to have data collected for the research study described above.*
* *I will receive a copy of this consent form after I sign it.*

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Signature of Participant Date

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

Printed Name of Participant

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

Signature of Person Obtaining Consent Date

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

Printed Name of Person Obtaining Consent

***Remove “signature of participant” above if the subject is a child or is incapable of consenting.***

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

Signature of Parent(s)/Legally Authorized Representative Date

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

Printed Name(s) of Parent(s)/Legally Authorized Representative

***Remove “Parent(s)” above if the subject is not a child or has an LAR other than the parent***

***If the IRB approved inclusion of cognitively impaired adult participants who cannot personally consent, you must obtain assent from that participant is s/he is capable.***

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

Signature of Adult Participant who is capable of Assent Date

***Assent is usually required for participants who are minors age 7 to 17 years.***

I described the data collection for this study to the child in a manner suited to the child’s age and ability to comprehend. I answered all of the child’s questions about this study. I asked the child questions to see if the child understood that the procedures are research and that s/he doesn’t have to participate if s/he doesn’t want to.

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Signature of Person Obtaining Assent Date

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

Printed Name of Person Obtaining Assent

A witness is only required if:

1. The subject, parent or LAR is unable to read the consent document;
2. The subject, parent or LAR is unable to sign the document due to physical limitations; and/or
3. Consent is obtained using the short form process, and this consent document is the summary.

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

Signature of Witness Date

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

Printed Name of Witness