|  |  |
| --- | --- |
| Title of Study: |  |
| Principal Investigator: |  |
| Department: |  |
| Phone Number: |  |
| Email Address: |  |
|  |  |
| Study Contact Name: |  |
| Study Contact Telephone Number: |  |
| Study Contact Email: |  |
|  |  |

## You are being asked to take part in a research study.

## Before you agree to take part, someone will explain to you:

1. You are being asked to take part in research
2. The purposes of the research
3. How long you will be in the research
4. What will happen to you
5. What is experimental
6. Risks or discomforts to you
7. Benefits to you or others
8. Other choices you might have
9. Who will see your information
10. You volunteer to be in a research study.
11. Whether or not you take part is up to you.
12. You can choose not to take part.
13. You can agree to take part and later change your mind.
14. Your decision will not be held against you.
15. You can ask all the questions you want before you decide.

## Who can I talk to?

1. If you have questions, concerns, or complaints, or think the research has hurt you, you can talk to the research team at (insert phone number) or (insert email address).
2. This research has been reviewed and approved by an Institutional Review Board. You may talk to them at 305-243-3195 if:

* Your questions, concerns, or complaints are not being answered by the research team
* 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

## When applicable, someone will explain to you:

1. Whether you will get treated or paid if injured
2. The possibility of unknown risks
3. When you may be taken off the research without your agreement
4. Added costs from taking part
5. What will happen if you stop taking part
6. Steps to safely stop taking part
7. When new information will be told to you

* The number of people expected to take part
* That the Food and Drug Administration may inspect the records
* What happens to collected data if you stop taking part
* An explanation of [www.ClinicalTrials.gov](http://www.ClinicalTrials.gov)

[There are three signature pages attached to this template consent. Use the signature page or pages appropriate for your study. The IRB recommends that you make separate consent documents for each signature page to be used.]

. **Signature Block for Capable Adult**

|  |  |  |
| --- | --- | --- |
| Your signature documents your permission to take part in this research. | | |
|  |  |  |
| Signature of subject |  | Date |
|  |  | |
| Printed name of subject |
|  |  |  |
| Signature of witness to consent process |  | Date |
|  |  | |
| Printed name of person witnessing consent process |

**Signature Block for Adult Unable to Consent**

|  |  |  |
| --- | --- | --- |
| Your signature documents your permission for the named subject to take part in this research. | | |
|  |  | |
| Printed name of subject |
|  |  |  |
| Signature of legally authorized representative |  | Date |
|  |  | |
| Printed name of legally authorized representative |
|  |  |  |
| Signature of witness to consent process |  | Date |
|  |  | |
| Printed name of person witnessing consent process |

**Signature Block for Children**

|  |  |  |  |
| --- | --- | --- | --- |
| Your signature documents your permission for the named child to take part in this research. | | | |
|  | |  | |
| Printed name of child | |
|  | |  |  |
| Signature of parent or individual legally authorized to consent to the child’s general medical care | |  | Date |
|  | | * Parent * Individual legally authorized to consent to the child’s general medical care (See note below) | |
| Printed name of parent or individual legally authorized to consent to the child’s general medical care | |
| **Note:** Investigators are to ensure that individuals who are not parents can demonstrate their legal authority to consent to the child’s general medical care. Contact legal counsel if any questions arise. | | | |
|  | |  |  |
| Signature of parent | |  | Date |
|  | |  | |
| Printed name of parent | |
| If signature of second parent not obtained, indicate why: (select one) | | | |
| * The IRB determined that the permission of one parent is sufficient. ***[Delete if the IRB did not make this determination]*** * Second parent is deceased * Second parent is unknown | * Second parent is incompetent * Second parent is not reasonably available * Only one parent has legal responsibility for the care and custody of the child | | |
|  | |  |  |
| Signature of witness to consent process | |  | Date |
|  | |  | |
| Printed name of person witnessing consent process | |