|  |  |
| --- | --- |
| 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 |

**UNIVERSITY OF MIAMI/JACKSON HEALTH SYSTEMS**

**HIPAA AUTHORIZATION FOR RESEARCH**

**What is the purpose of this part of the form?**

State and federal privacy laws protect the use and release of your protected health information. Under these laws, your health care providers generally cannot release your health information for the research listed above unless you give your permission. You will use this form to give your permission. By signing this form, you authorize the University of Miami, Jackson Health Systems, the Principal Investigator and his/her/their/its collaborators and staff to obtain, use and disclose your health information, as described below. These people and institutions are called “Providers” in this form.

**What Protected Health Information will be used or shared?**

You are authorizing the use and sharing of all of the information collected or created during this research as described in the first part of this document, including information in your medical records that is relevant to this research study. Information that may be relevant includes:

* Your past medical history,
* Medical information from your primary care physician,
* All other medical information relating to your participation in the study listed at the top of this document

**Who may receive my Protected Health Information?**

The Providers may use and share your health information with:

* The Principal Investigator and his/her research staff
* Representatives of government agencies that have oversight of the study or who the law permits to access the information such as the U.S. Food and Drug Administration, the Department of Health and Human Services, and the Florida Department of Health
* Groups that collaborate and sponsor research (Cooperative Groups)
* Institutional Review Boards (groups of people who oversee research)
* Other persons who watch over the safety, effectiveness, and conduct of research
* The Sponsor of the research, its agents, monitors, and contractors
* Other participating researchers; and
* Independent data and safety monitoring boards

Authorized staff such as doctors and nurses who are taking care of your health but are not involved in this research may be aware that you are participating in a research study and may have access to research information about you. If the study is related to your medical care, any study-related information may be placed in your permanent hospital, clinic, or physician’s office records.

**Why will my Protected Health Information be used and disclosed?**

* Researchers (those individuals in charge of the study) and research team members will use your information to conduct the research study described in this informed consent document and other activities related to the research, such as evaluating the safety of the study.
* The research sponsor and its authorized representatives, business partners, clinical research organizations and affiliates will use your information for the purposes described in this informed consent document and for other activities related to the research, such as assessing the safety or effectiveness of the drug, device or treatment being studied, improving designs of future studies or obtaining approval for new drugs, devices or health care products.
* The University of Miami’s clinical trial organizations will use your information to review and support clinical trials at the University.
* Other University of Miami offices involved in regulatory compliance, including the Institutional Review Board (IRB), Offices of General Counsel and Compliance, may use your information to ensure the research is performed correctly.
* U.S. government agencies, such as the Food and Drug Administration and the Office for Human Research Protections, government agencies from other countries, and others who are authorized by law may use your information to review or oversee this research or to see if a new drug, device or other health care product should be approved for marketing.

**What other information should I know?**

1. Once your information has been disclosed to a third party, the federal privacy law may no longer protect the information from further disclosure.
2. You do not have to sign this Authorization, but if you do not sign it, you may not participate in the research and receive the research treatment; however, your right to other medical treatment will not be affected.
3. You may change your mind and revoke (take back) this Authorization at any time and for any reason. To revoke this Authorization, you must write to the study doctor or to the Human Subjects Research Office at Gables One Tower, 1320 S. Dixie Highway, #650, Coral Gables, FL 33146.
4. If you revoke this Authorization, you will not be able to continue taking part in the research. Also, even if you revoke this authorization, the institutions and people listed above will continue to use and disclose the information they have already collected if the information is needed to protect the reliability of the research.
5. While the research is in progress, you may not be allowed to see your health information that is created or collected for this research by the University of Miami and/or Jackson Health System. After the Research is finished, however, you may see this research information as described in the University of Miami and/or the Jackson Health System Notice of Privacy Practices, whichever notice is applicable.
6. This Authorization does not have an expiration date. There is no set date at which your information will be destroyed or no longer used because the research will need to analyze the information for many years and it is not possible to know when they will complete the analysis.
7. You will be given a copy of this authorization after you sign it.

|  |  |
| --- | --- |
| *Signature of participant or participant’s legal representative*  *Printed name of participant* | Date  Printed name of legal representative (if applicable)  Representative’s relationship to the participant |

**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 | |