**UNIVERSITY OF MIAMI/JACKSON HEALTH SYSTEMS**

 **RESEARCH AUTHORIZATION**

You signed a Consent Form to join the research study described above. This form includes more information about that study, including your rights to the information obtained, created and collected about you and your involvement in the study.

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

State and federal privacy laws protect the use and disclosure of your Protected Health Information “PHI”. Under these laws, your health care providers generally cannot disclose 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 (UM), 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. We call these people and institutions “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 Consent 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,
* Genetic (DNA) analysis or genomic sequencing if these procedures are part of this research.

**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, we may include the study-related information 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 the informed consent document and other activities related to the research, such as evaluating the safety of the study.
* The research sponsor, its authorized representatives, business partners, clinical research organizations and affiliates will use your information for the purposes described in the Consent Document and for other activities related to the research. These activities include assessing the safety or effectiveness of the drug, device or treatment that we are studying, improving designs of future studies or obtaining approval for new drugs, devices or health care products.
* The UM/JHS’s clinical trial organizations will use your information to review and support clinical trials at the University and health system.
* Other UM/JHS’s offices involved in regulatory compliance, including the Institutional Review Board (IRB), Offices of General Counsel, and Compliance may use your information to ensure the study teams are performing the research 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 must use your information to review or oversee this research and to review the data so they can decide whether to approve a new drug, device or other health care product for marketing.

**What other information should I know?**

1. Once the study team has disclosed your information 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 r decision will not affect your right to other medical care.
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 1531 Brescia Avenue, Casa Bacardi, Coral Gables, Fl. 33146.
4. If you revoke this Authorization, you will not be able to continue taking part in the research.
5. While the research is in progress, you cannot access and read your health information that is created or collected by the institutions and people listed above. After the research is finished, you may see your health information.
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. A study team member will give to you a copy of this authorization after you sign it.

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*Signature of participant or participant’s legal representative (LAR) Date*

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*Printed name of participant*

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*If signed by LAR, document the LARs authority*

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