|  |
| --- |
| **Requirements for Informed Consent**  ***Institutionally-required*** *language that must be included by the reviewing IRB* |
| Unless consent is waived, the External IRB should approve a template consent document.  UM PI will need to obtain approval from the External IRB of a UM and/or JHS formatted consent document that includes the language required by the University of Miami and JHS.  The UM uses a HIPAA Addendum to the research subject consent form. The addendum is part of the consent document but is not embedded within the main body of the consent document. Informed consent and HIPAA authorization must be separate signatures.  **UM will not accept HIPAA authorization language embedded within the consent form.**  Researchers can choose to use a separate UM Standalone HIPAA FORM or use the HIPAA Form that is the addendum to the consent document. |

**Required Language for Consent Documents**

The external IRB will probably approve one or more consent template documents for the study. You are responsible for adding language required by the University of Miami to the consent template. The IRB should then approve a consent document that includes the required language.

The following language must be included in the consent document, when appropriate:

**Financial Compensation Language**

***If subjects are being financially compensated:***

We may ask you for your social security number for payment purposes. We will not use it for any other purpose without your permission.

If you receive $600 or more during a calendar year from the University for taking part in this research, you may receive a 1099 for tax reporting purposes. Reimbursements for travel and other expenses are not included in this amount.

***If the research collects specimens include:***

The sponsor and the University of Miami (UM) will use your information (data) and samples (blood, urine, etc.) for this study. They may keep, save, or dispose of the data they obtain from you or create about you. The UM or other researchers may use your data and samples for other studies after they remove all of the information that identifies you. They will not ask for your consent for this other research.

This study and other studies may result in products that can be sold. If this event happens, the sponsor or the UM may profit. They will not pay you or share any of the profits with you. Any blood, urine, tissue, or other biological specimens obtained from you for this study will become the exclusive property of the sponsor or the UM. ***[Or other institution, please specify.]***

***Include for Department of Defense (DOD) research that targets military personnel where subjects will be compensated:***

Military personnel should check with their supervisor before accepting payment for participation in this research. We may ask you for your social security number for payment purposes. We will not use the number for any other purpose without your permission.

**Compensation for Injury Language**

***[Non-Sponsored studies that involve greater than minimal risks:]***

If you are hurt or get sick because of being in this study, treatment will be available in most cases. If you have insurance, your insurance company may or may not pay for these costs. If you do not have insurance, or if your insurance company refuses to pay, you will need to pay. Funds to compensate you for pain, expenses, lost wages, and other damages caused by injury are not available. This policy does not prevent you from trying to obtain payment through the legal system.

***[Sponsored studies that involve greater than minimal risks:]***

If you are hurt or get sick because you are in this study, treatment should be available. If you are hurt because of ***[choose: a study procedure that is done correctly or because you took the study drug as you were told, because of the device you received],*** the Sponsor will pay to treat the injury. The UM and the sponsor are not planning to pay for pain, lost wages, and other costs you incur because you were hurt. If you sign this document, you do not give up any of your legal rights to obtain payment for an injury through the legal system.

If the sponsor pays any of your medical expenses, we may require you to give the sponsor your name, date of birth, and Medicare ID or social security number.

***[Studies that involve minimal to no risks:]***

Although risks are unlikely, if you are injured, treatment will be available in most cases. If you have insurance, your insurance company may or may not pay for these costs. If you do not have insurance, or if your insurance company refuses to pay, you will need to pay. Funds to compensate you for pain, expenses, lost wages and other damages caused by the injury are not available. This policy does not prevent you from trying to obtain compensation through the legal system.

**Conflict of Interest/Financial Interest Disclosure Language**

***[If the PI, any member of the study team, and/or their spouses or dependent children have an outside interest or have intellectual property rights related to this project, or if you are aware of any institutional conflict of interest pertaining to this study, include the applicable statements below:***

*[****Study doctor****]* has disclosed that he/she has a personal interest related to this study.

The UM has an interest related to the study.

Please ask any questions to assure yourself that this relationship has not overly influenced the conduct of this research study. If you require further information, please contact the study doctor or HRSO at 305-243-3195 to ask questions or discuss concerns.

If you have any questions about reviewing disclosures of financial interest or the conflict of interest management process at the UM, please call 305-243-0877.

University of Miami Electronic Medical Record Language

***[Include if the study team will access the Electronic Medical Record and/or if the consent form or any test results will be added to the UHealth Medical Record.]***

If you are, or have been, a patient at a UM facility, you will have a UM electronic medical record (EMR). We will add research data to your EMR so doctors taking care of you can use this information for your medical care. Your EMR will show that you are in a research study. We will also include a copy of this signed consent form in the EMR to show your doctors that you are in this research.

The data may describe the investigational products you received and anything else that may affect your medical care or place you at greater risk of harm. The intent is to give information to caregivers who provide your medical care while you are on this study.

UM doctors, nurses and other staff will have access to this data. These people are not part of the research team but are involved in providing your medical care, or they perform other tasks related to your medical care. Laws, such as HIPPA, will require them to keep your data confidential.

We suggest that you tell any non-UM doctors that you are in a research study and they can obtain more information if the request it.

The research team may use your information to notify you of appointments, send you appointment reminders, or schedule additional appointments.

***[Include for a clinical trial. Otherwise, delete.]*** UHealth will grant direct access to your medical records to the sponsor, monitors, auditors, the IRB, and the FDA so they can conduct or oversee the research. By signing this document, you are agreeing to this access.

***[Include if a HIPAA authorization is required. Otherwise, delete.]*** Federal law provides more protections for your medical records and related health information. The second part of this consent form, the University of Miami HIPAA Authorization for Research, describes these safeguards.

***[Include for research involving prisoners. Otherwise, delete.]***If you are a prisoner, we may need to give your records to people and agencies within the criminal justice system, when necessary, and allowed by law.

**Testing for information about special categories (HIV, Hepatitis, Sexually transmitted diseases)**

***Include if the study is testing for information about any special categories of information. Delete the categories of information that the study will not access. If the study will not access sensitive information, delete:***

For this study, we must access and share data about you that is sensitive. We will share this sensitive data with the sponsor and the other individuals listed above may see the information in your research file. This data includes ***[Select the applicable categories of information:*** ***information about your HIV status, hepatitis B and/or C infections, sexually transmitted diseases, treatment you have received for mental health conditions, and treatment you have received for alcohol or other substance abuse.]***  If you test positive for some of the diseases listed above, the UM must report this result to the Florida Department of Health.

***If the study involves HIV testing:*** The study sponsor, FDA and Department of Health and Human Services (DHHS) may review your records and the results of your HIV test. UM employees or other agents may also review your records for audit purposes. However, laws will require them to keep your data confidential. Florida law requires the UM to report all positive HIV test results to the Florida Department of Health. The results we report must include information that identifies the patient. By signing this consent form, you are agreeing to this use, access and disclosure of your sensitive information.

You can obtain an HIV test without giving the testing site your identity. You can find testing sites in many places in Dade County.  You can visit the following site, to find these testing sites: [http://miamidade.floridahealth.gov/programs-and-services/infectious-disease-services/hiv-aids-services/counseling-testing-sites.html](https://nam01.safelinks.protection.outlook.com/?url=http%3A%2F%2Fmiamidade.floridahealth.gov%2Fprograms-and-services%2Finfectious-disease-services%2Fhiv-aids-services%2Fcounseling-testing-sites.html&data=02%7C01%7Ccmg345%40med.miami.edu%7Cf0d56a1bb9cc408bc7e608d7d71c9342%7C2a144b72f23942d48c0e6f0f17c48e33%7C0%7C0%7C637214390034243850&sdata=eTGDgURO44ol45zXbUt1Sa%2FtNtRT0cpGVnuIBKmlYF4%3D&reserved=0)

Clinical Trials Registration

***[Include if registration on clinicaltrials.gov is required. For assistance determining if registration on clinicaltrials.gov is required, use the*** [Applicable Clinical Trial (ACT)](https://nam01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fprsinfo.clinicaltrials.gov%2FACT_Checklist.pdf&data=02%7C01%7CARobledo%40med.miami.edu%7C5fb8fe2f2e8a46d9f82f08d725a181fc%7C2a144b72f23942d48c0e6f0f17c48e33%7C0%7C0%7C637019247921039284&sdata=3NAbd8Ul0E26jQ%2FzqkKxRrMKZN2bh%2BtgwDwTKfax8Go%3D&reserved=0) ***Checklist found on clinicaltrials.gov.]***

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Florida DNA Law Genetic/Genomic Research Language

Include if this research will collect biospecimens for DNA analysis, conduct DNA analysis on biological samples collected for another purpose, share/transfer samples for DNA analysis, or share data on DNA analysis

***Does this Study Involve Genetic or Genomic Research?***

This study also involves genetic/genomic testing (analysis).

Genetic testing refers to the study of single genes. Genomic testing refers to the study of all of a person’s genes (genome). Genes are made up of DNA (deoxyribonucleic acid). You inherit genes from your parents. The genes control how your body grows and changes and how your body reacts to certain things. For example, genes you inherited from your parents determined your eye and hair color.

Scientists can collect genes from blood, saliva, or other tissue samples. We will collect DNA from your (***blood/saliva/cheek, etc***.). This testing and research may help us learn why some people are more likely than others to have ***[describe the disease or condition****]*.

We ***[will/will not****]* tell you what we find out about your genes. For example, we might find out that you have a certain kind of gene. We may know that if people have this gene, they sometimes get a certain disease or do not respond to treatment. You could have a gene that may make it more likely for you to have a health problem, but that does not mean you will get that health problem. You should ask the study team or a genetic counselor if you have any questions about genetic research.

***[Choose this paragraph or the next]*** We will not include your name or other identifying information on the ***[blood/ tissue]*** that came from you. We will apply a random code to this sample. We will link the code to your identity, but we will keep the link in a separate place. We will keep your ***[blood/ tissue]*** until it is all used up. We will also keep the information we learn about your DNA indefinitely. If you want to remove your ***[blood/ tissue]*** from this study, contact the study doctor or study team and let them know. If the link to your identity has not been destroyed, we will find your sample and destroy it. We cannot remove the information we learned about your DNA.

***[Choose this paragraph or the one above]*** No one will know that the ***[blood/ tissue]*** sample came from you. Since we will not link your name or other identifying information to the ***[blood/ tissue]*** sample, you cannot change your mind after you agree. We will not be able to find your sample to remove it. It will be forever separated or “unlinked” from your identifying information to protect your privacy. We will keep your ***[blood/ tissue]*** until it is all used up. We will also keep the information we learn about your DNA indefinitely. We cannot destroy this information.

***[Include if applicable]*** We may share your ***[blood/ tissue]*** the information we learn about your DNA with other researchers so they can use it to learn more about ***[insert condition] [or other conditions.]*** But we will not include any information that directly identifies you.

Even though your name will not be connected with the tissue or blood sample, other information about you might still be connected. Examples of this information may be your race, ethnicity, or parts of your medical history. This information may be important to scientists studying genes. The information they discover may be important for research or for public health.

[If this research involves genomic data sharing with NIH, insert] [Genomic Data Sharing Model Language](#GenomicDataSharing).

***See below HIPAA Authorization addendum and the Genetic/Genomic Sharing addendum***

**UNIVERSITY OF MIAMI**

**RESEARCH AUTHORIZATION**

**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, 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 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; and
* Genetic or genomic data obtained by analyzing the biological samples you provided, if the consent document describes genetic analysis.

**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 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 this 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 first part of this 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 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 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.

|  |  |
| --- | --- |
| *Signature of participant or participant’s legal representative*  *Printed name of participant*  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  *If signed by LAR, document the LARs authority* | Date |

**Addendum 2: Genetic/Genomic Sharing**

*[Include the language below if genetic data may be shared, now or at some time in the future, with public data repositories under the* [*NIH Genomic Data Sharing (GDS) Policy*](https://kb.wisc.edu/hsirbs/77276)*. This includes:*

* ***NIH-funded studies***
* ***Studies likely to receive NIH funding in the future***
* ***Collaborative research with someone who has NIH funding***
* ***Studies that will voluntarily share data with public repositories***

***If none of the above apply, remove this part from the consent document.***

Your blood and tissue samples contain DNA. DNA incudes the genes that serve as the "instruction book" for the cells in our bodies. Your samples and health information will help us study how genes play a role in diseases such as cancer, heart disease, and diabetes.

Researchers will use (analyze) DNA from the samples you provided to study your entire genetic sequence, known as your “genome.” We will use your genomic data to find how the data differs and is the same among people who have a disease or other health trait.

We ***[will/will not****]* tell you what we find out about your genes. For example, we might find out that you have a certain kind of gene. We may know that if people have this gene, they sometimes get a certain disease or do not respond to treatment. You could have a gene that may make it more likely for you to have a health problem, but that does not mean you will get that health problem. You should ask the study team or a genetic counselor if you have any questions about genetic research.

Since the NIH is funding this study, we will need to share genetic and genomic data with an NIH federal repositories (databank). The NIH is a US research agency that is part of the US government.

If you agree, we will share your genomic data (not your samples) with a databank approved by the NIH. These databanks collect the results of many genetic and genomic studies and pool the data with information from other research participants. If you allow us to share your data, scientists will use it to better understand many diseases and develop better treatments. This research may help others like you in the future.

These central databanks will store your genetic and genomic data and give them to other researchers for different studies. These researchers must be approved to receive your data.

We will not share your name, birth date, or any other information that could directly identify you. We will remove this information and apply a code to the data and keep the link between the code and your identity.

Even so, there is a chance that people may combine your genomic data with other data and identify you or a group you belong to like an ethnic group or other people with the same disease. If your genomic information is linked back to you, someone might use this information to learn something about your health.

Your genomic data is unique to you, but you share some genomic data with your children, parents, brothers, sisters, and other blood relatives. So, it may be possible that genomic data from them could be used to help identify you. It is also possible that genomic data from you could be used to help identify them.

There also may be other privacy risks that we have not foreseen.

The NIH prohibits people from trying to identify people whose genomic information is in an NIH-designated repository.

To help us protect your privacy, we have obtained a legal document called a Certificate of Confidentiality (CoC). The CoC helps us to protect your data from most subpoenas or other legal demands. With your consent, your genomic and health data can still be shared for purposes you agree to, such as with other researchers for research purposes.

You do not have to allow us to share your genetic or genomic data. You can decide not to allow us to share your data and you can ask us to remove data you allowed us to share. Whatever you decide, you will not be penalized or lose any benefits. You can still join this study if you decide not to allow us to share your data.

We do not think that there will be further risks to your privacy and confidentiality when we share your genetic or genomic data with these banks. However, we cannot predict how genetic data will be used in the future. Scientists could use the genetic data to study a wide variety of diseases.

Initial below to indicate your decision to allow this research to share your genetic and genomic data as described above.

I agree \_\_\_\_\_\_\_\_\_ I disagree \_\_\_\_\_\_\_\_

***Use the University of Miami footer if the study will take place at UM:***

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***Use the Jackson Health System footer if the study will take place at JHS:***

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***Use the combined UM/JHS footer if the study will take place at both UM and JHS:***

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