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| **Once completed, this form should be uploaded in initial IBIS submission for HSRO approval. A copy of the signed form must be included with your submission to the reviewing IRB and uploaded to IBIS submission. *NOTE: no study activities may be initiated until external IRB oversight has been confirmed in IBIS and the study is in the External IRB state.*** | | |
| **IBIS Number:** |  | |
| **Protocol Name:** |  | |
| **UM/JHS Investigator:** |  | |
| **UM/JHS Primary Contact:** |  | |
| **Person completing the form**  *(if different than the researcher)* | Name: | Institution/Affiliation: |
| Mailing address: |
| Phone number: |
| Email: |
| **Study Summary and Basic Information**  *(1-3 sentences)* | | |
| ***Check this box if this is a multi-site trial.*** | | |
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| **Statement of Justification for use of external IRB:**  Study is PHS-funded and external review is required per single IRB mandate  Industry-funded multi-site study and sponsor is requiring single IRB review ***as a condition*** of participation. – **Provide a statement from sponsor requiring external single IRB review**.  Investigator initiated study where UM is a site – Must provide compelling argument for using an external IRB.  Study is not exempt from the federal regulations.  Other | | |
| **Sponsor/Funding Source** | | |
| **Funding information** | Name of Funding Source: | |
| Mailing address: | Contact Name:  Phone number:  Email: |
| **Reviewing IRB and Reliance Agreement** | | |
| Name of External IRB/Institution:  Quorum Review IntegReview  WCG IRB  Advarra IRB  Other    External IRB Contact Name:  Phone number:  Email: | | |
| Yes  No The external IRB has a current IRB/IORG registration and/or Federalwide  Assurance (FWA) with the Office for Human Research (OHRP) and the Food  And Drug Administration (FDA).    Yes No The external IRB has AAHRPP accreditation.  Yes No The external IRB confirmed willingness to serve as the IRB of record for this  study.  Yes No The external IRB has appropriate structure and composition to conduct review of  the research and comply with applicable laws. This includes ensuring  the IRB is properly constituted; members are appropriately qualified; that  members do not participate in the review of the studies in which they have a  conflict of interest. | | |
| The UM and the External IRB must have a “Reliance Agreement” in place before the study can be approved. Agreements are in place with Western IRB, Advarra IRB, NCI CIRB and Quorum Review. If you are using a different external IRB, provide information about the agreement by choosing a selection below:  [SMART IRB](https://smartirb.org/agreement/) Agreement  The External IRB’s Template agreement (if checked, include the agreement in the IBIS submission)  Not sure – If checked send the UM Template agreement to the External IRB. | | |

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|  | **Describe your site’s role in this research. Check all that apply** |
|  | UM is the Grant Recipient |
|  | UM is the Data Coordinating Center |
|  | UM faculty or staff will be interacting or intervening with subjects to obtain data about them or specimens from them. |
|  | UM faculty or staff will be collecting information from subjects through surveys or interviews |
|  | UM faculty or staff will be accessing private identifiable information for recruitment purposes – Note: If checked, HIPAA Authorization waiver is required. |
|  | UM faculty or staff will be obtaining private, identifiable data about subjects through review of records or other information that was or will be collected for another purpose (EMR, student records, records from another study. Note: Do not check this box if the data received deidentified, coded and linked to the individual's identity when the UM researchers do not have access to the subjects' identities. |
|  | UM faculty or staff will be obtaining private, identifiable data about subjects through review of records or other information that was or will be collected for this study. **Note:** Do not check this box if the data received is deidentified, coded and linked to the individual's identity when the UM researchers do not have access to the subjects' identities. |
|  | UM faculty or staff will be obtaining anonymous or deidentified data about subjects that were collected for other purposes (e.g. a different research study, or a deidentified data base). Note: Check the box if the data you are receiving are in a Limited Data Set with a Data Use Agreement or when the data are coded and linked to the subjects' identity and the UM researchers will not have access to that link. |
|  | UM faculty or staff will be obtaining identifiable human bio-specimens that were collected for another purpose. Note: Do not check the box if the bio-specimens are coded and linked to the subjects' identity when the UM researchers receive them and UM researchers will not have access to that link. |

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| **Local Context/Institutional Requirements for Informed Consent**  *(This section includes Institutionally-required language that must be included by the reviewing IRB)* | |
| Unless consent is waived, the External IRB should approve a template consent document.  You will need to obtain approval from the External IRB of a UM-formatted (or JHS) consent document that includes the language required by the University of Miami.  Copy the required local language below and insert to the sponsor/external IRB provided consent document as applicable. | |
| **HIPAA Authorization Instructions**  The University of Miami recognizes HIPAA authorization to be separate from informed consent and requires that HIPAA authorization be obtained separately from informed consent.  The UM uses a HIPAA Authorization Addendum to the research subject consent form for this purpose.  *The HIPAA Authorization Addendum must be inserted at the very end of the consent document(s)* ***after*** *the consent signatures with a* ***page break****.*  The addendum is part of the consent document, but this is not an embedded authorization. The UM will not accept HIPAA authorization language embedded within the consent document before the consent signatures. Alternatively, researchers may choose to use our Standalone HIPAA Authorization form.  **The HIPAA addendum and Standalone version are both available on the HSRO’s website**:  <https://hsro.uresearch.miami.edu/researchers/forms-and-templates/index.html> | |
| **Institutionally Required Local Language Instructions**  It is the responsibility of study team to ensure that all language required by the University of Miami (UM) and the UM HSRO are included in the consent document(s).  When all required language and formatting has been added to the consent document(s), highlight the added required language. You must then submit this copy as a comment attachment. Below is the language that must be included in the consent document(s).  **Bold red text in [brackets] must be selected as applicable.** | |
| **The research will be conducted at:** | |
|  | **University of Miami only:** Use language found in the HRP-502a1 – Biomedical Studies – UM Only – ICF template |
|  | **Jackson Health Systems only:** Use local language found in the HRP-502a2 – Biomedical Studies – JHS only – ICF template |
|  | **University of Miami/Jackson Health Systems:** Use local language found in the HRP-502a3 – Biomedical Studies – UM/JHS Combined – ICF template |

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|  | **Include if Electronic Medical Record will be accessed for study and/or research information will be added to University of Miami Medical Record.** |
| If you are, or have been, a patient at a **[UM/JHS]** facility, you will have a **[UM/JHS]** 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/JHS]** 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/JHS]** doctors that you are in a research study and they can obtain more information if they request it.  The research team may use your information to notify you of appointments, send you appointment reminders, or schedule additional appointments. | |
|  | **This study is a clinical trial.** |
| 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.** |
| Federal law provides more protections for your medical records and related health information. The second part of this consent form, the **[University of Miami/Jackson Health Systems]** Research Authorization, describes these safeguards. | |
|  | **Include for research involving prisoners.** |
| 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. | |
|  | **Include if the research collects specimens.** |
| The sponsor **[and the UM / and JHS / , the UM, and JHS]** 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 **[and the UM / and JHS / , the UM, and JHS]** 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 **[and the UM / and JHS / , the UM, and JHS]**. ***[Or other institution, please specify.]*** | |
|  | **Injury Compensation Language for 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. | |
|  | **Injury Compensation Language for 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 / JHS / UM, JHS,]** 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. | |
|  | **Injury Compensation Language for 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. | |
|  | **Study involves payment to subjects exceeding $600 per calendar year.** |
| 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. | |
|  | **The study is testing for information about any special categories of information. Delete the categories of information that the study will not access.** |
| 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 / JHS / the UM and JHS]** 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. **[The UM / JHS / The UM and JHS]** 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 / JHS / the UM and JHS]** 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)  ***[If the study involves COVID 19 testing as a study procedure]*** The study doctor must also report positive results of COVID 19 tests to the Florida Department of Health. | |
|  | **The study 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](#Genomic). | |

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| **Check the Consents/Authorizations to be used** | | | | |
|  | Recruitment will require access to UM / JHS medical records. **(Excluding PI/study team patient population)**  Consent to contact and/or MyUhealth charts.  **If yes**, HIPAA waiver authorization determination will be granted by:  **External IRB**  **UM** - Please attach UM HIPAA application for waiver authorization determination. | | | |
|  | **UM/JHS standard HIPAA Authorization Addendum** | | | |
|  | **UM/JHS standard HIPAA Authorization Standalone Addendum** | | | |
|  | **Assent Form**  7-12 Years Old  13-17 Years Old  Other | | | |
|  | **HIV Consent Form**  A separate HIV consent may be used or pertinent language may be added to the ICF when HIV is being tested. | | | |
|  | **Audio/Video/Photo Consent Form**  Standalone form or pertinent language may be included in ICF. | | | |
|  | **Separate Pregnant Partner consent**  You do not need to submit a consent document for pregnant partner unless one of the subject’s partner becomes pregnant. | | | |
|  | **Genetic Consent Form**  Unlinked  Linked/no recontact  Linked/recontact | | | |
|  | Other: | | | |
| **Institutional Sign-Off From HSRO** | | | | |
| ***Signature*** | | ***Printed Name*** | ***Title*** | ***Date*** |