## (Principal Investigator’s or Department’s letterhead)

## Title of research study: ***[insert title of research study here with protocol number, if applicable]***

## Investigator: ***[insert name of principal investigator and full address]***

**Daytime Phone Number:** Phone Number

## ***Sponsor: [insert name of sponsor]***

***[Add the following statement only if the study protocol expressly allows the enrollment of subjects not capable of consenting for themselves:]***A person who takes part in a research study is called a research or study subject. In this consent form “you” always refers to the research subject. If you are a legally authorized representative, please remember that “you” means the research (study) subject.

|  |
| --- |
| *Instructions for Research Consent Summary****If your research is FEDERALLY funded/conducted, is submitted after 1/20/2019****,* ***and the consent document is longer than 4 pages (exclusive of face page, HIPAA section and signature block), an initial summary is required****. The initial summary should not exceed three pages or one third of the length of the remaining consent document (exclusive of face page, HIPAA section and signature blocks), whichever is shorter.* *The templated statements in the “RESEARCH CONSENT SUMMARY” below provide a guide to the content of the summary. The content should be adjusted to be appropriate for the specifics of the study. Under each heading, limit the description to the key information that is relevant to why one might or might not want to take part in the research. Defer the greater detail to the body of the consent form following the initial summary* *For example, with a cancer trial the initial summary should identify the most important risks, like the information that a doctor might deliver in the clinical context in telling a patient how sick the chemotherapy drugs will make them. The initial summary should emphasize how those risks are changed by taking part in the study. Include the complete list of reasonably foreseeable risks in the main body of the consent form.* |

**Research Consent Summary**

You are being invited to take part in a research study. Your participation is voluntary. It’s your choice whether to participate. This document provides a concise summary of this research. It describes the key information that we believe most people need to decide whether to take part in this research. Later sections of this document will provide all relevant details.

1. *The purposes of the research*
2. *The procedures to be followed in the research*
3. *The reasonably foreseeable risks or discomforts to the prospective subject*
4. *The benefits to the prospective subject or to others that may reasonably be expected from the research*
5. *Appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the prospective subject*

## Why am I being invited to take part in a research study?

We invite you to take part in a research study because \_\_\_\_\_\_\_\_\_\_\_\_\_. [Fill in the circumstance or condition that makes subjects eligible for the research].

## What should I know about a research study?

1. Someone will explain this research study to you.
2. Whether or not you take part is up to you.
3. You can choose not to take part. There will be no penalty or loss of benefits to which you are otherwise entitled.
4. You can agree to take part and later change your mind. There will be no penalty or loss of benefits to which you are otherwise entitled.
5. You can ask all the questions you want before you decide.
6. If you are an employee of AdventHealth Orlando, you should know that your participation or lack of participation in this study will not affect your employment or relationship with AdventHealth Orlando.

## Why is this research being done?

[Tell the subject the purpose of the research. Explain the background of the research problem. Explain any potential benefits to others].

## How long will the research last?

We expect that you will be in this research study for \_\_\_\_\_\_\_\_ [hours/days/months/weeks/years, until a certain event].

## What happens if I agree to be in this research?

[Tell the subject what to expect using lay language and simple terms. Whenever appropriate include the following items:]

* Describe where this research will be done
* Provide a time-line description of the tests and procedures that will be done, including screening procedures. You can use tables or charts if they are helpful to explain the schedule.
* Describe each group or arm

***[If the research may involve whole genome sequencing, include the following:]***

The research might include whole genome sequencing (determining the order of DNA building blocks (nucleotides) in your genetic code).

## What other choices do I have beside taking part in the research?

***If there are alternatives:***

Instead of being in this research, your choices may include:

* ***List the major approved alternative options such as drugs / devices / procedures***
* ***Consider, based on the indication and population, whether an alternative might include no active treatment but support and management of pain and other symptoms to be as comfortable as possible through the remainder of life***

[Example If there are no alternatives:]

This research is not designed to diagnose, treat or prevent any disease. Your alternative is to not take part in the research.

## Is there any way being in this study could be bad for me?

***[In simple language and in a simple bullet format (whenever possible), explain the known possible risks and discomforts.]***

***[List risks and discomforts in order of most common and most likely to occur, with least likely to occur listed last. Also, list any rare, but serious risks.]***

***[If there are many risks, use a bulleted format. If known, provide the percentage or range of occurrence for the risks.]***

***[Describe the duration of the risks and discomforts. Note whether the risks and discomforts will go away when the study drug, device, or procedure is stopped.]***

***[Describe the side effects of any comparator drugs.]***

***[Describe any risks of washout, withholding treatment, or randomization.]***

***[Consider:]***

* ***Physical risks (for example, medical side effect)***
* ***Psychological risks (for example, embarrassment, fear or guilt)***
* ***Privacy risks (for example, disclosure of private information)***
* ***Legal risks (for example, legal prosecution or being reported for child abuse)***
* ***Social risks (for example, social ostracizing or discrimination)***
* ***Economic risks (for example, having to pay money out-of-pocket for research or medical expenses, losing health insurance, or being unable to obtain a job)***

***[It is unnecessary to list details of previous clinical trials.]***

***[Include for research that involves questionnaires which ask about physical/emotional wellbeing.]***

The questionnaires used in this research will ask you about your physical / emotional well-being. Completed questionnaires may not be reviewed immediately. If you have concerns about your well-being, please let the study doctor or team know.

***[Include GINA language for studies involving genetic research]***

There is a risk of loss of confidentiality of your information. You should know that there are measures in place to prevent this from happening. A new Federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information**.** Please ask the study investigator or study staff if you would like to know more about how your information will be protected while you are in this study

## Will being in this study help me in any way?

[If there are possible benefits to the subject:]

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits to you include \_\_\_\_\_. ***[***Describe any direct benefits to the subject. If benefits from taking part may not continue after this research has ended, describe them.] Possible benefits to others include \_\_\_\_\_. ***[***Describe any benefits to others.]

[If there are no expected benefits to the subject but possible benefits to others/ scientific knowledge:]

There are no benefits to you from your taking part in this research. We cannot promise any benefits to others from your taking part in this research. However, possible benefits to others include \_\_\_\_\_. ***[***Describe any benefits to others.]

[Include for research involving prisoners] Taking part in this research study will not improve your housing or correctional program assignments. Your taking part in this research study will not improve your chance of parole or release.

***Are there any costs in this study?
[Explain the associated costs of the study and who is responsible for covering those costs]***

***[For example] [Sponsor Name]*** will provide the study ***[drug/device]***at no charge during this study. Tests and procedures that are done only for the study will not be billed to you or your insurance company. ***[You may list specific items/services below.]***

You might have unexpected expenses from being in this study. Ask your study team to discuss the costs that will or will not be covered by the sponsor. This discussion should include who will pay the costs of treating possible side effects.

***[If this is appropriate for this study, please include]***

You are likely here to be treated for an existing diagnosis or injury. That diagnosis or injury will have associated charges we refer to as routine care or conventional care items and/or services. These routine care charges will be billed as usual to you and/or your health plan. If you participate in this research, there may be additional items and/or services required for the research that may be reimbursed by the study sponsor. As a result, you may or may not have added charges by participating in this research study. ***[You may list specific items/services below.]***

***[If appropriate for this study]*** For all routine or conventional care items/services billed to your health plan, you will be responsible for any deductibles, co-pays, and/or charges the health plan does not cover.

You may want to talk with your insurance company about its payment policy for standard medical care given during a research study. If your insurance company does not pay, you may be billed for those charges.

***Will there be compensation for injury?***

In the event of research-related injury or illness, medical care will be made available. Generally, this care will be billed to you, your insurance, or other third party. [Insert the name of the institution] has no program to pay for medical care for research-related injury or illness. [Describe any compensation available for research related injury].

## What happens to the information collected for the research?

To the extent allowed by law, we limit your personal information to people who have to review it. We cannot promise complete secrecy.The IRB and other representatives of this organization may inspect and copy your information. Others include [Add to this list other organizations that may have access to the subject’s records such as the Food and Drug Administration, when the research if FDA-regulated, the Department of Health and Human Services, when the research is conducted or funded by DHHS, the sponsor, contract research organization, sponsor’s agent and other collaborating institutions].

[Describe any limitations on confidentiality based on possible legal issues. For example, if the research team is likely to uncover abuse, neglect, or reportable diseases, explain that this information may be disclosed to appropriate authorities].

[If the research involves collection of identifiable private information or identifiable biospecimens, include one of the following statements.] Information that identifies you might be removed from the data or specimens collected for this study. After that information is removed, your data and specimens might be used for future research studies or given to other researchers without your consent. OR The data and specimens collected for this study will not be used or given to other researchers for future research studies even if information that identifies you is removed.

[Include if a HIPAA authorization is required. Otherwise delete. HIPAA authorization may be used in combination with this form or split out into a separate form.]. Federal law provides additional protections of your medical records and health information. See the HIPAA section below.

[Include for research involving prisoners. Otherwise delete]. If you are a prisoner, your medical records may also be given to officials and agencies within the criminal justice system when necessary and permitted by law.

***[Include for NIH studies Note: You should edit the Suggested Consent Language as necessary for your study population, for example lower literacy or non-English speakers, so long as all relevant points related to disclosure and consent are covered.]***

**Certificate of Confidentiality from the National Institutes of Health**This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

**[*Use the following language as applicable*]** The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by **[*THE AGENCY*]** which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).  You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

**[*Language such as the following should be included if researcher intends to disclose information covered by a Certificate, such as potential child abuse, or intent to hurt self or others in response to specific federal, state, or local laws*.]** The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of **[*list what will be reported, such as child abuse and neglect, or harm to self or others*].**

**[*Language such as the following should be included if researcher intends to disclose information covered by a Certificate, with the consent of research participants*.]** The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document **[*restate what will be disclosed, such as including research data in the medical record*].**

## What else do I need to know?

[Delete if not externally funded]. This research is being funded by [Insert name of funder].

 [Include for research involving prisoners where there may be a need for follow-up examination or care after the end of participation. Otherwise delete]. If you are released from jail before you finish this research study, you should take steps to get insurance or Medicaid coverage. Regular office visits and standard treatment will be billed to you or your health insurance. You may continue in the research study after your release from prison. If you move out of the area, we will help you make arrangements to be followed by a physician.

 ***[When applicable indicate whether clinically relevant research results, including individual results, will be disclosed to subjects. If so, explain under what conditions].***

***If the subject’s biospecimens (even if identifiers are removed) may be used for commercial profit, include the following statement: (Modify if subjects will share in commercial profit.)***

Your specimens (even if identifiers are removed) may be used for commercial profit. You will not share in this commercial profit.

### ***HIPAA Authorization to Release Information for Research***

If you have not received a copy of the AdventHealth Orlando Privacy Notice, please request one. If you have questions about your privacy rights, you may contact AdventHealth Orlando’s Privacy Officer at PH: (407) 200-2961.

Privacy laws, including the Health Insurance Portability & Accountability Act (HIPAA) and other federal and state laws, rules, and regulations, protect your individually identifiable health information (also called Protected Health Information or PHI). If you agree to be in this study, privacy laws require you to sign this Authorization that describes your rights and explains how your Protected Health Information (PHI) will be used and disclosed for this research study.

By signing this informed consent/HIPAA Authorization, you will be authorizing the principal investigator, his/her research staff, and the sponsor (see top of page one) to use (which includes reviewing your medical records as necessary to conduct the study) and disclose your PHI for the purposes described below. By signing this form, you will also be authorizing your doctors, AdventHealth Orlando personnel, and individuals who provide health care services at AdventHealth Orlando to disclose your PHI for the purposes described below. This includes information from your past, present, and future medical records.

This Authorization does not have an expiration date. This means the researchers and others associated with this study may use and disclose your protected health information for as long as necessary to complete the study.

If you volunteer to take part in this research study, others may learn your identity. Study information may identify you in the following ways.

* Name
* Address
* Telephone number
* Other details about you ***[If the use of a social security number is needed, provide justification. Include SSN here if subjects will receive payment for participation or reimbursement of expenses.]***

***Revise the following sentence to read correctly, as needed.*** This study includes a number of researchers, businesses and government agencies. They may use your health information and share it with others. We want you to know who may use this information and how they may use it.

### **Who may use and give out information about you?**

The Investigator (study doctor) and research staff will have information about your health that tells us your identity. They may give this information to others during and after the study.

### **Who may see this information?**

The study sponsor may see your health information and know your identity. “Sponsor” includes people or companies working for or with the sponsor or owned by the sponsor.

### ***Change the following list as needed. Do not include agencies simply because they are listed, but only those who may be privileged to use or disclosure the information.***

In addition to the study sponsor and its agents, the following people, agencies and businesses may get information from us that identify who you are.

* Doctors and healthcare professionals taking part in the study;
* U.S. Department of Health and Human Services (DHHS), which includes:
* U.S. Food and Drug Administration (FDA)
* U.S. Office of Human Research Protections (OHRP)
* Government agencies that must receive reports, including reports about certain diseases
* Government agencies in other countries
* AdventHealth Orlando representatives
* Institutional Review Board (IRB)
* Accreditation organizations

### **What information may be used and shared?**

If you decide to be in this study, medical information that identifies you and relates to your participation will be created, used, and/or shared. This may include the following types of medical information.

* Information obtained from procedures used to find out if you are eligible to take part in this study. This may include physical examinations, blood and urine tests, x-rays and other procedures or tests, and any other information that you may release to us, including information about your health history.
* Information from your medical chart.
* Information obtained in the course of the study including information about your response to any study treatments you receive, information related to study visits and phone calls, physical examinations, blood and urine tests, x-rays and other tests or procedures that may be performed, and other medical information relating to your participation in this study.

### **Why will this information be used and/or shared?**

Information about you and your health, that might identify you, may be given to others to carry out the research study. The sponsor and/or the investigator will analyze and evaluate the results of the study. In addition, if this is a sponsored study (see page one) people from the sponsor and its consultants will be visiting the research site. They will follow how the study is done, and they will be reviewing your information for this purpose.

### **What if I decide not to give permission to use and give out my health information?**

If you sign this consent form, you will be giving permission to use and give out the health information listed above for the purposes described above. If you decide not to give permission, you will not be able to be in this research. However, this will not change your relationship with your doctor or with AdventHealth Orlando and you will still be able to receive all benefits to which you are entitled.

### **May I review or copy the information obtained from me or created about me?**

You have the right to review and copy your health information. However, if you decide to be in this study and sign this permission form, you will not be allowed to look at or copy your information until after the research is completed.

### **May I withdraw or revoke (cancel) my permission?**

Yes, but this authorization (permission) will never expire (end) unless you revoke (cancel) it in writing.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. If you withdraw your permission, you will not be able to continue being in this study. If you want to withdraw your permission and not have your information shared beyond what has already been shared, please send the written notice to:

***Name and address of principal investigator***

When you withdraw your permission, no new health information that might identify you will be gathered after that date. Information that has already been gathered may still be used and given to others.

### **Is my health information protected after it has been given to others?**

If you give permission for the hospital or the investigator to share your identifiable health information to other people or businesses, the information may no longer be protected. There is a risk that your information will be released to others without your permission.

Your personal information may be disclosed if required by law. Your records for this study may be sent by facsimile transmission (FAX machine) or over the Internet. It is possible that your records could be sent to the wrong person.

### **How long is my information kept?**

Research with private health information must be maintained for seven years after the research study has been closed at the AdventHealth Orlando site. The Sponsor may require a longer period of time.

**Will I be paid for taking part in this research?**

If subjects will be paid:

For taking part in this research, you may be paid up to a total of $\_\_\_\_\_ for your time and effort. Your compensation will occur as follows:

Describe payment schedule in terms of method. If it is determined you will not be utilizing the AdventHealth Orlando payment method (Vincent), please revise as appropriate.

* You will be provided a Mastercard® as a means to receive payments this study. The Terms and Conditions for this card will be provided to you for review.

Describe payment schedule in terms of amount

Describe when payments will be made

Describe the amount of payment if the subject drops out or is withdrawn from the study

***The following statements must be added if AdventHealth Orlando is providing the remuneration to the study participant. The statements should also be added if an external sponsor is providing the remuneration and requires a similar IRS reporting statement.***

**For participants who are not AdventHealth Orlando Employees**

If you receive more than $600 in payments in a calendar year from AdventHealth Orlando, this income will be reported to the IRS. You may be required to pay tax on this income.

For participants who are AdventHealth Orlando or AdventHealth Medical Group Employees

All payments will be reported as added income to your base salary and will be taxed on a future paycheck.

Add this for reimbursement of travel including mileage, hotel, meals, incidentals, etc

For taking part in this study, you will be reimbursed for (describe…….)

If subjects will not be paid, either delete this section, or include the following statement:

You will not be paid for taking part in this research.

## Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at the phone number listed above on the first page.

This research is being overseen by an Institutional Review Board (“IRB”). The IRB is a group of people who review and approve research at AdventHealth Orlando. You may talk to them at (407) 200-2677 or AH.IRB.General@adventhealth.com if:

* Your questions, concerns, or complaints are not being answered by the research team.
* You are not getting answers from 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.

 [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].

[Omit the signature page if there is no written documentation of consent].

**Signature Block for Adult Subject Able to Consent**

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

***[Use the following block if a witness will observe the consent process. E.g., short form of consent documentation or illiterate subjects.]***

|  |
| --- |
| My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject, and that consent was freely given by the subject. |
|  |  |  |
| Signature of witness to consent process Printed Name |  | Date |
| If signature of a witness not obtained, confirm the following: |
| * Subject is able to read in this language and write
 |

**Signature Block for Adult Subject Unable to Consent**

|  |
| --- |
| Your signature documents your permission for the individual named below to take part in this research. |
|  |  |  |
| Printed name of subject |  |
|  |  |  |
| Signature of legally authorized representative Printed Name |  | Date |
|  |  |  |
| Authority of Subject’s Legally Authorized Representative or Relationship to Subject |  |  |
|  |  |  |
| Signature of person obtaining consent Printed Name |  | Date |

***[Add the following block if you will document assent of the subject.]***

|  |  |
| --- | --- |
| Assent | * Obtained
* Not obtained because the capability of the subject is so limited that the subject cannot reasonably be consulted.
 |

 ***[Use the following block if a witness will observe the consent process. E.g., short form of consent documentation or illiterate subjects.]***

|  |
| --- |
| My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject, and that consent was freely given by the subject. |
|  |  |  |
| Signature of witness to consent process Printed Name |  | Date |
| If signature of a witness not obtained, confirm the following: |
| * Person providing permission is able to read in this language and write
 |

**Signature Block for Child Subject**

|  |
| --- |
| Your signature documents your permission for the child named below to take part in this research. |
|  |  |  |
| Printed name of child |  |
|  |  |  |
| Signature and Printed Name of parent or individual legally authorized to consent to the child’s general medical care |  | Date |
|  |  |  |
| Signature of second parent Printed Name |  | Date |
| 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 person obtaining consent Printed Name |  | Date |

***[Add the following block if you will document assent of children]***

|  |  |
| --- | --- |
| Assent | * Obtained
* Not obtained because the capability of the child is so limited that the child cannot reasonably be consulted.
 |

***[Use the following block if a witness will observe the consent process. E.g., short form of consent documentation or illiterate subjects.]***

|  |
| --- |
| My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject, and that consent was freely given by the subject. |
|  |  |  |
| Signature of witness to consent process Printed Name |  | Date |
| If signature of a witness not obtained, confirm the following: |
| * Person providing permission is able to read in this language and write
 |