The below institutional specific language is required for the following:

* Studies using sponsor/funder provided model consent forms
* Studies relying upon external IRBs

No changes may be made without written permission from AdventHealth IRB.

***Employee language:***

If you are an employee of AdventHealth, you should know that your participation or lack of participation in this study will not affect your employment or relationship with AdventHealth.

***Payment or Reimbursement to Subjects:***

*The following statements must be added if AdventHealth 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 Employees**

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

For participants who are AdventHealth 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.

***HIPAA authorization language:***

*May be incorporated into the consent document or used separately.*

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

By signing this consent form, you agree that your healthcare providers and/or associated staff affiliated, contracted with, or with access to records from AdventHealth, may see your information from research studies. This information could be considered and used in the course of medical care and related activities.

If you have not received a copy of the AdventHealth Privacy Notice, please request one. If you have questions or concerns about your privacy rights as a research subject, you may email us at [patientrequest@adventhealth.com](mailto:patientrequest@adventhealth.com).

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 personnel, and individuals who provide health care services at AdventHealth 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 (SSN) 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
* Health systems outside of AdventHealth with which you have a patient relationship
* AdventHealth 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 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 may not be allowed to look at or copy your information as it relates to this study, 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 site. The Sponsor may require a longer period of time.

***Signatures:***

*Use the following signature section if the sponsor or IRB of record requires the HIPAA authorization to be separate from the consent.*

|  |  |
| --- | --- |
| Your signature documents your authorization to release information for research. | |
|  |  |
| Printed Name of Subject |
|  |  |
| Signature of Subject or Legally Authorized Representative | Date |
|  |  |
| Printed Name AND Authority of Legally Authorized Representative or Relationship to Subject |  |
|  |  |
| Signature of Person Obtaining Authorization AND Printed Name | Date |

**PERSON OBTAINING AUTHORIZATION: *Only use an Impartial Witness to observe the authorization process for the following scenarios:***

A short form will be used   
Subject is unable to read or write (illiterate; visually/physically impaired)

|  |  |  |
| --- | --- | --- |
|  | | |
| **IMPARTIAL WITNESS TO AUTHORIZATION:** My signature below documents that the information in the authorization and any other written information was accurately explained to, and apparently understood by, the subject, and that authorization was freely given by the subject. | | |
|  |  |  |
| Signature of Impartial Witness AND Printed Name |  | Date |