**CONSENT TO TAKE PART IN A RESEARCH STUDY**

**and**

**AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION**

|  |  |
| --- | --- |
| **Study Title:** | |
| **Principal Investigator:** | **Office Number:** |

***INSTRUCTIONS – PLEASE READ FIRST:***

*Instructions are shaded in grey to distinguish from required information. If a required section applies to your study, please use the language provided with appropriate edits. Sections with recommended text may be modified as needed. Please delete all shaded and italicized instruction areas prior to IRB submission.*

# If I become ill or injured because of the study, who pays for my medical care?

***INSTRUCTIONS:***

*For research involving more than minimal risk (i.e., most device and drug trials), explain whether any compensation and any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.*

**Required text for more than minimal risk research (unless CTA indicates something different):**

If you receive any medical services, it is important that you tell them that you are in this research.

We will offer you the care needed to treat any injury that directly results from taking part in this research. We reserve the right to bill your insurance company or other third parties, if appropriate, for the care you get for the injury. We will try to have these costs paid for, but you may be responsible for some of them. For example, if the care is billed to your insurer, you will be responsible for payment of any deductibles and co-payments required by your insurer.

Injuries sometimes happen in research even when no one is at fault. There are no plans to pay you or give you other compensation for an injury, should one occur. However, you are not giving up any of your legal rights by signing this form. If you think you have been injured or have experienced a medical problem as a result of taking part in this research, tell the person in charge of the research as soon as possible. The researcher's name and phone number are listed on the first page of this consent form.

***INSTRUCTIONS:***

*This section is* ***required text*** *for all studies.*

Whom do I contact if I have problems or questions?

For questions about the research study, or if you have a research related injury or medical problem, please contact [name of investigator] at [phone number] during regular business hours or [emergency phone number] after hours and on weekends and holidays.

For questions about your rights as a research subject, please contact the Adventist HealthCare IRB Office at 301-315-3400 during regular business hours.

If you experience an emergency, you should get treatment immediately.

***INSTRUCTIONS:***

*If you are collecting Protected Health Information (PHI), this section (the next 3 pages) is* ***required text.***

**Permission to Use and Share Your Protected Health Information**

As part of this study, we will be collecting, using and sharing information about you. Please review this section carefully as it contains information about the federal privacy rules and the use and disclosure of your information.

Because information about you and your health is personal and private, it is protected by a federal law called the Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA) and generally cannot be used for research without your written authorization.

You may have already been given the Adventist HealthCare Notice of Privacy Practices, which contains more information about the confidentiality of your health information. If you have not already been given a copy or would like another copy of the Notice of Privacy Practices, please ask and we will provide a copy. Also, if you have any questions about the Privacy Rule you can speak to the Adventist HealthCare Privacy Officer by calling the Organizational Integrity hotline at 1-800-814-1434.

**Why Sign This Document?**

If you sign this document, you give researchers from [insert name of AHC entity] permission to use and share your protected health information for this study. We will give you a signed copy.

**What Information Will We Use and Share for the Study?**

The health information that we may use for this research may include information such as [tailor this to your specific resarch - your name, medical records, medical histories, research records, the results of this study, case reports, medical images, lab tests, results of physical examinations, admissions information, health care expenses and coverage and any other data created or collected during the study.]

Any information collected as part of this study will not be used for future research studies/may be de-identified and used for future research studies involving [insert type]. You will not be informed of any of the details of research studies using your information. Information will be stored, maintained, and used for research purposes indefinitely [or define period of time]. You will/will not be informed of any clinically relevant research results [include conditions] found in these studies.

The health information listed above may be used by and disclosed (released) to the following: [modify this list to be as specific as possible]

* the researchers and their staff involved in the research;
* federal and state agencies that regulate research (like the Food and Drug Administration) or that regulate [name of facility] or Adventist HealthCare;
* the sponsor of the study, [name of sponsor], and its agents, representatives or consultants working on the study, [modify as appropriate - including a Clinical Research Monitoring Group, Data Management Group, Data Safety Monitoring Group, Clinical Events and Adjudication Committee, and all core labs associated with the study];
* [include institutions/researchers that may use this information to conduct research, if applicable] may conduct future research studies with your de-identified information;
* research monitors and committees such as the Adventist HealthCare Institutional Review Board (IRB);
* accrediting agencies and legal counsel;
* clinical staff who are not involved in the study who may become involved in your care, if it might be relevant to treatment;
* [if applicable - regulatory agencies in foreign countries, for regulatory purposes;]
* your health insurer or payor, if necessary, in order to secure their payment for any services that are not paid for by the research; and
* others if required by law.

Adventist HealthCare is required by law to protect your health information. Those who receive your protected health information may not be required by federal privacy laws to protect it and may share your information with others without your permission, if permitted by laws governing them.

**What Happens if I Say No?**

You will not be able to take part in this research study if you do not allow the use and disclosure of your protected health information. The quality of care you get from your doctor will not change and you will not lose any benefits. You should ask questions about anything you do not understand before deciding whether or not to provide permission for us to use your protected health information.

**Can I Access My Medical Records?**

During and after your involvement in this study, you will have access to your medical records and any study information that is part of those records. However, you may not have access to research-specific information that is not part of your medical records.

**What Happens if I Say Yes, but Change My Mind Later?**

If you decide to stop participating in this study later, it will not affect the quality of your medical care in any way. To withdraw from this study, please contact them in writing at:

[Insert Investigator name and address]

**How Long Will My Health Information be Used?**

This Authorization does not have an expiration date/expires on [date]. You may change your mind and revoke (i.e., cancel or take back) this Authorization at any time. Once you revoke this Authorization, no further information about you will be collected, used or disclosed; however, the research team may still use or disclose health information about you that they already collected for this study.

Recommended text if published data or information:

If the results of this research are published or discussed in conferences, no information will be included that would reveal your identity. If photographs, videos, or audio-tape recordings of you will be used for educational purposes, your identity will be protected or disguised.

***INSTRUCTIONS:***

*This section is* ***required text*** *for all studies.*

**RESEARCH SUBJECTS’ BILL OF RIGHTS**

As someone being asked to volunteer as a subject in a clinical research study, I have the following rights:

* to be told what the study is trying to determine;
* to be told what will happen to me, including the procedures, drugs and devices that will be used, and whether any of these are different from what would be used in standard practice;
* to be told about the risks, side effects, or discomforts that may be expected from the research;
* to be told if I can expect any benefit from being in the study, and if so, what the benefit might be;
* to be told about the other alternatives I have and how they may be better or worse than taking part in the study;
* to be told what kind of medical treatment is available if any medical problems arise;
* to ask any questions about the study before I agree to take part and during the course of the study;
* to choose not to take part at all or to change my mind and withdraw from the study after it is started. My decision will not affect my right to receive the care I would receive if I were not in the study;
* to receive a copy of the signed and dated consent form; and
* to be free of any pressure when deciding whether I wish to participate in the study.

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**If you have any questions about the research, feel free to talk with your doctor or one of the researchers or research coordinators. If you have any questions or comments about your rights as a research subject, Adventist HealthCare has a department that you should call. This department, called the IRB Office, exists to protect your rights. The phone number of the Adventist HealthCare IRB Office is 301-315-3400.**