**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:***

*Many sections of this document include instructions to provide a general overview of information required in the section. These instructions are shaded so that you can tell the difference between the instructions and 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.*

*Use lay terms. Avoid long or complex sentences and excessive technical language or jargon. Define any words or terms that may be unfamiliar to lay persons and define acronyms or abbreviations the first time you use them.*

*Use simple language with a maximum 8th grade reading level. Use the pronoun “you” consistently throughout.*

*Please delete all shaded and italicized instruction areas prior to submitting this form to the IRB Office.*

**RESEARCH STUDY SUMMARY**

***INSTRUCTIONS:***

*This section is* ***required text*** *and should only include a few sentences per section describing the most important information about the stud and should be no more than 2 pages.*

Your participation in this study is entirely voluntary. Please read this document completely before making a decision.

Study Purpose:

Study Procedures:

Duration of Study Participation:

Principal Study Risks:

Potential Study Benefits:

Study Alternatives:

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

***INSTRUCTIONS:***

*Explain why the participant is being invited to participate in this study and how the investigator obtained their name DO NOT include inclusion/exclusion criteria.*

You are being asked to take part in a research study at [insert name of AHC entity]because \_\_\_\_\_.

**Required** t**ext**:

Your participation in this study is entirely voluntary. If you choose not to take part, your choice will not affect the quality of your medical care, hurt your relationship with the hospital or your doctors in any way, or cause you to lose any benefits to which are otherwise entitiled.

You should read all of the information below and ask questions about anything you do not understand. You may discuss this information with your family and friends before deciding whether or not to take part in the research study.

**Required text if applicable - Multiple study enrollment:**

You may not take part in this study if you are enrolled in another research study. Please let us know if you are enrolled in another study or if you are not sure.

# What is the purpose of the study?

***INSTRUCTIONS:***

*State what the study is designed to discover or establish. If applicable, describe the nature of the experimental design and how it differs from standard of care.*

**Required text if an investigational drug/device is being used and is not approved by the FDA:**

The use of study drug/device name in this research study is investigational, which means that it is not approved for marketing by the Food and Drug Administration (FDA).

**Required text if deception is involved:**

There are some details of the study that we cannot tell you about until the study is over. At the end of the study, we will give you all of the information and answer any questions you have.

# How many people will take part in this study?

About XXX people will take part in this study here and about XXX people will take part at different hospitals and medical facilities.

# What procedures are involved in this study?

***INSTRUCTIONS:***

*Describe the procedures chronologically using simple language and short paragraphs. Subheading use is recommended to increase readability. Specify which procedures are performed for the research study and which would be performed regardless of participation.*

**Required text when randomization is used:**

You will be randomly assigned (like flipping a coin) to receive either [group 1/ investigational procedure/the drug] or [group 2/the standard procedure/ placebo].

**Required text when a placebo is used.**

A placebo is a pill with no medicine in it (like a sugar pill) that looks the same as the pill containing the investigational drug.

*Procedure Table Example*

|  |  |  |  |
| --- | --- | --- | --- |
| ***Visit*** | ***Purpose*** | ***Main Procedures*** | ***Duration*** |
| *Visit 1* | *Screening visit*  | *Blood test* | *30 minutes* |
| *Visit 2, Day 0* | *Start study drug* | *Distribute medication*  | *30 minutes* |
| *Visit 3, Day 28* | *Routine Visit* | *Lab tests, distribute medication* | *1 hour* |
| *Visit 4, Day 56* | *End of Study* | *Return unused drug and Quality-of-Life Survey* | *1 hour* |

# Will research results be shared with me?

***INSTRUCTIONS:***

*Describe how long the subject will be involved in the study (days, weeks, months or years). If applicable, distinguish the procedure from on-going follow-up.*

**Will research results be shared with me?**

This study involves procedures that we do not expect will be clinically useful for you. We will not share these results with you.

It is uncertain if the research tests will produce clinically relevant results, so we will not share these results with you.

This study involves procedures that may produce clinical information that could be useful to you. We will share this information with you. *Be specific about type and timing of results that may be shared.*

**Recommended text for blinded studies**: After the study is over, you may contact the Sponsor at INSERT to find out which study intervention you received.

# How long will I be in the study?

***INSTRUCTIONS:***

*Describe how long the subject will be involved in the study (days, weeks, months or years).*

# What are the risks and discomforts of the study?

***INSTRUCTIONS:***

*Describe the risks, side effects, and discomforts that the subject may encounter as a result of participating in this study. Risks associated with procedures that are standard of care should not be included.*

*Identify each procedure with a subheading and then describe any reasonable risks, discomforts and inconveniences, and describe how these will be managed. Each medication must be listed. List risks in order of relative probability (e.g., likely, less likely, unlikely, and rare but serious).*

*Risk Table Example*

|  |  |  |  |
| --- | --- | --- | --- |
| ***Possible Risk/Side Effect*** | ***How often has it occurred?*** | ***How serious is it?*** | ***Can it be corrected?*** |
| *Headaches* | *may occur just after drug administration* | *usually of short duration*  | *Yes* |
| *Rash* | *occasionally occurs* | *usually involves the face and arms and may cause scratching* | *Yes, it will go away with treatment.* |
| *Skin discoloration* | *Uncommon* | *will not impact your overall health* | *It can be permanent.* |
| *Liver damage* | *extremely uncommon*  | *very serious* | *The damage is permanent and can affect the rest of your health.* |

Recommended text if the study excludes pregnant women or may harm a fetus:

**Reproductive Risks**

Women who are pregnant cannot take part in the study because of the risk to you and your fetus*.* If you are child bearing potential, we will give you a pregnancy test before the study begins. If you become pregnant at any time during the study, you must tell the Principal Investigator as soon as possible.

You should not father a baby while taking part in this research. If you have a female partner who is able to become pregnant, one or both of you must use some form of effective birth control. During the research, if your partner becomes pregnant, or if there is a chance that she is pregnant, you must tell the Principal Investigator as soon as possible.

**Required** t**ext**:

As with any experimental procedure [or investigational drug/device or medical research study], there may be risks or side effects that are currently unknown. You will be promptly told if we learn of any new risks, findings, or information which may cause you to change your mind about continuing in the study.

**Required text for research involving genetic testing or the collection of genetic**

**information only:**

**Risks of Genetic Studies**

A 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. This law generally will protect you in the following ways:

* Health information companies and group health plans may not request your genetic information that we get from this research.
* Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
* Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

All health insurance companies and group health plans must follow this federal law. This law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term insurance.

**Required text when there is a Certificate of Confidentiality in place:**

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate does not stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate cannot be used to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate does not stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also does not prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

# What are the benefits of participating in this study?

***INSTRUCTIONS:***

*Identify the anticipated benefits of the research to (1) the subject (if any) and (2) science or society.*

Recommended text if there is potential benefit to subject and to society:

Based on experience with this [drug, procedure, device, etc.] in [animals, subjects with similar disorders], researchers believe it may help people with your condition [or, it may be as good as standard therapy but with fewer side effects]. Of course, because people respond differently to therapy, no one can know in advance if it will be as effective or more effective as standard therapy in your particular case. The potential benefits may include: [Describe the anticipated benefits to subjects resulting from their participation in the research.] Also, we hope that what we learn will help other people with your condition in the future.

Recommended text if no benefit to subject is expected:

There may not be any direct benefit to you from participating in this study. You should not expect your condition to improve as a result of taking part in this research. However, we hope that what we learn will help other people with your condition in the future.

# What other choices do I have besides taking part in this study?

***INSTRUCTIONS:***

*Disclose any currently available treatments or procedures that may benefit the subject outside of study participation.*

If you decide not to take part in this study, you will get the standard treatment for [the condition]. This standard care may involve [list available options]. The Principal Investigator is available to discuss and answer your questions regarding alternatives to taking part in this research.

# Will I be paid for taking part in the study?

***INSTRUCTIONS:***

*If the subject will receive payment: describe the amount, when payments are scheduled, and any proration schedule should the subject decide to withdraw or is withdrawn by the investigator.*

Recommended text if no payment:

You will not receive any payment for taking part in the study.

**Required text if compensation exceeds $600 in a calendar year:**

If the total reimbursement for your participation in research is greater than $600 in a year, we will use your name, address, and social security number to report the amount to the Internal Revenue Service (IRS) as income.

# Will I be charged for taking part in the study?

***INSTRUCTIONS:***

*Indicate whether subjects may incur any costs as a result of participation in the study. Keep in mind that some insurance companies, as well as the Medicare and Medicaid programs, may not cover costs associated with certain research studies.*

# 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.

Are the researchers being paid for the study?

***INSTRUCTIONS:*** *If the institution and/or the researchers are being compensated by the study’s sponsor for their involvement in the study, this fact should be disclosed to subjects. If this section does not apply to your research, you may omit this entry and delete the heading.*

Recommended text, if applicable:

The company sponsoring the research is paying [insert name of AHC entity] and the research team for their work in this study.

What about privacy and confidentiality?

***INSTRUCTIONS:***

*Explain how subjects’ records/ identifying information will be kept confidential (i.e. will records be kept under lock and key, will there be limited access by the research team, etc.).*

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

***INSTRUCTIONS:***

*The Privacy Rule requires the authorization to be as specific as possible. Please use the text below as a model, but tailor it to the specific study. The Privacy Rule does not allow a subject to give permission to use or disclose protected health information for future unspecified research. All uses and disclosures must be clearly specified. If applicable, state if and when individual responses to survey questionnaires will be destroyed following analyses of the data.*

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/biospecimens 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] without additional consent. You will not be informed of any of the details of research studies using your information/biospecimens. Information/Biospecimens will be stored, maintained, and used for research purposes indefinitely [or define period of time].

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]

If you do withdraw your consent during the study, the research staff will not collect additional personal information from you, although personal information already collected may be retained and reviewed.

The research team may request continued follow-up and further data collection from you, which will be presented to you in a separate consent form.

**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.

1. How will my bodily samples be used?

***INSTRUCTIONS:***

*If this section does not apply to your research, please omit this entry and delete the heading.*

Recommended text:

All tissue and/or flu**i**d samples collected are important to this research study. Your sample will be owned by Adventist HealthCare or by a third party designated by Adventist HealthCare (such as another hospital, a university or a private company).

Recommended commercial ownership text if applicable:

If a commercial product is developed from this research project, the commercial product will be owned by Adventist HealthCare or its designee. You will not make money from such a product.

**Required text if whole genome sequencing may be included:**

Research on your samples may/will include whole genome sequencing.

Any sample 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] without additional consent. Your samples may be shared with [include institutions/researchers]. Samples will be stored, maintained, and used for research purposes indefinitely [or define period of time]. You will not be informed of any of the details of research studies using your samples. You will/will not be informed of any clinically relevant research results [include conditions.

Recommended text if a cell line will be created:

Cells taken from your body may be used to create a “cell line” that may be shared in the future with other researchers and have commercial value. A cell line is a collection of cells that will keep growing in the laboratory. Cell lines may be useful because of the characteristics of the cells and/or the products they may produce.

1. If I decide to take part in the study and sign this form, can I withdraw from the study later?

***INSTRUCTIONS:*** *When appropriate, the consent form should state the medical or health consequences of a subject’s decision to withdraw from the research.*

Recommended text:

You may withdraw from this research study at any time. Your decision to withdraw from the study will not affect the quality of your care or your relationships with [name of facility] or [name of investigators/research team] and the benefits to which you are otherwise entitled, and you will not be penalized for withdrawing. You should call and write to the investigator if you want to withdraw from the study. Any identifiable research or medical information already taken may still be used and disclosed by the investigators for the purposes described above.

[Include if appropriate:]

If you decide to withdraw from the study after you have received the [investigational device or drug], you may still be required to have certain follow-up tests and procedures to ensure your safety and health.

1. Can the researchers decide to take me out of the study?

Recommended text:

The investigator(s) may decide to take you out of the study under certain circumstances. You may be taken out of the study if:

* Staying in the study would be harmful.
* You need treatment not allowed in the study.
* You fail to follow instructions.
* You become pregnant.
* The study is canceled.

The decision may be made to protect your health and safety, or because it is part of the research plan that people who develop certain conditions may not continue to take part in the study. The investigator will tell you if this happens.

1. Whom do I contact if I have problems or questions?

Recommended text:

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.

1. Need more clinical trial information?

Required text for FDA-regulated drug, biologics and device clinical trials:

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.

|  |
| --- |
| **SIGNATURE OF RESEARCH SUBJECT OR LEGAL REPRESENTATIVE** |

I have read (or someone has read to me) the information provided in this document. I have been given time to consider taking part in the study. I have had a chance to ask questions, and my questions have been answered to my satisfaction. I have received a copy of the Research Subjects Bill of Rights. I will receive my own signed and dated copy of this consent form.

**By signing this form, I agree to take part in the research it describes.**

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Name of Subject (or Legal Representative) |  | Legal Representative’s Relationship to Subject (if applicable) |
|  |  |  |
| Signature of Subject (or Legal Representative) |  | Date  |
|  |  |  |
| Name of Witness |  |  |
|  |  |  |
| Signature of Witness |  | Date  |
|  |  |  |
| Name of Interpreter |  |  |
|  |  |  |
| Signature of Interpreter |  | Date  |

|  |
| --- |
| **SIGNATURE OF INVESTIGATOR OR APPROVED REPRESENTATIVE** |

I have discussed and explained the research to the subject or his/her legal representative, including any risks and adverse reactions that may reasonably be expected to occur, encouraged the subject or his/her legal representative to ask questions, and have answered all questions. The subject or his/her legal representative has been provided a copy of the Research Subject’s Bill of Rights, and a signed and dated copy of this consent form.

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Name of Investigator or Representative |  |  |
|  |  |  |
| Signature of Investigator or Representative |  | Date  |

**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.

**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.**