|  |
| --- |
| IMPORTANT NOTE: This Informed Consent Form Template is based on FDA Guidance "Investigational Device Exemptions (IDEs) for Early Feasibility Medical Device Clinical studies, Including Certain First in Human (FIH) Studies", Appendix 3\*. It is provided as a courtesy to Study Sponsors. Certain paragraphs and sections in this template may not apply based on investigational device and study requirements. The informed consent form should be adapted to reflect the device/procedure and prior experience with the device for the medical condition treated so the patient can make a well-informed decision. The informed consent form should reflect the study needs, regulatory and institutional review board requirements  \*https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm279103.pdf |

**INFORMED CONSENT TO PARTICIPATE IN AN EARLY FEASIBILITY STUDY**

**Title of Study: EARLY FEASIBILITY STUDY OF THE [INSERT DEVICE NAME]**

**Principal Investigator: [INSERT INVESTIGATOR NAME]**

**Sponsor: [INSERT SPONSOR NAME]**

**Emergency Telephone: [INSERT INVESTIGATOR PHONE]**

**INTRODUCTION**

You have been invited to join an Early Feasibility Study to evaluate the [INSERT GOAL OF STUDY] of [INSERT NAME OF THE DEVICE]. The device is investigational and not approved by the FDA for your medical condition.

This study is sponsored by [INSERT SPONSOR NAME]. Before you decide if you want to be involved in the study, it is important that you read and understand this information. Be sure to ask questions about anything that is unclear. Your Physician will answer your questions about the study, the device or any of the information being presented.

No study-related tests or procedures will be done before you sign this consent form.

**PURPOSE AND BACKGROUND**

The reason we are doing this research study is to look at the [INSERT STUDY DEVICE] to see if it can help treat [INSERT MEDICAL CONDITION]. This type of research study is called an “early feasibility study”. Early feasibility studies typically evaluate innovative devices or innovative uses of approved devices. These studies enroll a small number of patients and provide initial information on the basic safety and performance of the study device when used to treat [INSERT BRIEF DESCRIPTION OF MEDICAL CONDITION]. There is often only limited data and experience treating this condition with the study device. Since, this is an early feasibility study, some risks are unknown, and there is no guarantee that the device will help you or improve your condition. It is possible, however, that the device may help improve your condition, and the information obtained during the study may help others with your condition.

The device [INSERT DEVICE NAME] is a [INSERT BRIEF DESCRIPTION OF DEVICE CHARACTERISTICS, FUNCTION, MODE OF OPERATION, INNOVATIVE FEATURES, AND A DECRIPTION OF WHAT THE DEVICE IS INTENDED TO AND HOW IT IS DIFFERENT FROM CURRENTLY AVAIALBE THERAPY USING SIMPLE LANGUAGE].

This study is taking place in approximately X hospitals and up to X patients will be enrolled.

**PRIOR INFORMATION AVAILABLE ON THE DEVICE**

[NOTE IF THIS IS A FIRST IN MAN STUDY, OR INSERT PRIOR CLINICAL EXPERIENCE WITH THE DEVICE IN THE SAME OR DIFFERENT MEDICAL CONDITION]. Examples: This early feasibility study is the first time the Study Device will be used to treat humans, or the device has been used in [Europe and Canada in X patients with the same or different medical condition. Add details on the clinical experience, so the patient can make a well-informed decision].

**WHO CAN PARTICIPATE IN THE STUDY**

To find out if you meet all the requirements for this early feasibility study, your Physician will ask you questions and check your medical records. Before you decide to be in the study, be sure you understand all the information given and ask your Physician any questions you may have about your participation in this study.

If you decide to participate in this study, you can sign this form which will allow your Physician to perform additional study-related tests to see if you are a good candidate for this study. Please understand that your consent is required in order for your Physician to evaluate you further as a potential candidate for the study. You will not be actually enrolled into the study until your Physician confirms that you meet all the criteria for inclusion in the study.

You may be considered for this study only if you:

1. Agree in writing to participate in this study (by signing this consent form).

2. Are at least 18 years of age.

3. Meet all eligibility criteria as assessed by your Physician

**STUDY PROCEDURE**

Once your Physician determines you are good candidate for this study, your Physician will conduct study-related assessments to determine if you are eligible for the study. These assessments include:

 physical examinations

 medical and surgical history

 [LIST PROCEDURES, LAB TESTS, AND EXAMS TO BE PERFORMED FOR STUDY SCREENING AND INDICATE WHICH, IF ANY, ARE EXPERIMENTAL AND HOW THEY DIFFER FROM THE STANDARD OF CARE]

**General Study Procedures**

[DESCRIBE STUDY PROCEDURES AND INDICATE WHICH, IF ANY, ARE EXPERIMENTAL AND HOW THEY DIFFER FROM THE STANDARD OF CARE]

Your health will be monitored, and data will be collected for the study during your hospital stay . Following the study procedure, you will be required to have periodic health assessments [DESCRIBE FOLLOW-UP REQUIREMENTS INCLUDING VISITS, INTERVALS AND TESTING PERFORMED] [OPTIONAL you will be contacted and asked questions over the phone regarding any changes to your health]. Your participation in the study will end after [INSERT STUDY DURATION].

**RISKS AND DISCOMFORTS**

There might be unexpected risks from being in this type of early feasibility research study. This is because there may limited experience with the Study Device. New information from this research study may give the Sponsor useful information to improve the device and procedure to treat your medical condition. This may help support future research studies with the Study Device.

Since this device is in its early phase of development, there may not be information to fully predict the severity of the risks associated with device and how often medical problems might occur. There may be other risks that are unforeseen at this time. Precautions will be taken to avoid harmful side effects as a result of participation in this study. Your physician will closely monitor your health status throughout the study.

Some risks and discomforts in this study are similar to those associated with currently available devices used to treat [INSERT HERE MEDICAL CONDITION] including, but not limited to [LIST REASONABLY FORSEEABLE POTENTIAL RISKS AND DISCOMFORTS HERE]:

If you are female, this procedure and/or treatments during the study may involve unforeseeable risks to an embryo or fetus. If you are of child bearing age, please consult your Physician prior to consenting for this study.

**RISK MITIGATION STRATEGIES:**

[Bullets may be added or deleted as required.]

The Sponsor has done the following things to reduce the risks to subjects.

* The FDA or regulatory body has approved the clinical use of this device in an early feasibility study.
* Your Study Doctor was chosen to do this research study because he / she knows about your illness. Your Study Doctor has experience in treating [Insert medical condition or therapy].
* Your Study Doctor has been trained to use the Study Device in [Insert medical condition]. The Study Doctor’s training includes using a laboratory model and / or other hands-on training.
* Your Study Doctor and any responsible clinical research Site personnel have been trained to follow the research study Protocol. This training includes the design and proper use of the Study Device. It includes all Subject follow-up requirements.
* Every research Site must get approval to conduct this study from an Institutional Review Board (IRB) [or an Ethics Committee (EC)]. This group of people reviews the study Protocol and the informed consent to make sure the research study is ethical and your safety and welfare rights are protected.
* [Include examples as described in the Risk Mitigation section of the guidance and Appendix 3. (ability to revert to standard of care, additional imaging to assist with device placement…)]

**POSSIBLE BENEFITS IF YOU JOIN THIS STUDY**

There might be potential benefits to you, but there is limited information to predict how likely you will experience benefit. Potential benefits of the [INSERT DEVICE NAME] may include [INSERT POTENTIAL IMPROVEMENT OF PATIENT CONDITION OR DISEASE without overstating them].

It is possible that there may be no direct benefit to you as a result of your participation in this study. However, your participation in the study may help the Sponsor collect information to optimize the design and function of the [INSERT DEVICE NAME] or procedure associated with device use, which may help other patients in the future.

**OTHER TREATMENTS AVAILABLE**

Alternative therapies for your medical condition may include [INSERT POTENTIAL ALTERNATIVE THERAPIES AND THE BENEFITS, RISK AND LIMITS]. Your Physician will discuss your situation with you and will recommend the best treatment for you, including how the experimental therapy would differ from the standard of care.

**YOUR PARTICIPATION IS VOLUNTARY**

Your participation is entirely voluntary. If you wish to participate in this early feasibility study, you will be asked to sign this form. Please take time to read this information carefully and to discuss it with your family, friends, and Physician before you decide.

You have the right to refuse to participate in this study. If you decide to participate, you can change your mind and choose to withdraw from the study at any time without any negative consequences to the medical care, education, or other services you may receive from this clinic or hospital.

If you decide to stop taking part in this study, you must tell your study Physician. You do not need to specify the reason for your withdrawal. Your study Physician will discuss with you whether any testing or follow-up may need to be done for your safety. [INSERT IF APPLIABLE; If you withdraw from the study before completion, the following may occur: [INSERT LIST OF ANY POSSIBLE ADVERSE EFFECTS THAT MAY OCCUR RELATED TO THE STUDY DEVICE, ANY ADDITIONAL PROCEDURES RECOMMENDED TO ENSURE PATIENT SAFETY, OR NEED FOR CONTINUED FOLLOW-UP].

Your Physician or the sponsor can remove you from the study at any time without your approval. If your study participation is stopped, you may be asked to undergo a routine medical exam and/or medical testing for safety reasons. Any patient who is withdrawn from the study for any reason may not re-enter the study at any time.

**CONFIDENTIALITY OF STUDY RECORDS AND MEDICAL RECORDS**

Information collected for this study is confidential. Access to your personal medical information will be limited to the purposes of collection and processing information necessary for the completion of this study.

Your privacy is important. You will only be identified in the study by a code. This number is not derived from any of your personal information. Should results of this study be published (in a medical journal), you will not be identified through your name or other personal information. Data collected and reported to the sponsor for this study are the property of the sponsor. Your study records are just like hospital records. They may be subpoenaed by court order or may be inspected by federal regulatory authorities, including the Food and Drug Administration.

**PROTECTED HEALTH INFORMATION**

***Who may use and disclose information about you?***

The people who may use your Private Health Information include the clinician, [insert Physician name] and his/her staff; the [INSERT NAME OF IRB] Institutional Review Board and its staff; legal counsel; audit and compliance staff; and other people who need to see the information to help the study or make sure it is being done correctly. These people may disclose your Private Health Information to staff of the entities listed in the next section.

***Who may see your health information?***

Your Private Health Information may be disclosed to people associated with the following entities:

 Governmental agencies that have the right to see or review your health information, such as the Office of Human Research Protections and the Food and Drug Administration

 Other institutions that are participating in the study. The sponsor of the study and organizations that the sponsor may contract with for the study. The name of the sponsor is [INSERT SPONSOR NAME]

***Why will your information be used and disclosed?***

Your information will be used and disclosed in order to carry out the study and to evaluate the results of the study.

Your information may also be used to meet the reporting requirements of governmental agencies.

***Can you decide not to authorize the use and disclosure of your Private Health Information?***

Yes. You do not have to authorize the use or disclosure of your Private Health Information. However, if you do not sign this authorization, then you cannot participate in the study.

***Can you revoke your authorization?***

Yes. You may revoke your authorization to allow your Private Health Information to be used or disclosed at any time by sending a written notice to the principal investigator, [INSERT NAME OF PRINCIPAL INVESTIGATOR AND INSTITUTION]

If you revoke your authorization, you will be withdrawn from the study, and no health information about you will be gathered after that date. However, information gathered before that date may be used or disclosed if it is needed for the study analysis.

***Is your health information protected after it has been disclosed to others?***

If your health information is disclosed to someone who is not required to follow the Privacy Rule, then that information may no longer be protected, and it may be used or disclosed without your permission.

The Sponsor of the study, [INSERT SPONSOR NAME], the Investigator and all involved third parties have agreed to be bound by the provisions of the Privacy Rule of the Health Insurance Portability and Accountability Act.

***Can you see your health information?***

Yes. You may see and copy your information after the study ends.

***Does your authorization have an expiration date?***

Your authorization to use and disclose health information will continue until the end of the study and any necessary data analysis follow-up activities for the study. However, the information and data that are collected during your authorization period is effective can continue to be used and disclosed after your authorization has expired.

**STUDY RELATED INJURY**

If physical injury happens to you because of your involvement in this early feasibility study, medical treatment will be available, if appropriate, at the hospital. This may include [INSERT LIST OF TREATMENTS OR REFER TO SOURCE OF FURTHER INFORMATION]. Contact your Physician if you experience a study related injury.

**RIGHTS AND COMPENSATION**

You will not be paid to participate in this study. Your hospitalization and procedures will be considered part of your routine medical care. By signing this form, you do not give up any of your legal rights and you do not release the study Physician or other participating institutions from their legal and professional duties. There will be no costs to you for participation in this study. You will not be charged for any study procedures. If you become ill or physically injured as a result of participation in this study, medical treatment will be provided at no additional cost to you. The costs of your medical treatment will be paid by your medical plan and/or by the study sponsor [INSERT SPONSOR NAME].

**[IF APPLICABLE, INSERT THIS SECTION] PHYSICIAN CONFLICT OF INTEREST**

**[INSERT STATEMENT] Example: Your physician has a financial interest in the Study Device. If you have any questions about this, call [INSERT NAME] at [INSERT PHONE].**

**WHO YOU SHOULD CONTACT IF YOU HAVE QUESTIONS**

If you have any questions about taking part in this study, or if you think you may have been injured because of your participation in the study, call [INSERT INVESTIGATOR NAME] at [INSERT INVESTIGATOR PHONE]. If you have any questions about your rights as a study patient, you can call the [NAME OF INSTITUTIONAL REVIEW BOARD] at [IRB PHONE]. You should also inform your study Physician if you have been injured or hospitalized for any reason during the study.

**PATIENT'S STATEMENT**

I have been given a chance to ask questions about this study. These questions have been answered to my satisfaction. If I have any more questions about taking part in this study, I may contact **[INVESTIGATOR NAME]** at **[INVESTIGATOR PHONE]**.

I understand that my participation in this early feasibility study is voluntary. I know that I may quit the study at any time without harming my future medical care or losing any benefits to which I might be otherwise entitled. I understand that there might be other treatment alternatives for me. I also understand that the investigator in charge of this study may decide at any time that I should no longer participate in this study. If I have any questions about my rights as a patient in this study I may contact:

**[IRB Chairperson Name, Address, Telephone Number**]

By signing this consent form, I have not waived any of my legal rights or released the parties involved in this study from liability for negligence.

I have read and understand the above information. I agree to participate in this study. I have been given a copy of this form for my own records.

Signature of Study Participant:

Print Name of Study Participant:

Date:

Signature of Legal Representative:

Print Name of Legal Representative:

Date:

Signature of Person Discussing Consent:

Print Name of Person Discussing Consent:

Date:

Signature of Investigator:

Print Name of Investigator:

Date: