Informed Consent Document

Medical Device Clinical Study

Study Title: _____

Principal Investigator: _____

Institution: _____

Introduction

You are being invited to take part in a clinical research study involving a medical device. Please read this document carefully. It describes the study, its risks and benefits, and your rights as a participant. Your participation is voluntary.

Purpose of the Study

The purpose of this study is to evaluate the safety and effectiveness of the medical device named above. The information collected will help improve the understanding of this device and its potential impact on health.

Procedures

If you agree to participate, you will be asked to:

1. Undergo screening to determine eligibility.
2. Take part in study visits as outlined by the investigator.
3. Use the medical device as directed.
4. Report any changes in your health to the study team.
5. Complete questionnaires or interviews, if required.

Risks and Discomforts

Possible risks associated with the use of the medical device or participation in study activities may include:

- Side effects or complications from the device.
- Physical discomfort during procedures.
- Unanticipated risks.

The study team will monitor your condition and provide appropriate care as needed.

Benefits

You may or may not benefit directly from this study. Your participation may help advance medical knowledge and contribute to future patient care.

Alternatives

You do not have to participate in this study to receive medical care. Alternative procedures or treatments are available and will be discussed by your doctor if you choose not to participate.

Confidentiality

Your personal and medical information will be kept confidential and will only be used for the purposes of this study, except as required by law.

Costs and Compensation

There is no cost to you for participating in the study. You will not be paid for your participation unless otherwise stated.

Withdrawal

Participation is voluntary. You may withdraw from the study at any time without penalty or loss of benefits to which you are otherwise entitled.

Contact Information

If you have questions about the study, please contact the Principal Investigator at:

_____

If you have questions about your rights as a participant, contact the Institutional Review Board at:

_____

Consent

I have read and understood the information above. I have had the chance to ask questions, and all of my questions have been answered to my satisfaction. I voluntarily consent to participate in this study.

Participant Name (Print):

Participant Signature: Date: _____

Investigator Name (Print):

Investigator Signature: Date: _____