Informed Consent Form

Phase I Clinical Drug Study

Study Title: _____

Protocol Number: _____

Investigator: _____

Introduction

You are invited to take part in a clinical research study. Your participation is voluntary. Please read this document carefully and ask any questions you may have before agreeing to participate.

Purpose of the Study

This Phase I study is designed to evaluate the safety, tolerability, and pharmacokinetics of the study drug in healthy volunteers.

Study Procedures

- You will be screened to determine if you are eligible.
- If eligible, you will receive the investigational drug and undergo monitoring as specified in the protocol.
- Blood and urine samples may be collected.
- Your participation will last approximately _____ days.

Potential Risks and Discomforts

- Possible side effects of the investigational drug (unknown or known, e.g., nausea, headache).
- Discomfort from blood draws, such as bruising or infection.
- Other unforeseen risks.

Potential Benefits

- No direct benefit to you is expected from participation.
- Your involvement may help advance medical knowledge.

Alternatives to Participation

Your alternative is not to participate in this research.

Confidentiality

Records identifying you will be kept confidential as permitted by law. Your identity will not be released without your permission except as required by law.

Compensation

You may receive compensation for your participation as outlined in the study protocol.

Voluntary Participation and Withdrawal

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

Contact Information

For questions about the study, contact:
Investigator Name: _____
Phone: _____

For questions about your rights as a research participant, contact:
Institutional Review Board (IRB): _____
Phone: _____

Consent

I have read and understand the information provided above. I have had the opportunity to ask questions. I agree to participate in this study.

Participant Name

Participant Signature

_____

Date

Witness Name (if applicable)

Witness Signature

_____

Date

Investigator Name

Investigator Signature

_____

Date