Informed Consent Form for Participation in a Drug Clinical Trial

Protocol Title: _____

Study Sponsor: _____

Principal Investigator: _____

Investigator Contact: _____

Introduction

You are being invited to participate in a clinical research study involving the investigational drug named above. Please read this consent form carefully and ask any questions you may have before deciding whether to participate. Participation is voluntary.

Purpose of the Study

The purpose of this study is to evaluate the safety and efficacy of the investigational drug in participants with _____.

Procedures

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

- Undergo screening tests and assessments.
- Take study drug according to the schedule provided.
- Attend regular follow-up visits as outlined by the study team.
- Provide blood and/or other samples for laboratory testing.
- Report any side effects or changes in health during the study.

Risks and Discomforts

Participation in this study may involve risks or side effects, including but not limited to:

- Drug-specific side effects (list known side effects)
- Risks associated with blood draws or other procedures
- Unforeseen risks or side effects not yet known

Benefits

You may or may not benefit from participating in this study. Potential benefits include:

- Improvement of your condition (if applicable)
- Contribution to knowledge about the drug and future patient care

Alternatives

Participation is voluntary. Alternative options include:

- Standard treatments for your condition
- No treatment

- Participation in other clinical trials (if available)

Confidentiality

Your identity and personal health information will be kept confidential to the extent permitted by law. Study records may be reviewed by the sponsor, regulatory authorities, and the institutional review board (IRB).

Compensation and Costs

Any costs or compensation related to your participation will be explained to you. If you are injured as a result of this study, the following procedures apply: _____.

Your Rights

- Your participation is voluntary.
- You may withdraw from the study at any time without penalty or loss of benefits.
- Your decision will not affect your current or future medical care.

Contact Information

If you have any questions about the study or your rights, please contact:
Principal Investigator: _____
Phone: _____
IRB Contact: _____
Phone: _____

Consent and Authorization

I have read (or have had read to me) the information above. I have had the opportunity to ask questions, and all my questions have been answered. I voluntarily agree to participate in this clinical trial.

Participant Name (print):

_____

Participant Signature:

_____

Date:

_____

Person Obtaining Consent (Print & Signature):

_____

Date:

_____