Informed Consent Document for Phase 2 SLE Study

Introduction

You are invited to participate in a research study. This study is being conducted to evaluate the safety and efficacy of **XYZ123** for the treatment of **moderate to severe systemic lupus erythematosus (SLE).** Your participation is entirely voluntary.

Study Purpose

SLE is an autoimmune disease that causes inflammation in various organs. The purpose of this study is to determine if **XYZ123** can help reduce lupus symptoms while ensuring it is safe.

Procedures

- You will undergo screening tests to confirm eligibility
- If eligible, you will be randomly assigned to receive either **XYZ123** or a placebo
- Study visits every **4 weeks** for blood tests, physical exams, and questionnaires
- Total participation time: **36 weeks** (including follow-up)

Potential Risks and Benefits

Potential Risks:

- Common side effects: Headache, nausea, fatigue
- Serious risks: Risk of infections, allergic reactions
- Unknown risks as this drug is still under investigation

Potential Benefits:

- Possible improvement in **lupus symptoms**
- Contribution to future lupus treatments

Confidentiality

Information related to all patient identities will be kept strictly confidential and only used for research purposes in accordance with HIPAA and regulatory guidelines.

Your Rights

You may withdraw at any time without penalty. Your decision will not affect your medical care. This may be your only chance to join this trial.

Contact Information

For any questions, please contact the study coordinator at **[Phone]** or **[Email]**.

Consent Signature

By signing below, you confirm that you have read this document and agree to participate.

Participant's Signature: _____
Date: _____
Investigator's Signature: _____
Date: _____