**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.

**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**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_