Clinical Trial Protocol: Sample Document

1. Title Page

Study Title: A Phase II, Randomized, Double-Blind, Placebo-Controlled Study of XYZ Drug in Patients with Type 2 Diabetes
Protocol Number: XYZ-2025-001
Version Number: Version 1.0
Date: May 20, 2025
Sponsor: ABC Pharmaceuticals
Principal Investigator: Dr. John Doe, MD
Institution: University Hospital, Boston, MA

2. Synopsis

Study Objective: To assess the efficacy and safety of XYZ Drug in reducing HbA1c levels in patients with type 2 diabetes.
Design: Randomized, placebo-controlled, double-blind
Number of Subjects: 120
Study Duration: 24 weeks
Primary Endpoint: Change in HbA1c from baseline to week 24

3. Table of Contents

4. Background and Rationale

- Description of disease condition
- Current standard of care
- Preclinical and clinical data supporting XYZ Drug
- Justification for the study

5. Study Objectives

Primary Objective:
- To evaluate the effect of XYZ Drug on HbA1c levels at 24 weeks.

Secondary Objectives:
- To assess changes in fasting plasma glucose, weight, and insulin sensitivity.
- To monitor safety and tolerability.

6. Study Design

Type: Double-blind, placebo-controlled
Phases: Screening → Randomization → Treatment (24 weeks) → Follow-up
Randomization Ratio: 2:1 (Drug:Placebo)

7. Study Population

Inclusion Criteria:
- Age 18–70 years
- Diagnosed with type 2 diabetes for ≥1 year
- HbA1c between 7.0–9.5%

Exclusion Criteria:
- Type 1 diabetes
- History of DKA or pancreatitis
- Severe renal or liver disease

8. Study Procedures and Schedule

Visit	Procedures
Screening	Informed consent, labs, ECG, medical history
Week 0 (Baseline)	Randomization, study drug dispensed
Week 4	Safety labs, vitals
Week 12	HbA1c, fasting glucose, weight
Week 24	Primary endpoint assessment, study drug return

9. Investigational Product

Drug Name: XYZ Drug (oral tablet)
Dosage: 50 mg once daily
Placebo: Matching in appearance
Storage: Room temperature, protected from light

10. Safety Monitoring

Adverse Event (AE) Reporting: Collected at each visit
Serious AE (SAE): Reported within 24 hours of awareness by the site