**Protocol Title:** A study of medication X for treatment of hyperglycemia in patients with Type 2 Diabetes

**Principal Investigator:**

**Co-investigator:**

**Study coordinator:**

**Population:** xxx male and female xxx-xxx old, Type 2 Diabetes in xxx.

**Number of sites:** xxx

**Study duration:** xxx weeks

**Follow up:** xxx weeks screening, xxx weeks on treatment and xxx weeks on follow-up.

**General Information:** This is a double blind, randomized, xxx arm study.

**Study Type:** Interventional

**Study objectives:** This study will evaluate the potential to reduce high blood sugar (HbA1c), the tolerability and long term safety of people on medication X compared to placebo in patients with type 2 diabetes.

A reduction in Hba1c would have beneficial effects such as reducing the risk of cardiovascular disease.

Patients will be randomized to receive medication X or placebo once daily as oral doses. Time on study treatment will be for at least xxx weeks.

**Study endpoints:**

**Study Design:**

*Allocation:* Randomized

*End Points Classification:* Efficacy/Safety study

*Intervention Mode:* Parallel assignment

*Masking:* Double- blind

*Primary purpose:* Treatment

**Condition:** Diabetes Mellitus**,** Type 2

**Intervention:** Drug X one tablet daily, Placebo control daily

**Study population:**

*Inclusion criteria:*

*Exclusion criteria:*

**Study Procedures:**

**Data and Safety Monitoring:**

**Statistics:**

We will use xxx to compare baseline data with the last xxx measurement for each patient.

Level of significance = 5%,

Power = 80%,

Type of test: two sided.

Formula of calculating sample size is: xxx

Based on the formula (1) the sample size required per group is xxx patients. Total sample size is xxx.

So a sample size of xxx subjects, xxx in each arm, is sufficient to detect a clinically important difference of xx % between groups in reducing hyperglycemia - xxx assuming a variance xxx% using a xxx test for difference between means with 80% power and a 5% level of significance.

**Ethics:**

Approval from an ethical vetting board will be applied for.

**Data Handling and record keeping:**

**Publications plan:** Not in the time of writing this report.

**Attachments:** NA