LEV 101-D-022521	NCT04857320

A Physician-Initiated Multiple-Dose, Single Period, Phase 0-I Dose Ranging Study to Examine Levellor™ HypoSpray Human Insulin Adult Healthy Volunteer Patients

Protocol No.: LEV 101-D-022521
ClinicalTrials.gov Reference NCT04857320

Criteria for evaluation: Statistical Analysis Plan

21st APRIL, 2021

Version 1.3

SPONSOR: Langford Research Institute

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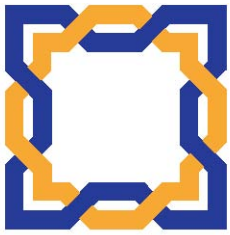

Approved by Langford Research Institutional Review Board April 21st, 2021

AMENDMENTS:

1.	2.	3.	4.

Criteria for evaluation: Statistical Analysis Plan	**Pharmacokinetics** ***Primary pharmacokinetic variables*** The primary pharmacokinetic variables include: the reduction of serum glucose from baseline and at typical post prandial spikes and the amount of insulin necessary to accomplish this reduction. In addition to 90% confidence intervals, the data will be summarized by medians, and maximum and minimum values. The elimination half-life of Insulin will be compared using non-transformed data and parametric techniques. Averages for the serum glucose and Post-prandial excursions will be compared against averages for experimental periods.