CLINICAL EVALUATION OF THREE DIFFERENT BIOACTIVE RESTORATIVE MATERIALS IN CERVICAL CARIOUS LESIONS IN HIGH CARIES RISK PATIENTS: A Randomized Controlled Clinical Trial

Protocol submitted to

Faculty of Dentistry, Cairo University
for partial fulfillment of the requirements **for the PhD Degree** in Restorative and Esthetic Dentistry.

By

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Date

Medical Biostatistics Unit review report for sample size calculation

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Research Information

Research title: CLINICAL EVALUATION OF THREE DIFFERENT BIOACTIVE RESTORATIVE MATERIALS IN CERVICAL CARIOUS LESIONS IN HIGH CARIES RISK PATIENTS: A Randomized Controlled Clinical Trial

Research question: Will the three different bioactive restorative materials have the same clinical performance in cervical carious lesions in high caries risk patients over eighteen months of follow-up?

Complete items used in sample size calculated *

- The outcome used: Post operative hyper sensitivity (after 12 months)
- Values used for outcome: Proportions
- Entry 1: (estimated) 0.675 for I1 and I2
- Entry 2: 0.975
- Alpha level of significance: 0.05 (5%)
- Effect size: minimal clinically important difference of 30%
- Power of the study: 80%
- Statistical test used: Z test for two independent proportions
- The calculated sample size: 24 per group
- Increased number for anticipated missing data (10%): 27 per group

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Vice Dean for Postgraduate affairs and research