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## **SRI DEVARAJ URS ACADEMY OF HIGHER EDUCATION AND RESEARCH**

**(A Deemed to be University declared under Section 3 of UGC Act 1956)**

**Comprising Sri Devaraj Urs Medical College**

**[Constituent unit of Sri Devaraj Urs Educational Trust for Backward Classes (Regd.)]**

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### **Letter of Association**

Date: 08.01.2022

**Project Title:** Assessment and Evaluation of Effectiveness of Carbohydrate Counting Method and Standard Diabetic Diet on Metabolic Control in Children and Adolescents with Type1 Diabetes Mellitus

#### **Preamble**

The collaborating institutions are Sri Devaraj Urs Academy of Higher Education (SDUAHER) Tamaka, Kolar, a deemed to be University and Center for Diabetes and Endocrine Care, Bangalore. This letter of Association facilitates the collaboration between these two institutes for the purpose of doctoral research activities. The Department of Clinical Nutrition and Dietetics, SDUAHER has planned to conduct doctoral research with a proposal titled, "Assessment and Evaluation of Effectiveness of Carbohydrate Counting Method and Standard Diabetic Diet on Metabolic Control in Children and Adolescents with Type1 Diabetes Mellitus" in association with the Center for Diabetes and Endocrine Care (CDEC).

#### **Investigators**

Mrs. Ayesha Tajuddin Pendhari, Clinical Dietitian, Ph.D. research scholar, Department of Clinical Nutrition and Dietetics, SDUAHER, Dr. M Madhavi Reddy, Professor and HOD Department of Clinical Nutrition and Dietetics, SDUAHER, Dr. Sudha Reddy V.R, Professor and HOD, Department of Pediatrics, SDUMC, SDUAHER, KOLAR, and Dr. Ganpathi Bantwal, Professor, Department of Endocrinology, St John's Medical College, Bangalore and Dr. Sanjay Reddy, Endocrinologist of Centre for diabetics and endocrine care (CDEC), Bangalore.

The doctoral research project is proposed by Mrs. Ayesha Tajuddin Pendhari for the purpose of obtaining her Ph.D. degree and she has expertise in the area of clinical nutrition. The literature review and project synopsis for the proposed study were carried out by Mrs. Ayesha Tajuddin Pendhari with the support of guide Dr. M Madhavi Reddy, Co-guide Dr. Sudha Reddy V. R and external expert Dr. Ganpathi Bantwal. Dr. Sanjay Reddy has proposed improvements to the ideas, specifically concerning population inclusion, literature review, and study methodology. Finally, after discussions involving all the five investigators and the doctoral research advisory committee, the proposal has been developed to the current format. It has been planned and agreed upon by all five investigators to recommend and carry out this proposed research work.

### **Project summary**

In this work, the research scholar will be studying to understand the effect of nutrition education on glycemic control and preventing long-term complications in type 1 Diabetes Mellitus subjects. Carbohydrate counting and standard diabetic diet approach will be used for nutrition education for type1 diabetic subjects.

This proposed research is a randomized control trial; hence the study would be conducted after obtaining ethical clearance from both the institutes, and it will be registered in the Clinical Trials Registry, India. The nutrition education will be performed for a period of 3 months and a follow-up period of 6 months.

The study also involves the collection of laboratory and diagnostic data, at baseline, 3<sup>rd</sup> month, and 6<sup>th</sup> month. This data collection will be carried out with the support of the central laboratory and diagnostics present in both institutional campuses for the convenience of the patients and the investigators with prior informed consent and permissions. The expenses involved in the study will be borne by the research grants.

### **Roles and Responsibilities**

Mrs. Ayesha Tajuddin Pendhari (PI): Primary role in the implementation of design and optimization of standard diabetic diet and carbohydrate counting, recruitment of study group, conducting nutrition education, follow-ups, and collection of data. Dr. M Madhavi Reddy (Guide), Dr. Sudha Reddy V.R (Co-guide), Dr. Ganpathi Bantwal (External Experts), and Dr. Sanjay Reddy (Endocrinologist): Primary role of the guide, co-guide, and experts will be in coordinating and guiding the doctoral research scholar through every single step of the research and ensure the research work is carried out without any quality compromise and bias as per RCT protocol, ethical interests, and also ensure timely completion of the research project.

### **Probable Outcomes**

The study is recommended as a need to improve Glycemic control of the type1 diabetes mellitus subjects, and the expected outcome of the study would be that the adherence to carbohydrate counting method could have an impact on metabolic control of children and adolescents with T1DM. This will help to determine the dietary prescription practices for children and adolescents with T1DM in India.

All five investigators shall be investigators ethically and the mother institution SDUAHER (as per the prevailing institutional IPR guidelines) shall be the owner of the research work. All IPR issues will be as per the prevailing institutional guidelines mutually agreed upon.

The authorship credits of publications that come as a result of this work will be decided based on mutual agreement, as per the international authorship guidelines.

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