

## **Recruitment and Management of a Healthy Human Panel for Clinical Trials to Analyze the Post-prandial Glycemic Response of Food**

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The glycemic index (GI) and glycemic load (GL) are valuable indicators of carbohydrate-rich diets that are used to assist people to manage their blood glucose levels and improve overall health. There is a growing demand for employing healthy participants for clinical trials in GI studies. However, there is no any commercially established, accredited GI testing laboratory in Sri Lanka. This study was conducted to recruit and manage a healthy human panel for clinical trials to analyze the post-prandial glycemic response of food. Initially, 301 university undergraduate students were recruited in the age group 21-25 years, and collected anthropometric and demographic parameters. The recruited participants were screened based on anthropometric and demographic parameters. Then 97 participants were screened and trained for clinical trials in GI studies. Finally, 50 interested and available participants were chosen as the “healthy human panel for GI studies”. Inter-laboratory validation of GI values was conducted using the GI data obtained by CIC Food and Nutrition Research Laboratory and Glycemic Index Research Unit, Singapore. The healthy human panel consisted of participants aged between 22-25 years, mean body mass index (BMI) of  $20.9 \pm 1.7 \text{ kg/m}^2$  and a mean waist-to-hip ratio (WHR) of  $0.8 \pm 0.1$ . The performance of the developed healthy clinical panel was evaluated according to ISO 26642:2010 (E). The results for the GI of super kernal, rathu suduru, red fragrant, and purple queen rice varieties were  $40 \pm 5.5\%$  (low GI),  $61 \pm 5.5\%$  (medium GI),  $54 \pm 3.8\%$  (low GI), and  $47 \pm 4.9\%$  (low GI) respectively. Results of inter-laboratory validation revealed no significant difference ( $P > 0.05$ ) in GI values of the selected rice varieties. Therefore, the proposed healthy human clinical panel for GI studies can be used in future GI studies of the food industry to facilitate GI labeling of food products.

**Keywords:** GI labeling, Glycemic index, Glycemic load, Inter-laboratory, Post-prandial

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