ProFiLE Study Human Trial – Participant Information Leaflet

1. What is this study about?

The Nutrition Research Centre Ireland (NRCI), based at the Southeast Technological University (SETU), is presently engaged in a research study aimed at examining the potential of lutein-enriched functional foods to effectively introduce lutein into the human body. This investigation will be carried out by the NRCI through a bioavailability study in collaboration with our industry partner, Cybercolors Ltd.

2. Why are we doing this study?

Lutein is a micronutrient naturally found in various fruits and vegetables. It is a vital component of a balanced diet and has been scientifically proven to enhance both visual and cognitive function with positive benefits for AMD (age related macular degeneration), the world's leading source of blindness. The human body cannot produce lutein on its own and so it must be obtained through nutrition. This is achieved by incorporating foods such as dark leafy greens and egg yolks into one's diet or by opting for dietary supplements. Recent findings indicate that the daily intake of lutein often falls short of providing the related health benefits. This confirms the huge potential for lutein fortification in functional foods.

We are developing two functional food products fortified with lutein to support human nutrition. These food products are sport isotonic beverages and cupcakes. We aim to evaluate the effectiveness of lutein-fortified foods as a method to deliver lutein directly into the human body, through a bioavailability study. This study involves measuring lutein levels in the blood at different timepoints before and after participants eat a single serving of the lutein-fortified isotonic beverage (500 ml) or cupcake (50g).

3. What does participation in this study involve?

The study will span over five days, commencing with a 10-hour session on Day 1, held at the NRCI. Each participant will be asked to consume one single serving of either the lutein fortified sport isotonic beverage or lutein fortified cupcake. After consumption, a qualified phlebotomist will withdraw blood from you employing a cannula or needle, at regular intervals throughout the day as outlined below (Table 1). Days 2, 3, 4 and 5 will entail one brief daily visit (15-20 minutes) to the NRCI, where a single blood sample will be drawn each day. The first blood sample of each day will be a **fasting blood sample**.

At the beginning of the study your carotenoid skin levels will be measured by the trained researcher using a non-invasive carotenoid skin scanner (Life meter). This measurement will take 1-2 minutes. Skin carotenoid level scores will help to indicate your dietary fruit and vegetable intake.

For Day 1, your meals will be provided by a catering company, and for Days 2, 3, 4, and 5, breakfast will be included. Throughout Day 1 of the study, you can engage in typical on-site activities, provided they are low-impact or metabolic in nature, such as desk work, reading, etc. Upon completion of Day 1, you will receive a list of foods you are allowed eat for the following three days. This diet restriction aims to maintain a low lutein intake during this period, ensuring the accuracy of your blood test results.

Table 1: Blood Sampling Schedule

Day	1				2	3	4	5
Number of withdraws	1st	2nd	3rd	4th	5th	6th	7th	8th
Time-points	Baseline (0h)	3h	6h	10h	24h	48h	72h	96h
Suggested time	8am	11am	2pm	6pm	9 am	8 am	8 am	8 am
Actions	Fasting blood sample, L Fortified food administration after 1st withdrawal	Breakfast provided after 2nd withdrawal	Lunch provided after withdrawal		Breakfast provided after each blood withdrawal			

4. Who can participate?

Participants must be between 18-65 years of age, a non-smoker, non-pregnant, in good general health status, have no allergies i.e., gluten, eggs, dairy, no chronic disease (e.g., diabetes, cardiovascular diseases, Alzheimer's disease, etc.), not currently taking medication or supplements that could potentially interfere with lutein absorption.

5. What are the possible side effects of participating in the study?

We anticipate that the consumption of the lutein-enriched foods will be free of side effects, as we will pre-screen participants to confirm the absence of any allergies. All food products used in this trial are fully compliant with all EU food safety regulations and standards and are safe to consume.

However, it's important to note that while uncommon, the blood withdrawal procedures may carry a slight risk of side effects, including bruising, pain, bleeding, fainting, and/or dizziness.

6. What are the benefits of participating in this study?

Upon successful completion of the trial, each participant will receive a **€250 voucher** as a token of gratitude for their involvement in this study. . The one-for-all voucher will be provided by funding related to the master's programme. Funding for this MSc degree has been wholly funded by the project Industry partner, Cybercolors Ltd. Additionally, meals will be provided to volunteers during their study visits. Your participation in this research will not only benefit you but also contribute to our understanding of how lutein and potentially other substances are delivered to the human body, furthering our knowledge in this field.

7. More information about study participation

After you have read this leaflet and the research staff have explained all aspects of the study to you and you have no more questions, you will be asked to sign a document called the "informed consent" form, which states that you understand and agree to participate in this nutritional research study. If after agreement to participate, you wish to withdraw from the study, you can do so without any negative impact.

Thank you for taking the time to consider taking part in this study. If you have any further questions at any time, please phone: **+353 51 845 505** or email: **nrciresearch@wit.ie**

We hope that this information has answered most of your questions. Should you have further questions or do not fully understand the information given, please feel free to ask us. The investigators who are carrying out this research would like to thank you for taking the time to read this information.