# Volunteer Information Sheet

**Researchers:** Prof. Lorraine Brennan and Claire Erraught

**School:** School of Agriculture and Food Science

**Project:** UCD Protein Study

**What is this research about?**

Plant and dairy proteins and their hydrolysates may have possible health benefits. This study aims to examine the effects of three different protein drinks (with different compositions) on our ability to control circulating glucose levels (and other related molecules).

Protein hydrolysates are proteins that have been broken down by enzymes into smaller molecules such as amino acids or peptides, similar to digestion. Enzymes are molecules that help to speed-up chemical reactions and break down large molecules like proteins into smaller molecules like hydrolysates.

**Why are you doing this research?**

This study will help us to investigate if a rice derived protein hydrolysate, on its own or in combination with a milk protein, have potential health benefits in terms of managing blood glucose levels. Obesity and type 2 diabetes are considered global public health issues and the concern needs to be urgently addressed. The number of people with type 2 diabetes is increasing and novel preventative solutions are necessary.

**Why have I been invited to take part?**

You have been asked to take part in this study because you are aged between 18 and 45 years, and have a body mass index (BMI) >18kg/$m^2$ and <30kg/$m^2$. In order to participate in this study, you should not:

- have any chronic or infectious disease
- be pregnant, breastfeeding or planning a pregnancy
- be undergoing hormone replacement therapy
- be taking any prescribed medication, (oral contraceptive pill allowed)
- have an allergy or intolerance to dairy or rice products

If you are unsure regarding any of the above criteria, please feel free to discuss this with us.

**How will the data be used?**

Data will be used to determine whether there is any benefit in drinking a plant protein based drink on its own or in combination with a milk protein, compared to a control (intact milk protein) drink for

glucose control. Blood samples taken will be analysed for glucose, insulin and a number of other molecules present in the blood which may give important indications of how the body handles sugar. A positive result from the study may result in your blood samples being used in future work to determine how the proteins are causing the observed results. The results may be published in the form of a scientific paper. The data will be assigned a study code and this code will be used to put all the data from the study together in a secure password-protected database, where it will be stored safely. Participants will not receive any individual results for the study; please see the section on Risks and Benefits for clarity on this.

**What will happen if I decide to take part in this research study?**

Participation is entirely voluntary. After having read this information sheet, we advise that you take some time to decide whether you would like to take part in this study or not. An expression of interest or a commitment to participate will not affect your right to withdraw at any time during the course of the study.

Initially, potential volunteers will be invited for a screening test where we will measure your weight, height, waist and hips and explain the study in detail to you. After successful screening, if you are still interested in taking part, you will come into the Intervention suite here in the Science building in the morning, having fasted overnight (so no food 9hours before your study visit, and no breakfast please, although water is allowed).

We will give you one of the 3 test drinks (rice protein, milk protein or a combination of both) and a glucose drink. A cannula (a small thin tube) will be inserted into your arm, and will remain there over the next 2 hours. We will take a number of blood samples from this. This allows us to take a number of small blood samples throughout the day without having to pierce the skin multiple times. 30 ml of blood will be taken at 6 timepoints throughout the 2 hours; a total of 180 ml of blood. (This is less than half what is taken at a standard one-pint blood donation).

A bed will be provided to rest on. A desk will also be available if volunteers wish to read, study or to use a laptop. There will be wireless internet available and if you wish to bring a book or DVDs to watch, you are very welcome to do so.

There are three different test drinks, and each volunteer will come in for two hours on each of the three test days, so that you will have consumed all drinks, in a random order, by the end of the study.

If you change their mind at any point, you may withdraw at any stage throughout the study and are under no obligation to complete it.

**How will you protect my privacy?**

All information obtained from participants during the research will be kept confidential. Recordings and notes about the research will be stored in a locked file. Each person who takes part in the research will be given a code number so that all samples and data are anonymous. Identifying information about participants will not be used in any reports of the research.

**What are the benefits for taking part in this research study?**

There are no notable benefits for those involved in the study.

You will get the opportunity to learn about research in this area. Furthermore, your participation in this project may help to contribute to a better understanding of the effects of proteins for managing

blood glucose. This information may ultimately be important in the long-term to help to develop more effective strategies to prevent type 2 diabetes, for example the development of novel foods.

**What are the risks of taking part in this research study?**

Whilst there are no risks, some people may find it uncomfortable to give blood samples. You can be assured that the researchers are experienced and will ensure you are comfortable with all procedures and assessments. If you are troubled by any of the procedures we would advise leaving the study. Women who are pregnant, breastfeeding, or planning a pregnancy are excluded from the study and if a subject becomes pregnant over the course of the study, they must inform the director and leave the study immediately.

It is important to understand that this is not intended to replace any routine blood tests you or your doctor would have arranged. You will not receive individual results so this cannot be treated as part of your routine healthcare screening.

Milk proteins derived from normal cow's milk and rice protein hydrolysates have been used in previous studies with no negative outcomes. If at any stage you have an adverse reaction you should stop taking the drink and immediately inform the researcher who will instruct you on what to do.

**Can I change my mind at any stage and withdraw from the study?**

Absolutely, participants are free to withdraw from the study at any time.

**How will I find out what happens with this project?**

You will not receive individual results. However, if you wish, your contact details will be kept on a database and when the study is over and the information has been analysed, you can be sent some information on the study outcome.

**Contact details for further information**

If you would like any more information on this study, please feel free to contact Claire Erraught at claire.erraught@ucdconnect.ie or phone 01 716 2471.

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