



PARTICIPANT INFORMATION SHEET

<u>Study Title:</u>	The U-GENE project: Research on genetic predisposition to cardio-metabolic disorders due to UCP1 gene polymorphisms.
<u>Principal Investigator:</u>	Petros C. Ntinis (Dinas), SSP, NCO, BSc, MSc PhD candidate, Researcher in Human Physiology University of Wolverhampton Tel: 07756745186
<u>Chief Investigator:</u>	Prof. George S. Metsios, BSc, MSc, PhD Clinical Exercise Physiology Russells Hall Hospital, Dudley Tel: 01902-32 3104

Invitation and brief summary

We'd like to invite you to take part in our research study. Before you decide we would like you to understand why the research is being done and what it would involve for you. One of our team will go through this information sheet with you, to help you decide whether or not you would like to take part and answer any questions you may have. We'd suggest this should take about 10 minutes. Please feel free to talk to others about the study if you wish.

Our study investigates a specific gene which may cause the development of heart disease. We will be investigating different variations of the gene called UCP. We want to know if it is associated with fat mass and blood pressure readings as well as with the chance of developing diabetes. To do this we need to test different groups of people. Participation in the study is voluntary. You do not have to take part, and it is important to know that you can withdraw from the study at any time without explaining the reasons if you wish not to. Joining the study is entirely up to you.

What is the research study about?

Literature findings suggest that the UCP1 gene may be associated with the development of specific diseases, mainly heart disease. We wish to investigate this association in healthy participants to correlate it with patients who have diabetes, high cholesterol levels or high blood pressure. We will compare your result with individuals from other countries. Based on our findings from this study we will develop novel pharmacological and lifestyle interventions in order to minimize heart disease.

Who is eligible to participate?

To participate in this study you should be:

1. generally healthy (not suffer from a chronic disease),
2. between 18-59 years old,
3. non-smoker (or have quit smoking at least one year ago),
4. not be pregnant or give breast feeding,
5. have no history of eating disorder (you shouldn't have an abnormal attitude towards food that causes you to change your eating habits and behaviour. Not suffering from anorexia nervosa, bulimia, or you feel compelled to overeat large amounts of food in a short space of time)
6. have no acute illness and/or infection during the last four weeks.

What will I have to do?

After explaining the project, we will give you up to four weeks to decide if you want to take part. If you agree you will only need to visit once our laboratory and spend less than 30 minutes with the investigator.

The assessments that you will have to do are simple:

1) you will be assessed for your blood pressure, height, weight and waist circumferences as well as your muscle/fat mass via a non-invasive bioelectrical impedance device.

You will also be asked:

- 2) to provide information about demographic characteristics,
- 3) your physical activity levels,
- 4) your personal as well as your family history of cardio-metabolic disease (i.e. if your relatives had heart problems),
- 5) a trained phlebotomist will take a blood sample of 4ml, (approximately a teaspoonful)

You should not eat anything, drink coffee and/or alcohol, or exercise for 12 hours prior to your appointment. Finally, you will need to drink two glasses of water two hours before your appointment to make sure that your hydration level is within the normal range.

All these assessments will be done on the same day in our laboratory in Clinical Research Unit, Russells Hall Hospital or the Cardiology department of the Royal Wolverhampton Hospital. You will only need to visit the laboratory once on a morning of your choice.

What are the benefits from this study?

Possible personal benefits: There are no personal potential benefits except you will help science that may have a positive impact on the society.

General benefits: The information we will gather from all the people taking part will help us to understand much better some of the mechanisms that may be responsible for causing heart disease in healthy individuals. Even more importantly, it may help us to identify ways of reducing these problems as we target specific pharmacological and lifestyle interventions. In the future we hope we will be able to apply our knowledge to clinical practice in order to improve the prevalence of heart disease in both healthy and diseased populations.

What are the risks?

There are no potential risks associated with the assessments; apart from the discomfort you may feel when you provide a blood sample. It is also possible that you will experience a small amount of bruising and, extremely rarely, an infection. However, we have access to experienced phlebotomists who will minimise this potential discomfort as much as possible.

What happens if I do not want to take part or change my mind during the study?

If you decide to participate, this is entirely of your own free will. If at any point and for any reason you do not want to carry on, you can stop.

What happens to the information?

All information obtained from you will be kept strictly confidential. Your information will be identified according to a unique number associated with this project.

Who else is taking part?

In this study we are asking approximately 250 healthy individuals to take part, and 250 patients with cardiovascular disease.

What if something goes wrong?

If something goes wrong during testing, we will stop immediately and a doctor will examine you and act accordingly.

What happens at the end of the study?

We will analyse the results and come to some conclusions. We hope to be able to present these at national and international meetings and publish the results in scientific journals. Any such publication will not identify individuals, but will summarise the findings for the whole group of people who took part in the study.

If I take part, do I get paid?

No, we are sorry that we are unable to pay expenses for this study.

What if I have more questions or do not understand something?

If you have any further questions, do not hesitate to ask Petros Ntinis (07756 745186) or Prof. George Metsios (01902-32 3104).

What happens now if I decide to take part?

If you want to take part please contact Jackie Smith (Chief Research Biomedical Scientist) on 01384 456111 ext 3707 to make an appointment.

This Information Sheet is yours to take home.