 

**Participant Information Sheet** **- Version 8, 16/7/18**

**Study title: RISSCI-1 Blood Cholesterol Response Study**

**Introduction**

We would like to invite you to take part in a research project. Before you decide, you need to understand why the research is being done and what it will involve for you. Please take the time to read the following information carefully and ask questions about anything you do not understand. Talk to others about the study if you wish.

**Who is conducting the study?**

The study will be undertaken by a research team from the University of Surrey, which includes: Dr Rona Antoni, Registered Dietitian and Nutrition Research Fellow; Dr Hasnaa Ayaad, PhD student; Professor Bruce Griffin, Principal Investigator and Professor in Nutritional Metabolism; Dr Denise Robertson, Reader in Nutritional Physiology; and Dr Barbara Fielding, Senior Lecturer in Nutrition. Where appropriate, some aspects of the study will be conducted by medically trained personnel from the Surrey Clinical Research Centre (CRC).

**Background to study**

The type of fat that we eat plays an important role in the development of heart disease. Diets high in saturated fats (found mostly in animal products such as meat and dairy foods) are related to greater levels of blood cholesterol which increases the risk of developing heart disease, while diets high in unsaturated fats (found in vegetable oils) are related to lower blood cholesterol which reduces the risk of developing heart disease. As a result, reducing intake of saturated fat has been a key dietary guideline to prevent heart disease for over 30 years. However, the effect of saturated and unsaturated fat intake on blood cholesterol levels (and thus risk of heart disease) is highly variable between people. Very little is known about the factors that determine this variability in blood cholesterol levels between individuals, and the different ways in which people process fat and cholesterol in the body.

An aim of this study is to increase understanding of the factors that determine the variability in the blood cholesterol response to different fat intake between people. This will enable us to tailor dietary advice to individuals who are at the highest risk of developing heart disease, and who stand to gain the greatest health benefit from specific advice about their dietary fat intake.

**What is the purpose of the study?**

The main purpose of this study is to measure variation in blood cholesterol levels in response to two diets containing different types of fats. Another aim is to identify those who show a cholesterol response (known as responders) to those who show little or no response (non-responders). Selected volunteers from this study will be given the opportunity to take-part in a similar follow-up study to determine in more detail the factors that determine the difference in blood cholesterol response to the type of fats eaten in these diets.

**Why have I been invited to take part in the study?**

You have been invited to take part in this study because you are a healthy, middle-aged man (30-65y), who can help us to understand how peoples’ blood cholesterol level respond to changing the type of fat eaten in the diet. The study is aiming to recruit a total of 75 men from the local area.

**Who can take part in this study?**

Suitable volunteers should have a body mass index of 19-32 kg/m2, be non-smokers, who drink no more than 14 units of alcohol (i.e. not more than 6 pints of beer or 6 small glasses of wine) per week, and who do not undertake regular vigorous exercise or fitness training on more than 3 occasions per week. Men who will not be able to take part in the study include those with diabetes, heart disease (previous stroke or heart attack), kidney, bowel or liver diseases or hormone abnormalities. We must also exclude men who are taking certain types of medication (e.g. drugs from your GP for high blood pressure, high blood fats, inflammatory conditions and depression), or dietary supplements, antibiotics in the last 6 months or who are actively trying to lose or who have lost more than 3kg of weight in the last 6 months. Volunteers who do not feel they can regularly consume butter/spreads, oil, dairy products and snack foods for the duration of the study will also be excluded.

It is up to you to decide whether you wish to participate in the study. We will describe the study and go through this participant information sheet, which we will then give to you. We will then ask you to sign a consent form to show you have agreed to take part. You are free to withdraw at any time, without giving a reason. The medical and lifestyle questionnaire that you have already completed over the phone or by e-mail will be used to find out if you have a medical condition or are taking medication that would exclude you from taking part in the study. If you are keen to take part after reading this information sheet, please contact Surrey Clinical Research Recruitment team on: **Freephone** **0800 269 847,** by email **crc-recruitment@surrey.ac.uk** or, if you have not done so already, register you interest on [**www.helpresearch.co.uk**](http://www.helpresearch.co.uk)

**Do I have to take part?**

No, you do not have to participate. There will be no adverse consequences in terms of your legal rights and your care, treatment, employment status, or education, if you decide not to participate or withdraw at a later stage. You can withdraw your participation at any time during the 8 week dietary intervention period without giving reason and without prejudice.

*If you withdraw from the study during the 8 week dietary intervention period, this will mean the following for your participation and data:*

Identifiable data already collected will be retained if you allow us to. Anonymous data and samples already collected will be used because we cannot trace the latter information back to you. There is the option to opt out of these in the consent form you complete prior to starting the study. No further data/tissue would be collected or any other research procedures would be carried out on or in relation to you.

**What will my involvement require?**

You will be asked to attend an initial screening visit of approximately 1 hour at the SCRC, which will allow us to ascertain if you meet the inclusion criteria of the study. If you meet the eligibility criteria, you will be invited to take part in a dietary intervention in which you will be asked to consume two, 4 week diets at home, for which you will be provided with a choice of supermarket foods. Before and after these diets, over a total of 8 weeks, you will be asked to attend 3 study visits, each lasting approximately 1 hour, at the SCRC. You will also need to visit the SCRC periodically to collect study foods during each 4 week diet, and to collect a pre-study visit meal, and containers to collect your \*urine and \*stool samples before each study visit (\* stool and urine samples are optional for this study).

**Screening visit:** You will be invited to come to the SCRC for an initial screening visit***. It is very important that you attend this visit, and all subsequent study visits, in the morning in an unfed, ‘fasted’ state (not having eaten or drunk anything, other than water, from 8pm the night before). You will also be asked to avoid any strenuous exercise and alcohol consumption in the 24 hours before your screening visit.*** Your consent for participating in this study will be taken first. After that, your weight, height, waist circumference and blood pressure will be measured before a small blood sample (~14 ml, volume equivalent to one tablespoon) is taken. The screening visit should take no more than 1 hour. Within two weeks of this visit you will be contacted by a member of the research team. You will be informed of the results of your blood tests which will test for anaemia, diabetes, kidney/liver function, and the levels of lipid (fat) in your blood. If these results show you are eligible for the study, you will be asked to confirm that you agree to continue to participate in the study. If these results show that you are not eligible to participate then we will tell you this. We will also notify your GP of your participation on the research study and provide a copy of your screening blood test results.

**Pre-study period:** After the screening visit, you will be asked to complete a 4-day weighed diet diary, so we can assess your usual dietary intake. When you return the diet diary, we will arrange the date of your first study visit and provide you with the containers to collect your urine and faecal samples in the days before your first study visit and instructions on how to collect these samples. The researchers will also provide you with a standard meal to consume on the evening before your study visit. In addition, we may ask you for some further information about the foods you have recorded in your diet diary. The appointment to drop-off your diet diary and collect the evening meal and sample containers should take no longer than 30 minutes.

**Diet interventions:** You will be asked to modify the types of fats in your diet for two, 4-week periods, by replacing your usual spreads, cooking oils, dairy products and snacks with the provided study foods (which will be familiar products that are available from the supermarket). The two diets will contain different types of fats and the second diet will follow immediately after the first, to give an intervention period of 8 weeks in total. During this period, you will be encouraged not to change other aspects of your diet, to exercise normally and to carry-out your usual activities. You will be supplied with 4 weeks of food at the beginning of the study, but can collect more foods from the SCRC if required. We will also give you advice on the amounts of replacement foods that we would like you to eat. You will be given a tick sheet to record the types and amounts of products you eat on a daily basis.

**Study visits:** The study involves making three ‘study visits’ to the SCRC, at baseline (week 0), at the end of diet 1(week 4) and diet 2 (week 8). At these visits you will be asked to come to the SCRC in an unfed, ‘fasted’ state (not having eaten or drunk anything other than water from 8pm the night after consuming the evening meal provided by the researchers). You will also be asked to avoid alcohol and any strenuous exercise in the 24 hours before each study visit (including the day of the study visit). During each study visit, your weight, blood pressure and body composition will be measured. Body composition will be measured using a tape measure (to measure waist/hip circumferences) and a bioimpedance machine, which measures the proportion of fat and muscle in your body by sending a very low, safe electrical signal from four metal electrodes through your feet to your legs and abdomen. After this, we will take a blood sample of 50 ml (volume equivalent to three tablespoons), a small portion of which will be stored for possible future related studies. You will also be asked to provide a brief 24 hour dietary recall, and to complete a physical activity questionnaire. At the first visit, we will also ask you to complete an ethnicity questionnaire, as lipid metabolism may be influenced by ethnic background.

At your first study visit (week 0) and second study visit (week 4), we will give you detailed instructions on how to incorporate the assigned cooking oils, spreads and snacks into your diet. You will also be given the opportunity to ask any questions or discuss any problems encountered with the study diets. Prior to each visit, you will be asked to collect a fasted spot urine sample (\*optional sample, taken the morning before your study day)) and a stool sample (\*optional sample, collected on the morning of your study day) into containers which we will provide you with. You should bring the containers with you when you visit the SCRC. Each study visit should take approximately 1 hour, after which, you will be provided with a light breakfast. You will also be asked to complete a 4-day diet diary on 3 occasions (pre-study period and during weeks 4 and 8). You will also be asked to self-report your body weight at the start and half-way through each 4-week dietary intervention period.

**What will happen to samples that I provide?**

The blood sample collected in the screening session will be used to measure levels of blood glucose, blood cholesterol, haemoglobin and markers of kidney and liver function. The blood, urine\* and faeces\* samples taken at the three intervention visits will be used to measure blood fats, markers of heart disease risk and fat intake, and changes in your gut bacteria. If requested, you will be supplied with your individual results within four months of completion of the study. The clinical significance of the screening results must be explained to you by your GP. \*optional

**Will any genetic tests be done?**

The genetic test that will be performed is to determine the type of a specific gene called apolipoprotein E (apoE genotype). The type of apo E gene varies between normal healthy people, and can influence how your blood cholesterol responds to different dietary fat intakes. A fact sheet about this genetic test will be given to you by the study researchers. Additional genetic tests for other relevant genes relating to lipid/cholesterol metabolism may be performed in the future, and you will be informed of the results of these. On the consent form, we will ask for your permission to store a portion of your blood, which will permit us to conduct these additional analyses. You are free to opt out of having your sample stored for possible future genetic analysis. This decision will not affect your participation in the study.

**What are the possible disadvantages or risks of taking part?**

Blood samples will be taken by research nurses, with ‘on-call’ medical cover provided throughout the study. The procedure for taking blood directly from a vein in your arm is routine. The volume of blood collected (50 ml, equivalent to three tablespoons), will cause no adverse effects, although on rare occasions a small bruise may result.

**What are the possible benefits of taking part?**

Although you will derive no further individual benefit from the study, the knowledge gained from this study will help us to understand how dietary fats influences blood cholesterol level, a risk factor for developing heart disease.

**What if there is a problem?**

Any complaint or concern about any aspect of the way you have been dealt with during the course of the study will be addressed; please contact Professor Bruce Griffin, Principal Investigator on 01483-689724 or b.griffin@surrey.ac.uk, in the first instance. You may also contact Professor David Blackbourn, Head of School of Biosciences & Medicine on 01483-68 6499 or d.blackbourn@surrey.ac.uk. The University has in force the relevant insurance policies which apply to this study. In addition, the Sponsor has made arrangements, in the event of harm where no legal liability arises, for “non‐negligent harm” claims. If you wish to complain, or have any concerns about any aspect of the way you have been treated during the course of this study then you should follow the instructions given above.

**Will my taking part in the study be kept confidential?**

Yes. Your details will be held in complete confidence and we will follow ethical and legal practice in relation to all study procedures. All of your personal data (e.g. name, contact details) will be handled in accordance with the UK Data Protection Act 1998, so that unauthorised individuals will not have access to them. The data and samples you provide will be anonymised (identified by means of a random code number allocated at the beginning of the study), and your personal data will be stored securely. You will not be identified in any reports/publications resulting from this research and those reading them will not know who has contributed to it.

**How confidential are the results?**

Information obtained from the study may be published in scientific journals, but only in the form of average values for the group; no results for the individual subjects will be published or presented in scientific meetings. Upon your request, we will inform you of the main scientific results of the study. Your GP will be notified regarding your research participation and your screening blood test results. If we discover any abnormalities of significance to your health at screening, we will inform you and your GP. Research data are stored securely for at least 10 years following their last access and project data for at least 6 years in line with the University of Surrey policies.

**Who is organising and funding the research?**

This research is a being conducted in association with the University of Reading and Imperial College London, and is funded by the Biotechnology and Biological Science Research Council (BBSRC), which is a government funded research council.

**Who has reviewed the project?**

This study has been looked at by an independent group of people, called an Ethics Committee, and has received a favourable ethical opinion from the University of Surrey Research Ethics Committee.

**What happens when the research study stops?**

On request, you will be sent your own set of blood results, and if interested, may request copies of any publications arising from the study. There may also be an opportunity to be selected for a follow-up study. This study will involve repeating the same two, 4 week diets in your home, and collecting blood, urine\* and stool\* samples for more detailed measurements (\* non-optional for this part of the study, as they are fundamental to the research project). These measurements would be made during two short visits (~0.5-1 h), and two longer visits (~9 h) to the SCRC, during which we would collect blood samples from a cannula.

**Expenses and Payments**

You will be remunerated for time with £120, on full completion of the third study visit, which takes place at the end of the 8 week dietary intervention period. You would also be renumerated if you agree to provide stool (£20) and urine (£10) samples, so the maximal you can expect to receive is £150. If you do not complete the study, we are unable to offer part payment.

**Thank you for taking the time to read this Participant Information Sheet.**

**RISCCI-1 Blood Cholesterol Response Study - Summary Flow Chart (Participant version)**

 **Initial Screening by Telephone or E-mail ~20 min**

- Medical and lifestyle questionnaire

 - Confirm if volunteer fits criteria for study

**2-3 weeks**

 - Researcher sends out participant information sheet

- Arrange screening visit by telephone or e mail when volunteer asks to take part

 **Screening visit ~1 hr**

- Researcher to answer any questions about study

- Consent form signed by volunteer and researcher

- Obtain a 14 ml fasting blood sample from volunteer, anthropometric and blood pressure measurements

- Measurements of height, weight, waist & hip circumference and body composition

- Breakfast

**2 weeks**

**Pre-study run-in period**

- Complete a 4 day diet diary of habitual diet

**Pre-study day visit ~30 min**

- To return diet diary

- To collect urine & faecal containers if applicable\* and receive instruction booklet. -Collect pre-meal to consume before first study visit (week 0) (\*optional samples)

- Arrange date for 1st visit

**Study visits 1 and 2 (weeks 0 (baseline) and 4) ~1 hour**

- To give a fasted blood sample (50 ml) and return your fasted spot urine sample (from morning before study visit, and faecal sample (from morning of study day).

- Blood pressure and anthropometric measurements performed

- To be advised on assigned intervention diet for the next 4 weeks

- During week 4 complete a 4-day diet diary

- 30 min pre study day visit to collect pre-meal and urine/faecal containers.

 **Study Visit 3 (Week 8, End of study) ~1 hour**

- To give a fasted blood sample (50 ml) and return your fasted spot urine sample (from morning before study visit, and faecal sample (from morning of study day).- Blood pressure and anthropometric measurements performed

- During week 8 complete a 4-day diet diary

**8 weeks**

 **Contact details :**

 Department of Nutritional Sciences (Macronutrients & Metabolic Medicine)

 *(*\* initial contacts for appointments and any other study issues)*:*

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