



UNIVERSITY OF LEEDS

**Human Appetite Research Unit
Institute of Psychological Sciences**
University of Leeds
Leeds LS2 9JT

Telephone: 0113 343 5753 or 0113 343 8073
Fax: 0113 343 5749

PARTICIPANT INFORMATION SHEET

Leeds Women's Wellbeing Study: A study to compare the effects of two 12-week healthy eating interventions on body weight, body composition, appetite control, biomarkers of health and wellbeing in overweight women

We would 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. Please take time to read the following information carefully and talk to others about the study if you wish. One of our team is available to go through the information sheet with you and answer any questions you have. Please take your time to decide whether or not you wish to take part.

Part 1 tells you the purpose of this study and gives a summary of what will happen to you if you take part.

Part 2 gives you more detailed information about the conduct of the study.

Ask us if anything is unclear or if you would like more information.

PART 1

What is the purpose of the study?

This study has been designed to compare the effects of two different healthy diets on the overall wellbeing of women over a period of 12 weeks. The results of this study will be used to advise women on the most effective dietary changes that they could make to improve their health and wellbeing and to maintain a healthy body weight. Women who are overweight and in good health and who do not have a cardiac pacemaker fitted can take part.

Both study diets will encourage healthy eating, but are not 'fad' diets and will not involve the use of any supplements or medicines. You will be asked to follow one of the two study diets. You will be encouraged to increase your consumption of healthy foods and provided with recipes and commercially available foods to help you do this. Our study dietitian will give you advice on getting started on the diet and will support you with dietary advice during the 12 week diet. In order to provide a fair comparison of the effects of the two diets, you will only be given information about the diet we ask you to follow. It is important that this is the only diet you follow during the 12-week period. However, at the end of the study we will offer you

full information about the diet that you did not follow, to give you the opportunity to try this out yourself.

Some results from the study will be used towards an educational qualification by a member of the research team.

Study Summary

The study will be carried out in The Human Appetite Research Unit (HARU) in the Institute of Psychological Sciences, University of Leeds under the supervision of Professor Louise Dye and Dr Clare Lawton.

The duration of the study is 16 weeks for each participant although the whole study will run for approximately 12 months (with over 100 women taking part). During the first 4 weeks, we will assess your current health, wellbeing and dietary habits. You will be asked to complete a 7-day food diary and a short wellbeing diary each day (more details are given in Part 2). If you are eligible to continue you will then start on one of the 12-week diets.

You will need to visit our research unit 6 times. There will be 4 short visits (each of which should last no more than 1 hour) and 2 longer visits (test meal days, each lasting about 8 hours). During each visit we will measure your body weight, body composition and waist circumference. We will also ask you to complete some questionnaires about your eating habits, feelings about your body shape and sleep quality. At each visit our study dietitian will give you some dietary advice, recipes and other tips to help you follow the study diet. We will also give you some commercially available foods to consume at home. You will be asked to complete a 3-day food diary 4 times during the 12-week diet and a short wellbeing diary each day (more details are given in Part 2). On 2 of the study visits (12 weeks apart) we would like to take some blood samples from you. These will be taken by qualified staff at the HARU and at Leeds General Infirmary (LGI). More details about what is involved at each study visit are provided in Part 2.

Why have I been invited?

You are invited to participate in the study because you are a woman aged between 18-48 years, reporting good health and a Body Mass Index (BMI) of between 26-35kg/m² (overweight and above). BMI is a number calculated from your weight and height that provides a reliable indicator of body fatness for most people. It is calculated by dividing your weight in kilograms by the square of your height in metres.

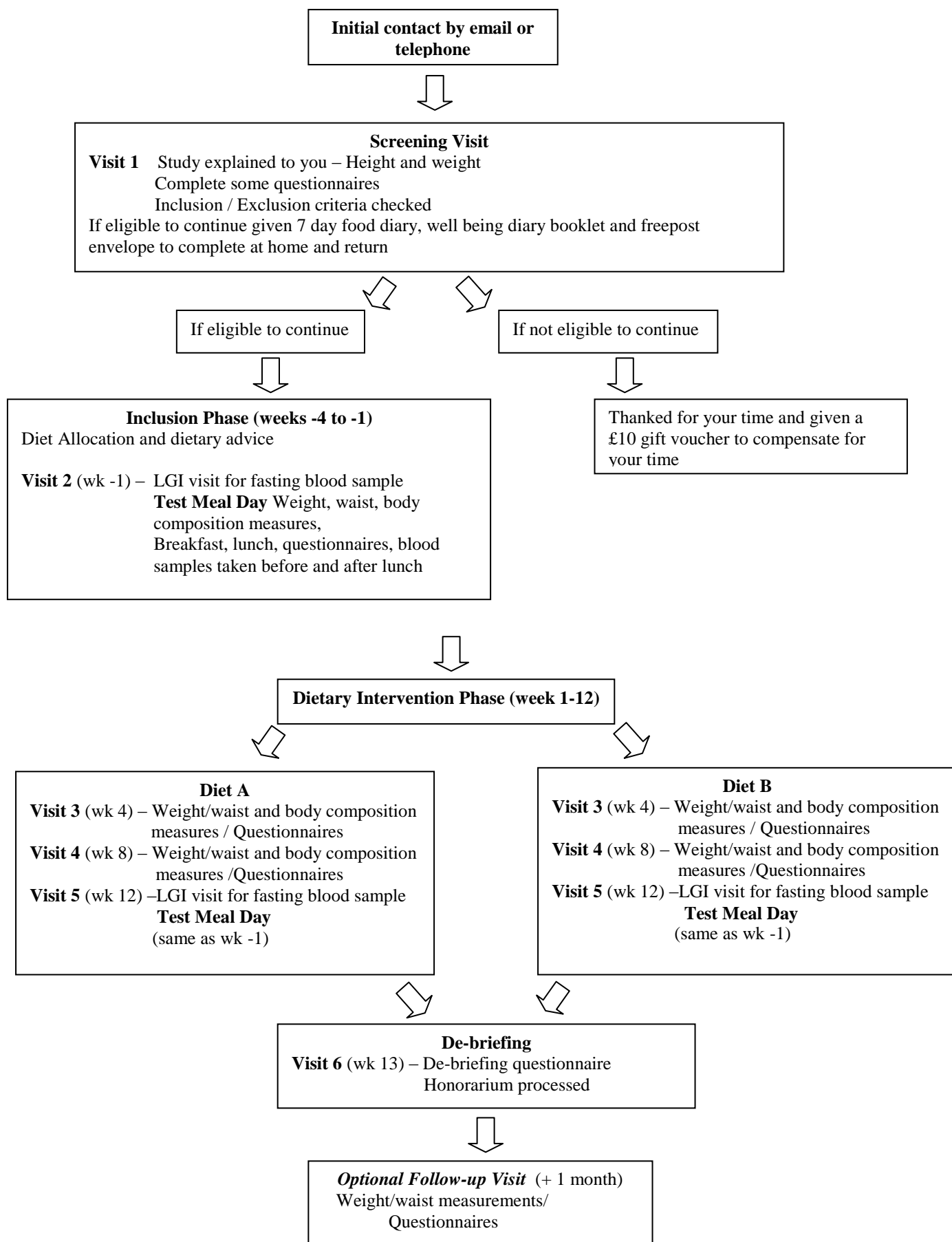
Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason.

What will happen to me if I take part?

This study is a randomized controlled trial. This means you will be randomly allocated into one of the two diet groups. Allocation will be decided by chance – rather like tossing a coin. There is an equal chance that you will be put into either of the two diet groups. Neither you nor the researcher will be able to choose which of the diet groups you are put into. However, after you have completed the study you can have access to the information about the other diet if you wish. If you do decide to participate in the study and remain eligible you will need to follow the diet prescribed to you for a period of 12 weeks and attend the HARU six times. A diagram of the study schedule is provided on page 3 of this information sheet.

A diagram of the study schedule



What do I have to do if I agree to take part?

Participating in a research study can be an inconvenience to your daily life. When considering taking part you should think carefully about the time commitments and responsibilities required by the study. For two of your visits (test meal days) you will be asked to attend the HARU for about 8 hours and you should consider any other commitments before agreeing to do this. However, we will try to be flexible and accommodate your schedule as far as is possible. You must carefully follow any instructions given to you concerning the study. It is important that you follow the advice given to you by the research team.

What are the possible disadvantages and risks of taking part?

The risks associated with cannulation and blood sampling include; infection, fainting, bruising and discomfort. All researchers taking blood samples will be fully trained, competent, first aid trained and will take every step to minimise any of the risks associated.

What are the possible benefits of taking part?

Participants, who follow either of the study diets for 12 weeks duration, should improve their nutritional and health status. Taking part in this research study may also improve your understanding of what is a healthy diet and how to maintain it. Taking part may also lead to modest weight loss and improved feelings of general wellbeing. The results from the study may provide important new information regarding the effects of the two study diets on the health and wellbeing of women of your age and BMI.

What if something goes wrong?

Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. The detailed information on this is given in Part 2.

Will my taking part in the study be kept confidential?

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. The details are included in Part 2.

Will I receive anything for taking part?

Upon completion of the study, a payment of £120 (taxable) will be paid to each participant to compensate you for the time that you have invested in the study. Participants will also receive a £10 gift voucher for completing the inclusion phase. If you decide to withdraw before completing the study you will be compensated in accordance with the number of visits that you have completed (at the rate of £20 per visit).

Thank you for reading Part 1.

If the information in Part 1 has interested you and you are considering participation, please read the additional information in Part 2 before making any decision.

PART 2

What will happen to me if I take part?

Detailed information about each study visit is provided below:

Screening Visit (Visit 1)

If you choose to take part you will be asked to come to the HARU for a screening visit which should take no more than an hour. We will explain the study procedures to you and show you round the unit. You will be free to ask any questions you may have about any aspects of the study. After signing the informed consent form (giving your consent to take part in the study), your height and weight will be measured by a researcher (to accurately calculate your BMI) and you will be asked to complete three questionnaires, one to assess your general health and to check that you meet the study inclusion criteria, one to assess your usual eating habits and one to assess your eating attitudes. If you do not remain eligible at this stage you will be informed of this and thanked for your time.

If you do remain eligible we will ask you to complete a 7-day food diary record at home and to post this back to us as soon as possible (a freepost envelope will be provided). The study dietitian will explain how to fill in the food diary. We will also ask you to complete a short wellbeing diary (asking how you have felt that day) every day (for approximately 4 weeks). This will only take a few minutes each evening. You should start completing the wellbeing diaries on the day that you start completing the food diary and then continue completing them every day until we re-contact you. The wellbeing diaries will be provided in the form of a small weekly booklet each containing seven pages (one for each day). We will provide you with freepost envelopes so that you can return your completed wellbeing diary booklets to us on a weekly basis. When we have analysed your food diary we will be able to confirm your full eligibility to take part in the study. If you remain eligible we will contact you to arrange your next study visit. If you are not eligible to continue at this stage you will be informed of this, thanked for your time, and sent a £10 gift voucher to compensate you for your time and effort.

Test Meal Days (Visits 2 and 5)

If you are eligible to participate in the 12-week dietary intervention you will be asked to attend the HARU to be briefed on your 12-week diet plan by the study dietitian. You will be given detailed information on the diet we would like you to follow, along with recipes to try, and given some commercially available foods appropriate to your diet. You will also be given a set of scales, measuring spoons and a measuring cup to keep and to enable you to measure quantities and help you follow the recipes. The dietitian will give you advice on getting started on the diet and will support you over the next 12 weeks. This information will be provided on the first of your two test meal days.

On both test meal days you will also be required to consume a standard breakfast (cereal and milk plus tea or coffee) followed by a test meal (a moderate portion of ice cream) at lunch. The first test meal visit will take place in the week before you start the diet (week -1) and the second test meal visit will take place in the final week of the diet (week 12). Each test meal visit runs from approximately 8.30am to 4.00pm.

On the day before each test meal visit we will ask you to have nothing to eat or drink (except water) after 10pm. On the morning of each test meal day, after having had an overnight fast, you will need to visit the Phlebotomy Outpatient Clinic at Leeds General Infirmary (LGI) to have a fasting blood sample taken (the amount of blood needed will be less than two

teaspoons). You will be given a study request card to show the staff at LGI. This blood sample will be used to measure your fasting levels of glucose, insulin, cholesterol (total cholesterol plus LDL and HDL), triglycerides (blood fats) and leptin (an appetite hormone which varies with body weight).

After the blood sample has been taken, you will need to come to the HARU before you eat or drink anything (except water). At the HARU we will measure your weight and waist circumference. We will also measure your body composition in two ways. The first method uses a technique called bioimpedance and requires you to stand on a machine, dressed but in your bare feet and to hold two hand-grips. This machine measures the amount of fat and muscle you have in your body by passing a small electric current through your body and measuring the resistance. This is completely safe, provided that you do not have a cardiac pacemaker fitted, and you will not be able to feel anything. The bioimpedance machine in the HARU is very similar to those which you might find in a commercial gym. The second method uses a machine called a 'BodPod'. This machine measures the amount of fat and muscle you have in your body by air displacement. For this to be measured you will be required to wear a swimming costume (or other very tight-fitting clothing) and sit in the carbon fibre 'BodPod' whilst relaxing and breathing normally for 5 minutes. We will show you the 'BodPod' when you come for screening.

Please remember to bring some tight-fitting clothing with you to this visit – a swimming costume is ideal. We will provide dressing gowns.

After having your body composition measured you will be asked to eat the breakfast provided. We will also ask you to complete four questionnaires; two questionnaires to assess your usual eating behaviour; one questionnaire to assess your sleep quality and one questionnaire on your feelings about your body shape. On your second test meal day (Visit 5, week 12) we will also ask you to complete a further questionnaire to assess your eating habits.

Before lunch on both test meal days, you will have a cannula fitted into a vein in your arm, in order to give 5 small blood samples (5mls per sample – equivalent to one teaspoon per sample) at specified times, before (1 sample) and after lunch (4 samples). These blood samples will be used to measure appetite hormones. At the same time as blood sampling we will also ask you to complete some ratings of your appetite (e.g. hunger). You will be taken to a room where a research nurse or a trained researcher will fit the cannula and take the first blood sample. Cannulas are designed to stay in the arm in order to take multiple samples therefore minimising the number of times you need to have a needle put in. The cannula (a flexible tube, not a needle) will be fixed securely so you can move your arm and still move around as normal. You are advised to wear comfortable clothing which allows access to the arm (e.g. a short sleeved shirt/top).

You will be asked to consume all of the test lunch after which the four blood samples will be taken (via the cannula) at 30 minute intervals for a period of 2 hours. Each blood sample is about a teaspoon and the total amount taken (25ml) is less than a quarter of what you would give if you are a blood donor. After the last of these measurements, the cannula will be removed by a research nurse or a trained researcher. Cannulation is usually a painless procedure, however there may be some minor discomfort or bruising at the cannulation site.

Before you leave the HARU on the first test meal day (Visit 2) we will provide you with food products tailored to the diet group to which you are randomised. The study dietitian will give you some dietary advice, recipes and other tips to help you follow the diet. We will also provide you with a 3-day food diary and ask you to complete and return this the following week. The 3-day food diary should be completed on 2 weekdays and 1 weekend day (ideally Thursday to Saturday or Sunday to Tuesday). You will be provided with more wellbeing diary

booklets so that you can continue to complete these every day for the duration of the study. You will then be free to leave the HARU.

Before you leave the HARU on the second test meal day (Visit 5) we will provide you with a 3-day food diary and ask you to complete and return this the following week. The 3-day food diary should be completed on 2 weekdays and 1 weekend day (ideally Thursday to Saturday or Sunday to Tuesday as before). You will be provided with another wellbeing diary booklet if required and we will ask you to complete a page each day for the duration of the study (12 weeks).

Interim Visits (Visits 3 and 4)

On two occasions during the diet (weeks 4 and 8) you will need to visit the HARU for additional weight, waist and body composition (using bioimpedance) measurements. We will also ask you to complete two questionnaires, one to assess your sleep quality and one on your feelings about your body shape. You will also be provided with more food products and dietary advice and a further 3-day food diary to be completed and returned the following week. More wellbeing diary booklets will be provided at Visit 3 (for completion in weeks 5 to 8) and at Visit 4 (for completion in weeks 9 to 12). Each of these visits should not take more than an hour.

De-briefing Visit (Visit 6)

On completion of the study, after returning the last food diary and wellbeing diary booklets, you will be asked to complete a de-briefing questionnaire. If you wish, you will be given the details of the diet that you did not follow. This visit will take about 30mins.

Optional Follow-up Visit

One month after completion of the study you will be invited to an optional follow-up visit of about 30mins duration. If you choose to attend this visit, you will be weighed and have your waist circumference measured. We will also measure your body composition using the bioimpedance method. You will be asked to complete five questionnaires, one questionnaire to assess your eating habits, two questionnaires to assess your usual eating behaviour; one questionnaire to assess your sleep quality and one questionnaire on your feelings about your body shape.

What if something goes wrong?

In the unlikely event of a study-related bodily injury or harm, signing the consent form will protect your rights to compensation. If you wish to make a claim for compensation then please ask the researchers for information on how to proceed. If you are harmed due to someone's negligence you may have grounds for legal action, but you may have to pay for this. Regardless of this, if you wish to complain or have any concerns about any aspect of the way you have been approached or treated during the course of this study you should contact the principal investigators (Professor Louise Dye or Dr Clare Lawton) who will investigate your complaint. If you remain unhappy and wish to complain formally, this can be done through the University complaints procedure.

Will my taking part in the study be kept confidential?

All information that is collected from you during the course of the study will be treated in the strictest of confidence at all times and will only be used for the purposes of this research. After initially completing the consent form and recruitment questionnaire you will be given a unique study identity code. All data will then be recorded safely using this code and not your name. The link between your name (and other personal data) and your unique study identity code will be maintained and stored securely in the HARU at The University of Leeds and will only be accessible to the University research team. Anything that you say will be treated in confidence and no names will be mentioned in any reports of the study. Some results from the study will be used towards an educational qualification by a member of the research team. Individuals will not be identifiable from any details in reports, presentations or scientific publications based on the results of the study. With your permission, we will inform your GP that you are taking part in this study.

What will happen to the results of the research study?

Once all participants have completed the study, the information obtained will need to be collected and analysed before any results are published. This is likely to take at least one year to be finalised. If you would also like to know the results of the study, the research team will be able to give this information to you when it becomes available. You will not be identified in any report or publication.

What will happen to the blood samples I give?

The blood samples that you give will be separated into plasma or serum and will be analysed by our collaborators at Leeds General Infirmary and Imperial College London. Any unused plasma or serum and all the red blood cells will be destroyed. There will be no genetic testing carried out on the samples. Your samples will only be labelled with your unique study identity code, date and time so you will not be identifiable from these samples. The researchers analysing your blood samples will not have access to the link between your name and your unique study identity code.

What will happen if I don't want to carry on with the study?

If you decide at any time that you no longer wish to take part in the study, you will be free to withdraw without having to give a reason for this. If you decide to drop out before completing the study you will be invited to a final visit at which we would like to obtain some final data from you (i.e. your body weight, composition and waist circumference). Attendance at this final visit is entirely optional and you may decline to attend without having to give a reason. We would like to use the data and the blood samples that you provide, up until the point at which you drop out but we will give you the opportunity to withdraw your data and samples from the study analysis if you so wish.

Who is organising and funding the research?

The research is a collaboration between the HARU, University of Leeds and colleagues at Leeds General Infirmary and Imperial College London. The research will be carried out with financial support from a food manufacturing company.

Who has reviewed this study?

All research is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given a favourable opinion by South Humber NHS Research Ethics Committee.

Who do I contact for further information?

If you want further information about this study or information regarding this research or in the event of an emergency or if you need extra advice please contact one of the following researchers:

Diana Camidge (d.c.camidge@leeds.ac.uk; 0113 3435753)

Iria Myrissa (k.myrissa@leeds.ac.uk 0113 3435753)

Fiona Croden (f.c.croden@leeds.ac.uk; 0113 3435753)

Dr Clare Lawton (c.l.lawton@leeds.ac.uk; 0113 3435741)

Professor Louise Dye (l.dye@leeds.ac.uk; 0113 3435707)

Finally, thank you for taking the time to read this information.

INFORMED CONSENT FORM

**Please
Initial**

Leeds Women’s Wellbeing Study: A study to compare the effects of two 12-week healthy eating interventions on body weight, body composition, appetite control, biomarkers of health and wellbeing in overweight women

1. I confirm that I have read and understood the Participant Information Sheet dated 17th March 2010 (version 2) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. _____
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. _____
3. I have been informed that two study visits will involve having a cannula fitted by a research nurse/trained researcher. I agree to provide five blood samples over a period of 2 hours. I have been informed that these samples will be stored and analysed for appetite hormones. I also agree to provide a fasting blood sample for measuring glucose, insulin, triglycerides and leptin on each of these visits. _____
4. I understand that data collected during the study, may be looked at by individuals from the HARU, collaborators on the research project and the University of Leeds for the purposes of research governance. All data will be anonymised with the exception of the recruitment questionnaires containing personal data. I give permission for these individuals to have access to my data. _____
5. I agree to my GP being informed of my participation in the study _____
6. I agree to take part in the above study _____

Participant’s name..... Date ____ / ____ / ____

Signature

Researcher’s name.....Date ____ / ____ / ____

Signature