

**Wellcome Trust Clinical Research Facility**

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**Reference Measurements for Studies of Metabolism**

**Participant Information Sheet**

**Overnight Calorimeter Visit, with GEM and MRI/S**

Dear

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Talk to others about the study if you wish.

- Part 1 tells you the purpose of the study and what will happen if you take part.
- Part 2 gives you more detailed information about the conduct of the study.

Please ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

**Part 1**

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

We are studying several disorders that may influence energy expenditure, body composition, hunger, appetite and satiety. These currently include thyroid hormone disorders, severe insulin resistance, and obesity. Each area of study requires data from unaffected individuals for comparison purposes. We would like to make measurements in a broad range of healthy people to build up a pool of data against which we can compare data from our study patients. The study is not testing involve any experimental treatments or procedures. Your participation would contribute to the pool of reference data.

**Why have I been chosen?**

You have been chosen because you fit the criteria we need to compile pool of data from healthy men and women, spanning an age range 17 to 65 years, and including body weights up to 130kg or 20 stones. We think that your participation would provide a valuable contribution to our data pool.

## Do I have to take part?

No. It is up to you to decide whether or not to take part. If you do, you will be given this information sheet to keep and will be asked to sign a consent form. You are still free to withdraw at any time and without giving a reason.

## What will happen to me if I take part?

1. Participating in this study requires one visit to the Wellcome Trust Clinical Research Facility at Addenbrooke's Hospital.
2. Your visit would last from mid afternoon on day one until 12.00pm the following day. It will involve an overnight stay.
3. During your stay we would provide an evening meal and breakfast.
4. At the start of your visit we would ask for your written consent to participate in the study. We would also appreciate your consent to write to your GP to tell him/her that you are participating in the study. We would not seek any medical information from your GP.
5. During the afternoon of the first day we would make measurements of your body composition – the amount of lean, fat and bone in your body. These measurements are made in two ways. The first uses a combination of two different DXA scanners, a Prodigy DXA and an iDXA. The measurements involve a small amount of X-ray, no more than the amount you receive from the atmosphere in 5 days. The measurements take between 10 and 20minutes, during which you would lie on the scanner bed as the scanner arm passes over you. The second measurement is made by the BOD POD. This is an egg-shaped capsule in which you would sit for about 5 minutes whilst we measure the volume of your body. Results of the measurements are available immediately and we would share these with you. Leaflets describing these measurements are provided with this letter. In addition we will perform an ultrasound scan to see how much fat you have within the abdominal cavity. For this you will lay on a couch, some gel will be applied to your stomach and an ultrasound probe will be placed onto the skin so that a clear image is displayed. Importantly the ultrasound scan will not image anything (e.g. your internal organs) other than your body fat, so we will not obtain any diagnostic information from this procedure.
6. During your first visit we would like to measure your total body water content. This measurement is made by asking you to drink some water which has a raised concentration of a heavy form of water. Before giving you the drink, and at 4, 5 and 6 hours after the drink, we will ask you provide a sample of saliva in which we will measure the concentration of the heavy water. Please be assured that the heavy form of water is naturally present in all water, and is not radioactive.
7. Following this, you may be taken to the Sports and Exercise Medicine Unit within the hospital for your maximum leg strength to be measured. To assess this, we would seat you in a chair designed specifically to measure strength. We would attach your lower leg to a weighted lever and ask you to push against this as hard as possible. You would have 2 practice attempts to familiarise yourself with the technique and then 2 real attempts. This allows us to calculate 10-15% of your maximum leg strength. This is the weight we would attach to your leg for the exercise in the MRI scanner the next day.
8. We would measure your energy expenditure during a stay of 12 hours in a calorimeter room. This period starts at 20.00 on the first day of your visit. The room is like a small bed-sitting room, comfortably furnished and with TV, DVD, Video, and computer to pass the time. During your stay in the room we would ask you to follow a programme of activities which includes defined times for meals, and sleep. A leaflet describing the calorimeter room is provided with this letter.
9. During your time in the calorimeter room we would like you to wear a heart rate and movement monitor. This is a small disk, about the size of a 50p coin, which attaches to two self-adhesive electrodes placed on your chest. An additional movement sensor is worn like a small wristwatch. When these have been fitted we would ask you to

undertake a brief period of mild exercise, such as stepping or exercising on a treadmill, to calibrate the devices and measure your fitness.

10. We would retain samples of your urine from which we would analyse the amount of protein your body uses, and the levels of catecholamines - chemicals involved in the control of energy expenditure
11. In the morning we would wake you at 7.00. We would ask you to lie still on the bed, but to remain awake, whilst we measure your Basal Metabolic Rate (BMR). We would place a transparent canopy over your head and shoulders and draw the air you breathe out away from this. We analyse this air and calculate the amount of energy your body expends in the resting, "basal" state.
12. After measuring your BMR we would measure your body temperature.
13. Before you rise, we would take a sample of blood which we would analyse for chemicals and hormones related to your metabolism, such as blood sugar, blood fats, cholesterol, insulin and thyroid hormones.
14. Finally, we would perform a magnetic resonance imaging/spectroscopy (MRI/S) scan to measure muscle or liver glycogen/abdominal fat or energy (ATP) levels. This takes place in another part of the hospital and you would be taken there using a wheelchair to avoid any physical activity of the legs prior to your scan. This measurement involves lying in a scanner (a tube-like structure) for approximately 1hr. You would then have a short break, followed by a second scan involving a small amount of exercise. We would ask you to lift your leg up and down with a light weight resting on the ankle. This scan lasts around 20 minutes with 2 minutes of exercise. It carries no health risks, but some people may feel claustrophobic in the scanner. As with all our investigations, you are free to decline or withdraw from this test if troubled by claustrophobia. MRI/S has no known long term adverse health effects. A leaflet describing the MRI/S scan is provided with this letter.

Expenses and Payments - We would reimburse you for your travelling expenses and on completion of the study we will arrange for you to receive a "thank you" payment of £40.

### **What do I have to do?**

We would like you to visit the Clinical Research Facility before agreeing to participate so you can see the area where you would stay and meet some of the staff, so we can describe the research in more detail, and so we can answer any questions. We would then like you to come to the Clinical Research Facility for a single, overnight study visit on the day and at the time we agree. We would ask you to eat normally and avoid alcohol during the 24 hours before your visit. During your visit we would like you to remain within the Clinical Research Facility until around 12.00 on the day after your arrival. We would like you to eat the evening meal that we provide (we would discuss your food preferences before you come, and would try to accommodate them). We would provide drinks when you wish, but these would be free from caffeine. We would like you to undergo the measurements of body composition, and resting metabolic rate and provide a single blood sample as described above.

### **What are the possible disadvantages and risks of taking part?**

Your GP will not be routinely informed if your participation in this study has been as a normal volunteer. In this study we will only be looking at a very small area of your leg, and hence the chances of seeing anything abnormal are very small. However, you must be aware that in this very unlikely event you will be appropriately counseled and that you will be referred to the appropriate specialist in consultation with your GP if that is what you would like. Such early detection has the benefit of starting treatment early but, in a small number of cases, may have implications for future employment and insurance.

No new medications or medical devices are being tested in this research. The BOD POD measurement requires participants to wear minimal and close fitting clothing such as a swimming costume. Though the BOD POD and the Basal Metabolic Rate canopy are largely

transparent and provide a panoramic view, some participants could find these claustrophobic. The blood sample would be taken by a trained person and should cause nothing more than mild local discomfort, and possibly a little local bruising.

### **Ionising Radiation**

During the DXA scan, we will discuss the type of scan(s) you will undergo. Different scans generate different amounts of radiation. All are deemed low compared to standard hospital scans (chest X-Ray is equivalent the amount you receive in five days of background atmospheric exposure.. You may only be asked to have a whole-body scan which is equivalent to less than a day of atmospheric radiation or asked to have a range of scans on your hip, spine and forearm. These scans are still low in radiation compared to standard hospital X-rays, equivalent to five days of atmospheric radiation.

### **For Women**

When you attend for the study we would ask you to confirm that you are not pregnant. If you are in any doubt we would provide offer a pregnancy test. We are not permitted to make any investigation using X-ray, however small the dose, if a woman is pregnant.

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

There are no benefits to you from taking part, though we will happily share with you the results of measurements made during your stay.

### **What if there is a problem?**

Any concerns or complaints about which arise from your taking part in the study will be addressed. Detailed information on this is given in part 2.

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

Yes. All information about your participation in this study will be kept confidential. The details are included in Part 2.

### **Contact Details**

If you would like any further information before or during the study please contact Metabolic Research Area at the NIHR/Wellcome Trust Clinical Research Facility. Their direct telephone number is 01223 596077. There is an answer phone if you call out of hours. A message may also be left with reception on 01223 596055.

### **This completes Part 1 of the Information Sheet.**

Thank you for reading about this study. If the information in Part 1 interests you and you are considering participation then please continue to read the additional information in part 2 before making any decision.

## **Part 2**

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

If you withdraw from the study we would like to retain any useable data and sample analyses that we have obtained up to the time of your withdrawal. We will confirm with you that you are happy for us to do this. If you are not, we will destroy the data and samples.

### **What if there is a problem?**

Complaints:

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. You can contact the researchers on 01223 596077 or 01223 596055. If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from Addenbrooke's Hospital Patient Liaison Service on 01223 216756.

Harm:

In the event that something does go wrong during the research study there are no special compensation arrangements. If you are harmed and this is due to someone's negligence then you may have grounds for a legal action for compensation against Addenbrooke's Hospital but may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

### **Will my taking part in this study be kept confidential?**

If you join the study, some parts of your medical records may be looked at and the data collected for the study will be looked at by authorised persons involved in running and analysing the research. They may also be looked at by authorised persons from the Addenbrooke's Hospital Research and Development Department to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant and nothing that could reveal your identity will be disclosed outside the research site.

Procedures for handling, processing and storage and destruction of data are compliant with the Data Protection Act 1998.

Data will be stored securely by Laura Watson or his appointed deputy or successor. Data will be held, processed and reported anonymously through an identity code.

Data will be retained for a period of up to 15 years.

MRI/ MRS scan data will also be stored in the Wolfson Brian Imaging Centre (WBIC) where we do the scans. The data will be stored for 10 years and your identity will be linked to the scans and accessible to WBIC staff.

Data will be used to provide as a reference from healthy people when we are studying people with disease or disorders. It may be used as a reference for several different studies both currently and in the future.

### **Will my GP be informed of my taking part?**

With your consent, we will advise your GP that you are taking part in this study. We will not ask you GP for any information. We will inform your GP of any concerns about your health which come to light during the study.

**What will happen to any samples I give?**

Blood samples will be analysed shortly after your study visit for chemicals related to your metabolism. Samples will not be retained once valid analysis results have been obtained. If any results are outside the normal range we will advise you and discuss the implications with you, and will then advise your GP.

**What will happen to the results of the research study?**

The results will be used as a normal reference when we study people with diseases or disorders of their metabolism, for example diabetes, obesity and thyroid disorders. The results will become part of the analysis of these studies and will be published in scientific journals and/or presented at scientific meetings. When data is published or presented it will be completely anonymous.

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

The study is organised by medical doctors and researchers at Addenbrooke's Hospital. It is funded by a grant from the Wellcome Trust and sponsored by Addenbrooke's Research and Development Department.

**Who has reviewed the study?**

This study has been given a favourable ethical opinion for conduct in the NHS by the Cambridge Research Ethics Committee, an advisory committee to the Norfolk, Suffolk and Cambridgeshire Strategic Health Authority.

**Thank you.**

We would like to thank you for considering taking part in our research and for taking the time to read about this study. If you now go on to participate in the study you will be given a copy of this information sheet and of your signed consent form to keep.