

Reference Measurements for Studies of Metabolism

Participant Information Sheet

Measurement of Basal Metabolic Rate and Body Composition

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, from the age of 17 and upwards, 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 the late afternoon of one day until the morning of the next. It will involve an overnight stay.
3. During your stay we would provide an evening meal and breakfast. Eating behaviour, e.g. rate of eating, may be monitored using the Universal Eating Monitor. This is a weighing scale attached to a computer. Food is served from a plate placed on the weighing scale.
4. At the start of your visit we would ask for your written consent to participation 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. Either during the afternoon of the first day or the following morning 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 iDXA. These will measure whole body fat, lean and bone in your body plus hip, spine and forearm bone density. The measurement involves a relatively small amount of X-ray, no more than the amount you receive from the atmosphere in 5 days. A measurement takes between 20 and 30 minutes, 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. 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. Whilst you are asleep at night 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.
8. In the morning we would wake you between 7.00 and 8.30. 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.
9. After measuring your BMR we would measure your body temperature.
10. 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.
11. Finally, we would perform a magnetic resonance imaging/spectroscopy (MRI/S) scan to measure muscle or liver glycogen/ fat or energy (ATP) levels. This measurement involves lying in a scanner (a tube-like structure) for up to 90 minutes. 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. The scanner can be noisy, but you will be provided with protective ear-phones to wear during the scan. MRI/S has no known long term adverse health effects.

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 £20 and an additional £20 if you choose to undergo MRI/S.

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 9:30 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 measurement and provide a single blood sample as described above.

What are the possible disadvantages and risks of taking part?

There is a chance of less than 1:100 that your MR scan may show a significant abnormality of which you are unaware. In such circumstances, you will be appropriately counseled by one of the study doctors. You will be referred to the appropriate specialist in consultation with your General Practitioner 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 scans, the total amount of X-ray given would be no more than you normally receive from the atmosphere in five days, and each scan is comparable to the extra X-ray received during a European air flight. A standard chest X-ray you may receive in hospital is also equivalent to 5 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 the 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 in by Laura Watson or her 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 Brain 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.