

NIHR/Wellcome Trust Clinical Research FacilityACCI Level 5, Box 127
Addenbrooke's Hospital
Hills Road
Cambridge CB2 2QQ
01223 596055**Parent/guardian Information Sheet**

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Metabolic Reference Measurements in Childhood and Adolescence**Introduction**

Your son/daughter is being invited to take part in a research study and because they are 16 years of age and under we would like to ask you to consent on their behalf for them to join the 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 your child takes 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 metabolism, which is the term that describes how the body regulates energy expenditure, body composition, hunger, appetite and satiety. These disorders 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 does not involve any experimental treatments or procedures.

Your child's participation would contribute to the pool of reference data.

This study is also being undertaken as part of a PhD project.

Why has my child been invited?

Your child has been invited because they fit the criteria we need to compile pool of data from healthy boys and girls, spanning an age range from 6 to 16 years. We think that their participation would provide a valuable contribution to our data pool.

Does my child have to take part?

No. It is up to you and your child 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 and your child are still free to withdraw at any time and without giving a reason.

What will happen to my child if they take part?

1. Participating in this study requires one visit to the NIHR/Wellcome Trust Clinical Research Facility at Addenbrooke's Hospital.
2. The visit would be discussed with you before hand to establish how much time is convenient for you and your child to stay with us. We will also run through some screening questions with you over the phone including food preferences. The full protocol starts after school on day one until midday the following day. It will involve an overnight stay and a 30 min MRI scan. However, we will tailor the visit to you and your child, for example to avoid missing school the next morning your child could return in the school holidays for an MRI scan.
3. During the stay we would provide evening meals and breakfast for you and your child.
4. At the start of the visit we would ask for your written consent and your child's written assent to participate in the study. We are continuously developing new measures for metabolic research and would like to be able to contact you in the future to offer your child the opportunity to undergo new measurements under this study. This will be discussed with you during the consent process.
5. During the afternoon of the first day we would make some measurements of your child's body composition – the amount of lean mass, fat and bone in their 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 very small amount of X-ray, no more than the amount you receive from natural background radiation in a day. The measurements take 10 minutes, during which they would lie on the scanner bed as the scanner arm passes over them. This gives images of their skeleton and their soft tissue. You are welcome to a copy of these results
The second measurement is made by the BOD POD. This is an egg-shaped capsule in which your child would sit for about 5 minutes whilst we measure the volume of their body. They would need to bring with them a swimming costume or swim shorts for this measurement as it requires tight clothing for an accurate result Results of the measurements are available immediately and we would share these with you and your child if you wish. Leaflets describing these measurements are provided with this letter.
In addition we will perform an ultrasound scan to see how much fat there is within the abdominal cavity and then measure the volume of the thyroid gland. For this your child will lay on a couch, some gel will be applied to their stomach and neck and an ultrasound probe will be placed onto the skin so that a clear image is displayed. Importantly the ultrasound scan will not acquire information other than body fat or thyroid volume, so we will not obtain any diagnostic imaging information (e.g. internal organs) from this procedure.
6. During the visit we would like to measure total body water content. This measurement is made by asking your child to drink some water which has a raised concentration of a heavy form of water called Deuterium. Deuterium is natural and a small amount is already produced by the body. Before giving the drink, and at 4, 5 and 6 hours after the drink, we will ask for 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. We would measure energy expenditure during a stay of 12 hours in a calorimeter room. This period starts at 19:00 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. A leaflet describing the calorimeter room is provided with this letter. If your child is not comfortable staying in a room by themselves then we can offer a double room for you and your child. We will then only measure energy expenditure in the morning.
8. We would also like to know at what stage of maturation your child is at. To do this we would like to show your child pictures of different maturation levels appropriate for their age, and ask them to choose which picture best describes their maturation level. This can be conducted with one of the study clinicians or with a parent.
9. During the visit and for the 3 days after the visit we would like your child 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 the chest. An additional movement sensor is worn like a small wristwatch. When these have been fitted we would ask your child to undertake a brief period of mild exercise, such as stepping and a treadmill test, to calibrate the devices and collect a measure of fitness.
10. We would retain samples of your child's urine from which we would analyse the amount of protein the body uses, the trace element iodine and the levels of catecholamines - chemicals involved in the control of energy expenditure
11. If your child is not comfortable staying in the Calorimeter on their own then we can offer a double inpatient room where they can stay with you for the night.
12. In the morning we would wake your child at approximately 7.00 but we will discuss normal waking times with you beforehand. We would ask them to lie still on the bed, but to remain awake, whilst we measure the Basal Metabolic Rate (BMR). We would place a transparent canopy over their head and shoulders and measure the air they breathe from this. We analyse this air and calculate the amount of energy the body expends in the resting, "basal" state. You are welcome to sit in the room while your child is having this measurement.
13. After measuring the BMR we would measure body temperature with a digital thermometer placed gently in the ear canal. We would also weigh your child and then once they are changed weigh their night clothes to deduce an accurate "naked" body weight.
14. We would also like take a 25ml (less than 2 tablespoons) sample of blood which we would analyse for chemicals and hormones related to metabolism, such as blood sugar, blood fats, cholesterol, insulin and thyroid hormones.
15. Finally, we would perform a magnetic resonance imaging/spectroscopy (MRI/S) scan to measure abdominal fat. This takes place in another part of the hospital and you and your child would be taken there by a nurse. This measurement involves lying in a scanner (a tube-like structure) for a maximum of an hour. This will either be performed at the end of the visit after breakfast on day 2 or another day that is more appropriate. It carries no health risks, but some people may feel claustrophobic in the scanner. As with all our investigations, your child is 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. In the unlikely event that incidental abnormalities are found on the MRI scan then these will be reported by a radiologist and fed back to your child's GP with your permission.

Expenses and Payments - We would reimburse you for your travelling expenses and on completion of the study we will arrange for your child to receive a "thank you" payment of £50 in Amazon vouchers.

What do I have to do?

We would like you and your child to visit the Clinical Research Facility before agreeing to participate so you can see the area where you and your child 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 and your child 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 ensure your child eats normally during the 24 hours before the visit. During your visit we would like your child to remain within the Clinical Research Facility until around midday on the day after your arrival. We would like your child to eat the evening meal that we provide (we would discuss food preferences before you come, and would try to accommodate them). We would provide drinks when your child wishes, but these would be free from caffeine. We would like your child 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 child's GP will not be routinely informed of their participation in this study. In this study the chances of finding anything abnormal are extremely small. However, in this very unlikely event you will be appropriately counselled and your child 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, the total amount of radiation given would be no more than half the amount you receive from natural background radiation in one day, and comparable to the extra radiation received during a European air flight.

For Females

We do not wish to expose any potentially pregnant female to radiation, however small the dose. For this reason, we will routinely carry out a pregnancy test on all females aged 11 years and above who have consented to having a DXA scan.

What are the possible benefits of taking part?

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

What if there is a problem?

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

Will their taking part in the study be kept confidential?

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

Contact Details

This completes Part 1 of the Information Sheet.

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

If you would like any further information before or during the study please contact:

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ACCI Level 5 Box 127
Hills Road
Addenbrookes Hospital
Cambridge
CB2 0QQ
01223 596077

crf-volunteer@medschl.cam.ac.uk

There is an answer phone if you call out of hours

A message may also be left with reception on 01223 596055.

Part 2

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

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

What if there is a problem?

Complaints:

If you or your child has 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 your child is 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 their taking part in this study be kept confidential?

If your child joins the study, some parts of their medical records may be looked at and the data collected for the study will be looked at by authorised persons involved in undertaking 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 your child as a research participant and nothing that could reveal their 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 Dr Peter Murgatroyd (Senior Scientific Officer, CRF) 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 child's 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 child's GP be informed of my taking part?

Your child's GP will not be routinely informed of their participation in the study. We will not ask their GP for any information. We will inform their GP of any concerns or incidental findings about their health which come to light during the study.

What will happen to any samples my child gives?

Blood samples will be stored on the Clinical Research Facility until they are analysed shortly after the study visit for hormones and metabolic parameters. Residual plasma and serum will be stored for future measurement of other relevant hormones and metabolic markers that are relevant to the study. If any results are abnormal we will advise you and your child and discuss the implications with you, and will then advise their 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 metabolic diseases or disorders, 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 to the NIHR/ Wellcome Trust Clinical Research Facility and sponsored by CUH NHSFT and the University of Cambridge.

Who has reviewed the study?

This study has been given a favourable ethical opinion for conduct in the NHS by the East of England - Cambridge South Research Ethics Committee.

Thank you.

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