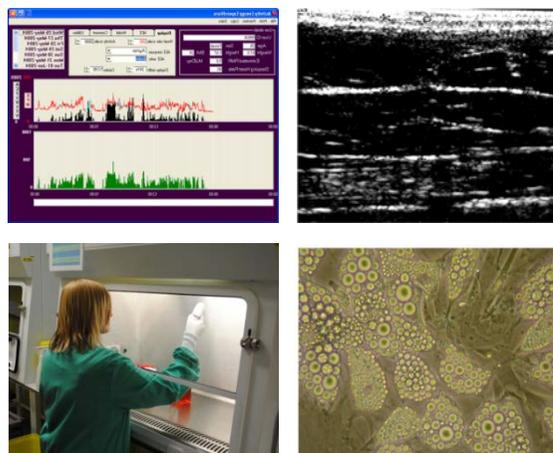




The Oxford Biobank

Supplementary Information



Oxford Centre for Diabetes, Endocrinology and Metabolism (OCDEM)
University of Oxford, Churchill Hospital
Oxford, OX3 7LE

Oxford Biobank 08/H0606/107
Oxfordshire Clinical Research Ethics C

When you participated in the Oxford Biobank (OBB) we indicated that you might be invited to take part in further research.

It is possible that we would invite you back for a second visit which might involve a fat biopsy, an ultrasound scan or measurement of energy expenditure.

Obviously, at that time you are completely free to state that you are not willing to participate, and you should not feel committed to participate because you have previously donated a blood sample.

Information relating to fat biopsies, ultrasound of fat tissue and daily energy expenditure (studies you might be asked to participate in), are detailed below.

1. If you have been invited back for a fat biopsy

If you agree to come for a fat biopsy we would ask you to come in fasted and we would obtain written informed consent from you again. The procedure would be carried out by one of the trained study nurses or a study doctor. We would like to take two small samples of adipose tissue (fat), one from your tummy and one from your buttock or both from your tummy. We would use local anaesthetic to numb the skin and fat underneath, which may cause a momentary sting. The biopsy would then be taken by inserting a needle into the fat tissue and applying suction through the needle. Approximately 1 gram of tissue is taken out (about the size of a couple of grains of rice). If we took the two samples from your tummy we would use ultrasound to look at the two fat layers, further information on the ultrasound procedure can be found in the next section.

Both sites will have an adhesive dressing that can be removed the next day. The whole procedure will take about one hour.

What do I have to do?

You would be asked to have your evening meal before 9pm the evening before, and not to eat or drink anything except water before the biopsies.

What would happen to the fat samples taken during the study?

The samples will be stored securely within OCDEM, for future analysis. As new methods are developed, and in order to gain additional information about different diseases, we may be working with other researchers in the UK or Internationally and we may send them some of these samples, for different types of analysis.

You would have the right to withdraw your samples from the study at any time and the samples would then be destroyed.

All storage of samples will be done in accordance with the Human Tissue Act 2004.

2. If you have been invited to have an ultrasound scan of your abdominal adipose tissue.



Central adiposity (tummy fat) is strongly associated with cardiovascular and metabolic diseases. The fat in the tummy is divided into two layers, an upper and a deeper layer. We would like to use ultrasound to determine the depth of the two layers. The measurements are taken either side of your tummy button; we will ask you to lie on your back

and the measurements will be done when you are breathing out. Ultrasound gel will be used on your skin. The scan takes about 8 to 10 minutes to complete and will be performed by a doctor or by one of the trained research nurses.

3. If you have been invited to have your daily energy expenditure measured



We might also ask you to come back for an assessment of your habitual daily energy expenditure, which would involve wearing a pedometer-like device called an Actiheart for 5 - 7 days.

The Actiheart is a compact, chest worn monitoring device that records heart rate and physical activity over a 24 hour period and is encased in a light weight waterproof unit.

The visit will take approximately one hour.

What are the possible disadvantages and risks of taking part?

Taking a fat sample may leave a bruise that could be quite large and possibly become hard underneath, but this should disappear after a week or two; we would try to reduce the bruising by pressing on the site for 10-15 minutes. There is a small risk of a local infection following both biopsies but we would do everything possible to prevent this.

The ultrasound scan and the Actiheart measurement are not invasive procedures and have no risks associated with them. There is a very low chance that you might develop an allergic rash to the pad that is placed on the skin when measuring energy expenditure.

What are the possible benefits of taking part?

There are no advantages, but these supplementary studies will allow us to have a better understanding of common diseases and how to prevent them.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak with the OBB Team (01865-857284). If you remain unhappy and wish to complain formally, the University of Oxford has a formal complaints procedure and one of the team members will provide you with the information.

Confidentiality

As with your original visit to the Oxford Biobank the data that we obtain from you will be strictly confidential; all samples will be anonymised as will any data provided to researchers.

How do I take part

If you decide that you would like to take part or you have any queries about anything regarding the Oxford Biobank please contact the team on:

Phone: **01865 857284**

Email: obb@ocdem.ox.ac.uk

Address: OBB Team, Clinical Research Unit
Churchill Hospital, Oxford, OX3 7LE

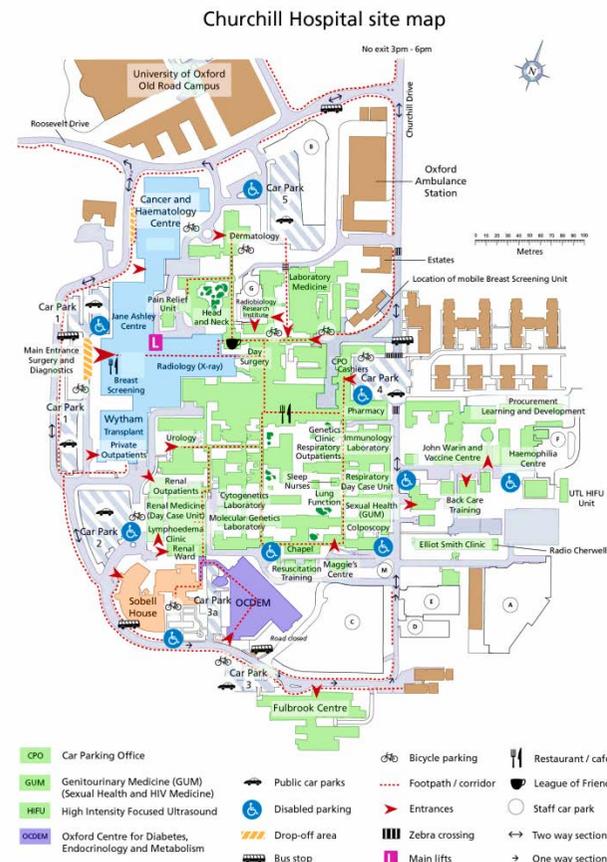
Further information

If you would like more information before deciding, please visit our website at:

<http://www.oxfordbiobank.org.uk/>

Thank you for your interest and contributing to the Oxford Biobank

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This site map can be found at the following link:

www.ouh.nhs.uk/hospitals/churchill/documents/ch-site-map.pdf



NIHR Oxford Biomedical Research Centre