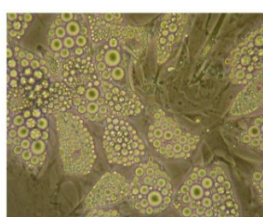
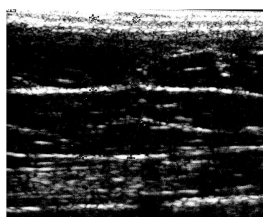




The Oxford Biobank

Additional Procedures

REC no' 23/SC/0411



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

Obviously, at this 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.

If you have been invited to give another blood sample or a urine sample

We would like to invite you back to give another blood sample of up to 100 mls blood, either for ourselves or for one of our collaborators.

We might also ask you to give us a urine sample.

If you have been invited for a DEXA scan

We may invite you to attend for a DEXA scan. This maybe at your request due to lifestyle changes. The DEXA information sheet is attached.

If you have been invited for a fat biopsy

If you agree to come for a fat biopsy we would ask you to come in fasted (or non fasted depending on the research question) 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 or with a device that takes a core fat sample. Approximately 1 gram of tissue is taken out (about the size of a few grains of rice).

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

We might also ask you to fill in a Food Diary.

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 may send them some of these samples, for different types of analysis. All samples will have a unique study number and no personal information about you would be sent.



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.

What are the possible disadvantages and risks of taking part?

- Blood sampling may cause some discomfort and a possibility that a small bruise may develop.
- Taking a fat sample may leave a bruise that could be quite large and possibly become hard underneath; 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 radiation exposure from a DEXA scan is very small. Please find additional information about the scan on the DEXA Information Sheet enclosed.

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

What are the possible benefits of taking part?

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

Will taking part in the study be kept confidential?

Yes. The data that we obtain from you will be strictly confidential. All study records and samples will be identified only by a code which is a unique identifier in our database. We will only use your personal and contact details where this is necessary to contact you about future studies. Information that can identify you is stored securely in a department that routinely handles sensitive information and procedures are in place to ensure the highest possible data security and integrity. Any data released to researchers will be in an electronic form and will be pseudonymised; it will contain no means of identifying you outside of our secure system. If your samples are released for further analysis to scientific collaborators, for example academic or industry, those researchers can request information such as your BMI, age, blood sample results etc, which will enable them to analyse their data. However, none of your personal information or data that could be traced to you will be released. Responsible members of the University of Oxford and regulatory organisations may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

For more information of how your data will be used, how long it will be held, and your rights please follow the link to our Privacy Notice below - <http://www.oxfordbiobank.org.uk/for-volunteers/data-protection/>

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,
OCDEM, Churchill Hospital, Oxford, OX3 7LE

Who is organising and funding the Oxford Biobank?

The Research is organised by a team from the Oxford Centre for Diabetes, Endocrinology & Metabolism, Churchill Hospital, Oxford and is funded by the NIHR Oxford Biomedical Research Centre and is part of the NIHR Bioresource.

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.

The University of Oxford takes responsibility for the biobank and has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in the Biobank.

Who has reviewed the 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 Central-Oxford C Research Ethics Committee.

Further information

If you would like more information before deciding, please visit our website at: <http://www.oxfordbiobank.org.uk/>



The site map can be found at the following link:

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

**Thank you for your interest and
contributing to the Oxford Biobank**

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IRAS Project number: 329964

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Oxford University Hospitals NHS Trust



NIHR Oxford Biomedical Research Centre