

UCL Eastman Biobank for Studying Health and Disease**ADULT DONOR INFORMATION SHEET****Why have I been asked to read this document?**

We are inviting potential donors at the Eastman Dental Hospital, University College London Hospital NHS trust (UCLH) to donate saliva, plaque, blood, tissue such as extracted teeth, and provide access to your clinical notes and imaging to the UCL Eastman Biobank for Studying Health and Disease.

Please read the following information carefully and discuss it with others if you wish. Please ask us if there is anything that is not clear or if you would like more information.

Why do we want to study your notes and imaging (x-rays)?

Research will add to our overall understanding of human dental disease and the normal functioning of the mouth and human body. It may help us to design new ways to diagnose and treat dental disease.

What is the UCL Eastman Biobank for Studying Health and Disease?

The biobank is a collection of human material including saliva, plaque, blood, teeth and other normal and diseased tissue from donors attending the Eastman Dental Hospital or their relatives who are interested in donating the above material to our Biobank. Samples from the biobank are used in ethically approved research.

What is the purpose of the UCL Eastman Biobank?

The purpose of the biobank is to have tissue or other types of samples (saliva, blood or plaque) available, now and in the future, for research projects investigating oral and human disease and the normal functioning of the human body. The biobank will primarily be for the use of scientists conducting research at the UCL Eastman Dental Institute, however potentially it could be used by any scientists working in the UK but not for commercial research. Only projects that fall under the described remit of the Biobank will be approved.

Do I have to take part?

No. Whatever your decision, it will not affect any treatment or care you receive in this or any other hospital, now or in the future.

What will it involve if I decide to take part?

You will be asked to sign a consent form:

- that allows clinical information to be extracted from your notes and imaging (x-rays and scans) from the Eastman Dental Hospital or University College London Hospital NHS trust (UCLH);
- that allows your data to be stored on a secure database in a coded/anonymised form;
- that allows storing a small piece of tissue eg a tooth, that is surplus to diagnostic requirements, for research projects including research on new therapies for managing dental disease;
- that allows collection of saliva or plaque specimens for research projects including genetic research. Genetic analysis of your saliva often explains why certain diseases develop;
- that allows donation of your blood up to 50 mL [up to 10 teaspoons]. This is unlikely but does occur from time to time. Blood sample taking may result in minor discomfort and slight bruising. You can choose to opt out of this if required.

Additional tissue purely for research purposes is not removed at any time.

All these samples will be collected when visiting your hospital.

Plaque samples will be collected by inserting sterile paper points or rubbing a cotton swab around your gum and the tooth for 15 seconds.

Donation of saliva sample is straight forward. You will be instructed by a clinician to spit into special tubes specifically for genetic or microbiological analyses. This usually takes 2 minutes.

Donation of blood sample will involve drawing of upto 50 mL of blood from your arm by a trained clinician or nurse. Firstly, we will examine your arm and place a cuff on your arm to maintain a small amount of pressure. We will then examine your arm to find a suitable vein and clean it with an antiseptic sponge, and subsequently insert a needle in your arm which will collect your blood into a blood tube. You should not feel any discomfort or pain. If you do, tell a member of staff. This usually takes less than one minute. The needle will be removed and a sterile dressing applied to your arm.

We may ask for any of the above samples on more than one occasion randomly but you can refuse at any time without giving a reason and without your medical care being affected.

What are the advantages and disadvantages of taking part?

There are potentially no advantages to you if you participate in research but it may help others in the future. You will not receive a financial reward. Donated tissue is considered to be a 'gift' to the biobank.

Will my information be kept confidential?

Yes. All information about you and your tissue samples will be treated with the strictest confidence. All information about you cannot be traced back to you by the researcher.

Results from genetic studies will be placed on a database to which only authorised individuals have access. Before having access to your clinical information and/or tissue samples researchers must agree to conditions which safeguard your confidentiality.

Am I going to receive feedback on the sample(s) I donated?

We do not expect significant health-related findings from the studies which are approved by the UCL Eastman Biobank to use your donated teeth, plaque, saliva or blood. Feedback of the test results including genetic tests will therefore not be given. Donating saliva, blood or plaque will have no impact on your medical insurance.

What will happen to the results of the study?

The results of our research will be published on our website <https://www.ucl.ac.uk/eastman/research/departments/clinical-research/biobank>, in dental or medical journals.

Family members

It is sometimes useful to have saliva, plaque or even blood samples from family members as this allows us to study the impact of genetic and environmental factors on the development of a disease. Therefore in some instances we may ask you to consent to allow us to contact your family members (parents/grandparents/cousins etc). You will also be given the Information Sheets to pass on to your relatives.

What if there is a problem or I require further information?

If you would like further information or you have concerns about this research at any time you can:

- discuss it with your dentist or nurse, or
- email us on eastmanbiobank@ucl.ac.uk, we will try to answer your questions

Normal NHS complaints procedures will apply.

What will happen if I do not want to carry on with the study?

You are free to withdraw your consent at any time. This means that researchers will no longer be able to access any of your notes and images, and your tissue samples in the biobank will be destroyed. You do not have to give a reason for changing your mind. However, if the data have already been used it is not always possible to recall it.

What will happen to any samples that I give?

Your samples will be used in a variety of studies and may include detailed analysis of your DNA to compare healthy DNA with the abnormal DNA found in patients with various diseases, or analysis of the bacteria and other organisms found in your mouth. Samples and data may be given for research purposes to other approved researchers in UK.

What will happen to the results of the study?

The results of our research will be published on our website <https://www.ucl.ac.uk/eastman/research/departments/clinical-research/biobank>, in dental or medical journals.

Who is organizing and funding the UCL Eastman Biobank for Studying Health and Disease?

The biobank is overseen by the Research & Development Unit of UCL and UCLH. The cost of operating the biobank will be funded by UCL Eastman Dental Institute.

Who has reviewed the project?

The UCL Eastman Biobank for Studying Health and Disease has been given a favourable ethics opinion for conduct in the NHS by the NRES Committee Yorkshire and the Humber - Leeds East.

Many thanks for taking the time to read this information.