

OOB

Ocular Oncology Biobank

PATIENT INFORMATION
COLLECTION AND STORAGE OF OCULAR
BIOSAMPLES AND ASSOCIATED DATA
FOR RESEARCH

Version 7: 26/05/2021

Contact Information for Ocular Oncology Biobank

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Dear Patient,

We would like to invite you to take part in a research study. Before you decide whether to take part 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 and discuss it with others if you wish. If there is anything that is not clear, or if you would like more information, please ask your doctor or research nurse. Alternatively, contact the members of the Biobank using the contact information on the front of this booklet.

What is the Ocular Oncology Biobank (OOB)?

The OOB works closely with local and regional hospitals to collect and store ocular biosamples, blood and associated clinical data for use in research relating to eye cancers and other eye diseases. By doing this, the OOB can build a valuable collection that will be used by research groups to address key basic and clinical research questions necessary to improve the healthcare of future patients. The OOB is a collaborative effort between surgeons, theatre staff, nurses, pathologists and researchers.

What are Ocular Biosamples?

Ocular biosamples are materials such as eye tissues and eye fluids.

Why have I been chosen?

Your hospital has agreed to help the OOB collect biosamples from its patients. You are about to undergo a surgical operation or biopsy procedure as a part of your treatment. We are asking for your consent to store any material remaining after your clinical care team have completed all the necessary tests.

What will happen if I choose to take part?

The tissue or organ removed at your surgical operation is in most cases sent to the Department of Cellular Pathology at the Liverpool University Hospital NHS Foundation Trust (LUHFT), to be examined and to help in the diagnosis and treatment of your medical condition. Often, it is not necessary to test the whole sample, which means that there will be material left over.

If you agree to take part in this study, we are asking for your informed consent to store any remaining eye material in the OOB for use in research projects.

As part of your treatment and continued care, a doctor will normally take a routine blood sample. We would like your informed consent to take a small additional amount at the same time as this routine sample. This will usually be taken at the time of your surgery or at an outpatient clinic and will be approximately 20ml, equivalent to about 4 teaspoons.

We would also like your consent to access the medical records related to your disease. These will be reviewed by OOB staff, who hold honorary research contracts with the Hospital, in order to update information on the OOB database. All information will be treated with the strictest confidence and held securely within the OOB. This information is essential to help researchers understand what your illness was like and relate what is found in the laboratory to what happens to patients.

Your biosamples and associated clinical data will be pseudonymised, which means that a unique laboratory code is used for identification. The laboratory researchers who are carrying out the tests on your biosamples will only be able to see this code; your name, address, date of birth and

any other personal data is removed before information is given to researchers.

How will my ocular biosamples and blood be used?

Researchers will be able to use your gifted material to understand the causes of eye cancer and other eye diseases in order to improve treatment and care for patients in the future. Your biosamples will not be used for transplantation or reproductive cloning. Nor will they be used for non-medical or non-scientific purposes.

The research carried out on the samples will be performed primarily by scientists working at the University of Liverpool, in the Liverpool Ocular Oncology Research Group (www.loorg.org). Some research, however, may be performed by researchers outside the University of Liverpool: for example, other academic institutions, hospitals or commercial Companies involved in eye research worldwide. In all cases, you will be anonymous to the researcher.

Some of your tissue will be used to extract and grow the cancer cells. These will not be used for any purpose other than research conducted

within the University of Liverpool Ocular Oncology Research Group.

When we store samples we would like to use some of them to obtain genetic material (DNA and RNA). We are asking you for specific consent to allow us to obtain genetic material so that this can also be made available to researchers. Genetic material will not be used for any purpose other than research and the research team will not be able to identify you in any way.

If you do not wish your eye and/or blood samples to be used for this purpose please do not initial statement number 8 on the consent form.

Sometimes we need to conduct experiments involving animals to understand how a disease develops and progresses. We are asking you for specific consent to allow researchers to use your biosamples in such experiments if necessary.

If you do not wish your biosamples to be used for this purpose please do not initial statement 9 on the consent form.

What if researchers find new information about my condition?

Research studies using your gifted biosamples

may take several years to complete. Therefore, the information discovered during research will not be directly relevant to your current or future care and treatment. It is hoped that the results from these studies will be used to improve future treatments and care of patients.

Will anybody make a profit from my ocular biosamples and/or blood?

We are asking you to donate your ocular biosamples and blood for research as a gift and you will not receive a financial reward either now or in the future.

The OOB will not sell your samples or data for profit to other researchers. However, they may be used in a research project that could lead to the development of new drugs or treatments. It will not be possible for you to make a claim for money as you will be waiving all commercial rights relating to the biosamples you donate. Any drug, treatment or test developed may help all of us in the future.

What will happen to the results of the research study?

Results from the research conducted with biosamples from the OOB will be published in

scientific journals and presented at scientific meetings. It will also be publicised on the University of Liverpool Ocular Oncology Research Group website, www.loorg.org.

You will not be able to be identified if research using your gifted biosamples is published in any scientific papers.

What are the advantages and disadvantages of taking part?

The biosamples taken for the OOB will only be collected once the necessary diagnostic tests have been performed. The results of research carried out using your biosamples, and those of others, may help in the future discovery of new drugs and treatments for eye cancer patients or other eye diseases.

There will be no direct benefit to yourself as you will not be identifiable to the research team.

When the blood sample is taken, occasionally, this may require an additional entry site to the routine blood sample. On the small number of occasions that this may occur, there is a chance that you may experience some bruising at the site.

There will be no additional risks if you choose to participate.

Do I have to take part?

It is up to you to decide whether or not to allow us to collect ocular biosamples, blood and clinical data. If you do decide to take part then you can keep this information booklet and you will be asked to read and complete a consent form.

If you decide not to take part, you do not need to give a reason.

Whatever your decision, it will not affect the standard of care that you receive.

What will happen if I change my mind?

If you do decide to take part you are still free to change your mind at any time. You have the right to withdraw your consent to store your ocular biosamples, blood and data without giving a reason. If you do withdraw your consent, then it will not affect in any way the treatment that you are receiving. You can withdraw your consent by using the contact details found at the front of this booklet. Alternatively, just speak to a member of your healthcare team who can contact us on your behalf.

The ocular biosamples and blood stored in the OOB, along with any information held about you, will be destroyed and a letter of confirmation will be sent to you. If you change your mind a long time after the samples were donated, then some research may have already taken place on your samples. The OOB would not be able to recall biosamples and information once they have been used, but any unused biosamples would be disposed of appropriately. This would ensure that no further research work will be undertaken.

Will my taking part in this study be kept confidential?

All information that is collected about your disease will be kept strictly confidential. Your name, address and other personal information will be removed and replaced with a unique code. You will not be able to be identified by the researcher. It may be necessary as part of regulatory processes for your personal data to be viewed by regulatory authorities/other third-party individuals such as the Human Tissue Authority.

University of Liverpool is the sponsor for this study based in the United Kingdom. We will be

using information from your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. University of Liverpool will keep identifiable information about you for 15 years after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information by contacting Professor Sarah Coupland at s.e.coupland@liverpool.ac.uk. Our Data Protection Officer is Victoria Heath and you can contact them at V.Heath@liverpool.ac.uk.

Who has reviewed the study?

The collection and storage of ocular biosamples, blood and associated clinical data by the OOB has been approved by the NHS Health Research

Authority Research Ethics Service
(<http://www.hra.nhs.uk/>), an external independent body. The OOB is part of the University of Liverpool, which is licensed by the Human Tissue Authority.

What should I do if I have concerns/complaints about the study?

If you have a concern or complaint about participating in the OOB, please contact any of the individuals below:

- Chief Investigator or Biobank Custodian using the details on the front page of this participant information sheet.
- A member of your clinical care team
- Patient Advice and Complaints Team at the Royal Liverpool University Hospital NHS Foundation Trust on 0151 706 4903 or email quality@rlbuht.nhs.uk.