



General biobank enquiries and correspondence:  
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## **Oxford Radcliffe Biobank**

### **Personal Consultee Information Sheet**

### **Donating samples for medical research: General**

We are inviting your relative/friend to take part in the Oxford Radcliffe Biobank but we feel he/she is unable to decide for himself/herself whether to participate in research.

To help decide if they should provide samples for research, we would like to ask your opinion whether or not they would want to be involved. We ask you to consider what you know of their wishes and feelings, and to consider their interests. Please let us know of any advance decisions they may have made about participating in research. These should take precedence.

If you decide your relative/friend would have no objection to taking part we will ask you to read and sign the Consultee Declaration Form. We will then give you a copy to keep. We will keep you fully informed during the study so you can let us know if you have any concerns or you think your relative/friend should be withdrawn.

If you decide that your relative/friend would not wish to take part it will not affect the standard of care they receive in any way.

If you are unsure about taking the role of consultee you may seek further information in leaflets produced by the Department of Health and the Mental Capacity Implementation Programme (MCIP) available from the ORB website: [http://orb.ndcls.ox.ac.uk/info\\_for\\_patients](http://orb.ndcls.ox.ac.uk/info_for_patients), or discuss it with a member of the clinical team looking after your relative/friend. We will understand if you do not want to take on this responsibility.

The following information is the same as would have been provided to your relative/friend.

**If your relative/friend regains the ability to make a decision about this research, we will consult them about any stored samples we have already taken and ensure we have their consent to use these samples, as well as any future samples, in research through the Oxford Radcliffe Biobank.**

We are inviting your relative/friend to take part in the Oxford Radcliffe Biobank. We want to emphasise that this is entirely voluntary. Your decision will not affect their care in any way. Before you decide, it is important to understand how a biobank makes medical research possible and what your relative/friend's participation would involve. If they regain the ability to make a decision about this, we will consult them before taking or releasing any further samples for research.

### **1. What is the Oxford Radcliffe Biobank about?**

The Oxford Radcliffe Biobank collects blood, samples of other body fluids and tissue samples, as well as information about donors for use in medical research. Researchers want to develop new and better ways to manage disease and medical conditions. An important part of our work is to collect and make available both normal and abnormal (diseased) samples. Researchers can then study changes caused by disease at the very earliest stages, and use this information to develop new tests and treatments. The biobank takes care of samples and makes certain that they are shared properly.

Sometimes samples are used for genetic research (about diseases that are passed on in families) in order to study differences between normal and abnormal cells. These genetic tests are different from the genetic screening offered to families at high risk of developing disease. Researchers will be studying diseases and not individuals, so the results of this research will not be fed back to the participant's doctors unless it might make a difference for decisions about their healthcare.

Because samples and data will be stored for future use, many different tests, methods and techniques may be used in the future to provide information that we cannot foresee.

### **2. Why has my relative/friend been invited?**

All adult patients undergoing investigations, treatment or monitoring at the hospital may be invited to participate so that the Oxford Radcliffe Biobank has a representative set of samples from people with different conditions. We also ask a number of healthy people to join.

### **3. Does my relative/friend have to contribute to the Oxford Radcliffe Biobank?**

No. It is completely up to you to decide whether or not you believe they would have wished to join. If you decide to decline, your decision will not affect their healthcare in any way.

### **4. What will happen if I think they would agree to take part?**

If you believe that your relative/friend would have been willing to take part, we will ask you to sign a Consultee Declaration form. We will try to take samples during a routine test or a planned treatment so that donating samples will cause as little inconvenience to your relative/friend as possible. During a blood test, for example, we may take up to 50 mls (about 3 tablespoons) more blood than is needed for their test or treatment. However we may also take some samples that are not part of routine care, as well as

some follow up samples. We may also use any surplus samples left over from any routine surgery, biopsy or diagnostic tests.

The samples will likely be used soon after collection but it is possible that they will be stored for many years. We will not contact you or your relative/friend in future if we want to make use of these samples, although if your friend regains the ability to make a decision about this research we will contact them to ask whether they consent to be part of the biobank and for any remaining samples not yet used in research to be held.

## **5. What if I change my mind?**

You can change your mind about your relative/friend's participation at any time and without having to give a reason. We would destroy any unused samples and data so that they cannot be used in future research. Data and samples that have already been used cannot be taken out of that research.

## **6. Who will use the Oxford Radcliffe Biobank?**

We supply samples and medical data to researchers whose research fits with the biobank's research programme. The kinds of research for which we will supply samples and data has been reviewed and approved by an independent Research Ethics Committee (South Central - Oxford C). Your samples will be used mainly by local researchers, but projects may take place in hospitals, universities, non-profit institutions or commercial laboratories/ companies worldwide. The research may be funded by research councils, research charities, government bodies, commercial companies or other organisations. All projects are reviewed and must meet regulatory conditions before being allowed to use the samples. We sometimes charge researchers for providing samples to cover our running costs but would never make a profit from these samples.

## **7. What are the advantages and disadvantages of my relative/friend taking part?**

Research tests will not affect the standard medical care your relative/friend receives. We do not routinely report individual results. Research involves testing large numbers of samples from many different people to try to identify factors that influence disease. Findings often need many years of further research to prove if they are truly important. You and your relative/friend will not receive any personal financial reward for involvement.

## **8. How will my relative/friend's information and privacy be protected?**

Biobank staff will access their medical records to collect information needed for research. To maximise the value of samples that we keep, we will maintain an electronic database with relevant details about them, such as the diagnosis (if any) and factors that may affect disease, such as lifestyle and family history. We may ask your relative/friend's medical care team for regular follow-up reports. This information will help us understand the meaning of our laboratory findings. We will hold the link between their medical data and research samples in strictest confidence. We will not

give researchers information that could identify them. Individual patients are never identified when research results are published. We will be using information from medical records in order to undertake this study.

Data protection regulation requires that we state the legal basis for processing information this personal information. In the case of research, this is 'a task in the public interest.' The University of Oxford is the data controller and is responsible for looking after personal information and using it properly. We will use the minimum personally-identifiable information possible. We, the Oxford Radcliffe Biobank, will keep identifiable information for up to 12 months after the biobank ethical approval ends. The local NHS trust will keep identifiable information, such as the declaration form, in keeping with local policies for retention of medical records.

Data protection regulation provides a participant with control over this personal data and how it is used. Some of those rights may be limited in order for the research to be reliable and accurate. Further information about rights with respect to personal data is available at: <https://compliance.web.ox.ac.uk/individual-rights>.

You can also find out more about how we use this information on <http://orb.ndcls.ox.ac.uk>.

## **9. What happens if something goes wrong?**

The University of Oxford has appropriate insurance in place in the unlikely event that your relative/friend suffers any harm as a direct consequence of their participation in this study.

You may also contact the hospital's Patient Advice and Liaison Service (PALS) on their website: [www.ouh.nhs.uk/patient-guide/feedback/pals.aspx](http://www.ouh.nhs.uk/patient-guide/feedback/pals.aspx), by phone: 01865221473, or by email: [PALS@ouh.nhs.uk](mailto:PALS@ouh.nhs.uk).

## **10. How can I get more information?**

Please ask any questions before deciding whether you believe your relative/friend would have been happy to take part. You can speak to the consultant or specialist nurse responsible for their care. You can also contact us at the address on the cover.

**Thank you for considering your relative/friend's participation.**

Place patient sticker here if available



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Name	
Hospital number	
NHS number	
D.O.B	

### CONSULTEE DECLARATION FORM Donating blood and tissue samples for medical research

If you think your friend/relative would agree to take part in the biobank, please **initial each box** and sign this form.

		Initials
1.	I, <u>initial surname</u> , have been consulted about the participation of <u>initial surname</u> in this research. I have read and understood the Consultee Information Sheet for this biobank (Version <u>   </u> dated <u>dd mmm yyyy</u> ). I have had the opportunity to ask questions and have had these answered satisfactorily.	
2.	In my opinion, they would have no objection to taking part and giving samples for research and/or allowing samples already collected as part of their medical care to be used by the biobank.	
3.	I understand that further blood and/or tissue samples may be taken for the biobank during the course of their hospital care.	
4.	I understand that I am free at any time to reverse this declaration regarding the storage and distribution of any of samples that have not already been used in research. Withdrawing from the biobank will not affect the participant's present and future medical care and legal rights of their care in any way.	
5.	I understand that biobank staff can collect and store information from relevant sections of their health care records for research that uses the samples. I understand that the biobank will keep this information confidential. Information will only be passed on to researchers in a form that protects the participant's identity. Authorised individuals from the University of Oxford, NHS organisations and research governance monitors may access this information.	
6.	I understand that results from research tests might be medically important to the participant. In my opinion, they would have no objection to their hospital consultant and GP being informed. <i>(circle your answer, cross out the other)</i>	Yes No
7.	I understand and agree that these samples will be considered a gift to the University of Oxford. If a commercial product were developed as a result of research in which a sample was used, there would not be any financial profit for me or the participant.	
8.	I understand that the biobank will store their samples and distribute them for use in any UK medical research that has research ethics committee approval and any research conducted outside the UK that has necessary country-specific approvals. I understand that future laboratory research may use new tests or techniques that are not yet known.	
9.	I understand that relevant sections of their medical notes and data collected by the biobank may be looked at by authorised individuals from The University of Oxford, NHS organisations and research governance monitors.	
10.	Genetic research: I understand and agree that these samples may be used in genetic research aimed at understanding the genetic influences on disease and that the results of these investigations are unlikely to have any implications for the participant personally.	

Name of Consultee (please print)	Signature	Date	Relationship to participant

**For completion by person taking declaration:**

I confirm that the purpose of the research, its voluntary nature and its procedures have been explained in terms understandable to this participant's consultee.

Name (please print clearly)	Signature	Date

*When completed, one copy for medical notes; copy to be kept in ORB site file; copy for patient and consultee*