Oxford Radcliffe Biobank

Information Sheet
Donating samples for medical research (healthy volunteers)

Local study contact details:

General biobank enquiries and correspondence:
Biobank Manager, Oxford Radcliffe Biobank
Nuffield Department of Surgical Sciences
Level 6, John Radcliffe Hospital, Oxford OX3 9DU
Email: orbmanager@ndcls.ox.ac.uk
Phone: 01865 220550

If you change your mind about taking part, please write to withdraw permission. You do not need to give any reason for your decision.

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1. Invitation

We are inviting you to take part in the Oxford Radcliffe Biobank. We want to emphasise that this is entirely voluntary. Before you decide, it is important to understand how a biobank makes medical research possible and what your participation would involve.

2. 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. 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 you and your GP unless it might make a difference for decisions about your 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.

3. Why have I been invited?

It is important that we collect and make available samples from people who are not undergoing hospital treatment so that researchers can detect changes between healthy and diseased samples. We are inviting a small number of adults who are not currently undergoing investigations or treatment at hospital to participate so that the Oxford Radcliffe Biobank has a representative set of samples from healthy people.

4. Do I have to contribute to the Oxford Radcliffe Biobank?

No. It is completely up to you to decide whether or not you wish to join.

5. What will happen if I decide to take part?

- If you decide to take part we will ask you to sign a consent form.
- We will ask you to give samples of blood and/or other body fluids such as urine or saliva, for research. These will be taken in an appropriate research facility by a trained phlebotomist. We may collect up to 100 mls (about 6 tablespoons) of blood. We may ask permission to take further samples at a later date if you agree.

Your samples may be used soon after collection but it is more likely that they will be stored for many years. We will not contact you in future if we want to make use of the samples you have already provided.

6. Contraindications to donating blood

You should not donate if you:

- know you are, or think you might be, infected with Hepatitis B or Hepatitis C
- know you are, or think you might be, infected with HIV (the AIDS virus)
- have, or have had, a sexual partner who is infected with hepatitis or HIV
- are unwell at the moment
- are anaemic or receiving treatment for anaemia or iron deficiency
- are, or may be, pregnant
- have given blood in the last month (if more than 100ml was taken)

7. What if I change my mind?

If you agree to participate, you can still withdraw 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.

8. 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 research projects may take place in hospitals, universities, non-profit institutions or commercial laboratories and companies worldwide. The research may be funded by research councils, research charities, government bodies, commercial companies or other organisations. All projects are reviewed independently and must meet regulatory conditions before being allowed to use your samples. We sometimes charge researchers for providing samples to cover our running costs but would never make a profit from your samples.

9. What are the advantages and disadvantages of taking part?

Giving blood samples may cause a little discomfort. 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 will not receive any personal financial reward for your involvement.

10. How will my information and privacy be protected?

Biobank staff will collect information needed for research. To maximise the value of samples that we keep, we will maintain an electronic database with relevant details about you, such as your age and gender. This information will help us understand the meaning of our laboratory findings. We will hold the link between your data and research samples in strictest confidence. We will not give researchers information that could identify you. Individual participants are never identified when research results are published.

Data protection regulation requires that we state the legal basis for processing information about you. 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 your information and using it properly. We will use the minimum personally-identifiable information possible. We, the Oxford Radcliffe Biobank, will keep identifiable information about you for up to 12 months after the biobank ethical approval ends. Data protection regulation provides you with control over your personal data and how it is used. When you agree to your information being used in research, however, some of those rights may be limited in order for the research to be reliable and accurate. Further information about your rights with respect to your personal data is available at:

http://www.admin.ox.ac.uk/councilsec/compliance/gdpr/individualrights/

Further information about your rights with respect to your personal data is available at http://orb.ndcls.ox.ac.uk.

11. What about other research projects?

If you agree, and only if you have signed that part of the consent form, we will use the electronic database to check whether there are any other studies that might be relevant for you. If any suitable studies are planned or occur in future we would contact you and invite you to consider taking part. These studies would require your direct input, not just the use of what you have already provided to the biobank. The studies will be fully explained and you will have ample time to consider whether or not you wish to be included in them. Your participation will be entirely voluntary. All such studies would first have to have approval from a Research Ethics Committee. Agreeing now to this possible contact does not commit you to participating in any future studies.

12. What happens if something goes wrong?

The University of Oxford, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this study.

13. How can I get more information?

Please ask any questions before deciding whether to take part. You can also contact us at the address on the cover.

Thank you for reading this leaflet.

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Level 6, John Radcliffe Hospital
Oxford,OX3 9DU
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ORB OXFORD RADCLIFFE BIOBANK

Volunteer Name:....................................
Date of birth:..
GP surgery (*if yes to statement 6 below*):
....
Postcode: ....

HEALTHY VOLUNTEER CONSENT FORM
Donating samples for medical research

If you agree to take part in the biobank, please **initial each box** and sign this form.

1.	I have read and understood the information sheet for this study (Version __ dated dd mmm yyyy). I have had the opportunity to ask questions and have had these answered satisfactorily.	
2.	I agree to give samples for research and allow the samples to be used by the biobank.	
3.	I agree that further blood samples may be taken for the biobank. I understand that I will be asked for permission each time.	
4.	I understand that my participation is voluntary and that I am free at any time to withdraw my permission for the storage and distribution of any of my samples that have not already been used in research. Withdrawing from the biobank will not affect my present and future legal rights in any way.	
5.	I understand that relevant sections of data collected by the biobank may be looked at by authorised individuals from The University of Oxford, NHS organisations and research governance monitors. I permit these individuals to access my research records. I understand that the biobank will keep my information confidential. Information will only be passed on to researchers in a form that protects my identity.	
6.	I understand that results from research tests on my samples might be medically important to me. I agree to provide contact details for my GP, and that my GP may be informed about research findings that are important for treating serious medical conditions, which may be discussed with me via my GP. *(circle one and cross the other out)*	YES NO
7.	I understand and agree that my samples will be considered a gift to the University of Oxford. If a commercial product were developed as a result of research in which my sample was used, I would not profit financially.	
8.	I give permission for the biobank to store my 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 agree that anonymised samples and data may be shared with other researchers, non-profit institutions or commercial organisations worldwide.	
10.	Genetic research: I understand and agree that my 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 me personally.	
Additional – not part of consent to Oxford Radcliffe Biobank:		
11.	I agree to be contacted about ethically approved research studies for which I may be suitable. I understand that agreeing to be contacted does not oblige me to participate in any further studies.	

Name of participant (please print)	**Signature**	**Date**

For completion by person taking consent:

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

Name (please print clearly)	Signature	Date

When completed, 1 for participant; 1 for ORB site file.