

RJAH Biobank for Studying Health and Disease

ADULT VOLUNTEER INFORMATION SHEET

Why have I been asked to read this document?

The RJAH Biobank for Studying Health and Disease is interested in researching human disease and the normal functioning of the human body in order to try and find ways of better diagnosing and treating diseases. Hence, we want to try and recruit as many volunteers to donate blood and other samples as they are valuable experimental controls.

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 you would like more information.

Am I being asked to take part because I am ill?

No. We are interested in involving healthy participants as this allows us to learn more about the impact that environmental and genetic factors have on the development of disease. The RJAH Biobank for Studying Health and Disease does not carry out diagnostic testing on research samples.

What is the RJAH Biobank for Studying Health and Disease?

The Biobank is a collection of human material including blood, urine, saliva, sputum, faeces and normal and diseased tissue (e.g. bone, breast, etc) from patients attending various hospitals in the UK and abroad. Samples from the Biobank are used in ethically approved research. Samples donated to the Biobank may be used in research using animal models.

What is the purpose of the RJAH Biobank for Studying Health and Disease?

Studying tissue from patients and healthy volunteers is an excellent way of discovering why and how a disease develops and progresses; this in turn helps in the development of new diagnostic tests and drugs. The purpose of the Biobank is to have tissue available, now and in the future, for research projects investigating human disease and the normal functioning of the human body.

What will happen to my sample?

The Biobank will consider applications from all scientists conducting research in areas covered by the RJAH Biobank for Studying Health and Disease. Ethical approval is required for any research. Research may be conducted in the UK or overseas by either public sector or commercial organisations. In order to defray some of the costs of running the Biobank, researchers may be charged for the use of tissue.

Do I have to take part?

No. Whatever your decision, it will not affect your legal rights or 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 blood samples of up to 50ml (6-8 teaspoons) to be taken for research. Taking a blood sample may result in minor discomfort and slight bruising. All samples will be collected by appointment at a time convenient for you. We may ask for blood samples on a number of occasions, but you may refuse to donate at any time without giving a reason.

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.

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What will happen if new information becomes available?

We do not expect to report the results from the research on your samples to you although very exceptionally a finding might be reported to your clinical team if it were considered that it may have an impact on your clinical treatment, and they would discuss this with you.

Will my information be kept confidential?

Yes. All information about you and your blood samples will be treated with the strictest confidence. No information about you can be traced back to you by the researcher.

Results from genetic studies will be placed on a database to which only authorized individuals have access. Before having access to your clinical information and/or tissue samples researchers must agree to conditions which safeguard your confidentiality. You will not be informed of the results of genetic testing and donating tissue to the Biobank will have no impact on your medical insurance.

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 doctor or nurse
- Contact the Biobank Manager on 01691 404120 , who will try to answer your question or will arrange for you to speak to an appropriate person
- 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 blood samples being held in the Biobank and all tissue samples will be destroyed. Blood samples will also be recalled from studies where they are in use and destroyed. You do not have to give a reason for changing your mind. However, if some data have already been used it is not always possible to recall it.

To withdraw your consent, please contact the Biobank Manager on 01691 404120 or write to us at RJAH Biobank for Studying Health and Disease, Robert Jones and Agnes Hunt Orthopaedic Hospital NHS Foundation Trust, Oswestry, SY10 7AG.

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

The Biobank is overseen by the Joint Research Office of RJAH. The cost of operating the Biobank will be funded by sponsors.

Who has reviewed the project?

The RJAH Biobank for Studying Health and Disease has been given a favourable ethics opinion from the National Research Ethics Service (NRES) Committee, Yorkshire and the Humber – Leeds East Research Ethics Committee. The REC number is 17/YH/0108

Thank you for taking the time to read this information.