PNH National Service
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The Leeds Teaching Hospitals
NHS Trust

The PNH Research Tissue Bank

INFORMATION SHEET

We are inviting you to donate tissue samples for research into disorders of the blood and bone marrow.

To help you decide whether to take part, it is important for you to understand why the PNH Research Tissue Bank (referred to as the PNH RTB or the tissue bank) is needed and what research will be carried out using tissue stored in it. Please take the time to read the following information carefully and discuss it with relatives or friends if you wish. A member of your clinical team will be happy to answer any questions you might have or give you more information.

Important things you need to know

- We want to collect tissue from patients to use in research to improve the understanding and treatment of PNH and related conditions
- Your samples will be stored and used in research now and in the future
- Donating to the tissue bank fits into your normal clinic appointments so there are no extra clinic visits
- You may be asked to provide samples on several occasions. You can refuse at any time
- Your samples and information will be given a code to protect your identity
- You can withdraw from the tissue bank at any time

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Contact us

If you wish to speak to anyone about the PNH Research Tissue Bank, please contact the PNH Team on **0113 206 8625** or by email at: **pnh.leeds@nhs.net**

What is the purpose of the PNH Research Tissue Bank?

The purpose of the tissue bank is to collect and store blood and other samples as well as health data from patients and healthy individuals. The samples and data will be used by scientists who are carrying out research into the causes of PNH and related disorders such as aplastic anaemia, myelodysplastic syndrome, myeloproliferative disorders, leukaemia and thrombosis. A supply of tissue from patients is vital as it allows scientists to learn about these diseases and may help to improve the treatment of them. The PNH RTB is ongoing and samples will be collected over many years.

Why am I being invited?

You are being invited because you are under the care of the PNH Team for your condition. We are asking you to donate an additional sample for research as well any samples that are left over after diagnosis from your normal haematology care.

Do I have to take part?

No, it is entirely up to you whether you wish to donate samples to the tissue bank. You are free to withdraw from the tissue bank at any time without giving a reason and without your medical care being affected.

What will happen to me if I take part?

A member of the PNH Team (or other appropriate person) will explain the tissue bank to you and if you decide to take part, you will be asked to sign a consent form. You will be given a copy of this information sheet to keep.

You will then be asked to provide samples of blood, buccal cells (from your mouth, taken by a swab or mouth wash), urine or bone marrow (if applicable) to the tissue bank.

Blood samples

During your normal visit to the clinic, you will be asked to give an additional blood sample (up to 6 teaspoons) for the tissue bank. This will be taken from the same needle as the samples taken for your normal haematology care. When you visit the clinic in the future, samples will normally be sent to the diagnostic laboratory as part of your care. In many cases some of the samples will be left over. With your permission, the laboratory may give the tissue bank these left over samples. We are also asking you to allow any leftover material from samples taken in the past and retained by the laboratory to be transferred to the tissue bank.

You may be asked to provide additional blood samples for the tissue bank to those that are taken as part of your care in the future. You can refuse these on any occasion.

We also ask your permission for any PNH-related research samples that may have been collected in the past to be transferred to the tissue bank.

Buccal cells

You may be asked to provide a sample of the cells from your mouth (called buccal cells). These cells will be collected either by a cheek swab or by using a salty solution. Both methods will not cause you any discomfort. You may be asked to provide further samples in the future. You can refuse on any occasion.

Urine

You may be asked to provide a urine sample for the tissue bank on more than one occasion. You can refuse at any time.

Bone marrow

Bone marrow will only be taken if a routine marrow test is being performed – you will not be asked to have an additional bone marrow test.

If you have a bone marrow test as part of your routine care, samples are sent to the laboratory to make a diagnosis. In some cases, part of these samples will be left over. With your permission, the laboratory will give the tissue bank these left over samples. We are also asking you to allow any material that may have been taken and stored in the past to be transferred to the tissue bank. We may ask you for an additional sample to be taken from the same needle during your bone marrow test for the tissue bank. You can refuse this.

Health data

When your samples are collected we would also like to collect some information from your hospital notes. This is because information about your condition greatly increases the usefulness of your donated samples. This will only be accessed by members of your clinical team or authorised members of the tissue bank staff. Information such as your name and address will not be passed to researchers.

What will happen to the samples I provide?

Your samples will be stored and used in research both now and in the future. They will be used in a variety of studies researching PNH and related disorders. Any tests carried out are not part of your medical care and the bank will not test for infectious diseases.

We may send your samples and associated information (with personal identifiers removed) to researchers in universities, hospitals, or in commercial companies, both here in the UK and abroad. Researchers must provide an explanation in writing of what they intend to do with the samples. A panel of doctors and scientists as well as a patient representative will decide if the research is of medical value before they give permission for your samples to be used.

We request that researchers give us data from any studies carried out using donated samples and information from the tissue bank. This adds to the richness of information linked to your samples. Your information and related research results may be shared with other tissue banks, research groups or institutions or placed in scientific databases in a way that does not identify you.

We may charge researchers a fee for access to your samples and data to cover the costs of collection, storage and transportation. If scientists develop a beneficial new test or treatment tested or developed in part using your samples, a commercial company or other research organisation may then make a profit out of the product they have developed. However, we regard your sample as a gift and you will not receive any personal financial reward for your donation or from the results of the research, either now or in the future.

The samples you provide will be stored in a way that ensures they remain useable in research for many years. Your samples and data may therefore be stored indefinitely unless an ethics committee decides otherwise, or you choose to withdraw from the tissue bank.

Will any genetic testing be carried out on my samples?

Some of the research carried out using your samples may include looking at the genetic material in your cells (your DNA – this is what your genes are made of) which may help to predict the development of disease and response to treatment. This type of research may look at aspects of your disease that may be inherited or to discover ways in which abnormal cells have changed compared with healthy cells. Your samples will not be used for any form of reproductive or animal research.

What are the possible risks or disadvantages of taking part?

No additional discomfort is expected from the procedures carried out for this study. Blood sampling is a routine procedure carried out in the haematology department. For most patients venepuncture for drawing blood is usually well tolerated. However, rarely it may cause bleeding, bruising, swelling, clotting, and possibly infection at the needle site. If you are having a sample taken to look at your bone marrow, taking an extra sample for the tissue bank may prolong the procedure by a couple of minutes.

What are the possible advantages of taking part?

Research using the collected samples may lead to a better understanding of the causes of blood disorders and therefore may lead to better treatment in the future. It is unlikely that the research will help you directly. You will not receive any payment for donating samples to the bank.

Will my information be kept confidential?

To keep your information and samples confidential, we have put many safeguards in place. We will:

- Remove personal identifiers such as your name and full date of birth from your samples and information. This will be done by a member of the PNH Team before your samples leave the hospital
- Assign a unique code to you and your samples/information
- Only provide researchers with the coded information and samples
- Ensure that researchers sign a contract that includes rules on how they may use and store the samples and information
- Use security measures to control access to unauthorised use of samples and information such as physical access controls, computer security, confidentiality agreements and staff training
- Not identify you in any publications
- The PNH Team will be able to re-link your personal details with your samples and information, to allow you to withdraw from the tissue bank, and to let you know of any significant health related findings
- Ensure that your samples are stored, used and disposed of in accordance with legal requirements (e.g. the Human Tissue Act 2004).

You can find more information about how we collect, store, use and protect your personal information in the accompanying privacy leaflet.

What will happen to the results of the research?

Research that is carried out using the samples that have been donated to the tissue bank may be listed on the PNH website www.pnhserviceuk.co.uk. The results of the research, which may not be available for many years, will be published in scientific journals or presented at international meetings and conferences. You will not be identified in any publications. Details of these will be made available to donors and other interested parties *via* the PNH website.

Significant health-related findings

Research using your samples may occasionally identify unexpected information that could be important to your health, or that of your family members. These are known as significant health-related findings. Examples might include evidence of a serious inherited condition or another finding that may have important implications for future healthcare.

Any potential significant health-related findings will be checked by suitably qualified members of the research team. If you have agreed on the consent form, the tissue bank research team may inform the PNH Team, who may contact you to discuss the finding and any appropriate follow-up.

If, in the future, you stop seeing this team, you will need to keep them updated if you change your contact details. You may change your mind about receiving these results at any time by completing an opt-out form.

What if I change my mind?

You are free to withdraw from the tissue bank at any time and you do not have to give a reason. It will not affect your medical care in any way. If you wish to withdraw you should speak to the PNH Team or contact the PNH RTB directly (Section of Experimental Haematology, Wellcome Trust Brenner Building, St. James's University Hospital, Tel: 0113 3438640, email: PNHRTB@leeds.ac.uk). We will send you a withdrawal form to complete and return. Once we receive this, we will destroy all of your samples we hold that have not been used or distributed. We will also destroy all information we have collected about you. We will then write to you to confirm that your samples have been destroyed. If some time has passed your samples and information may have already been used in research projects. We cannot remove related research data from studies that have already started.

Who is organising and funding the PNH RTB?

The PNH RTB is run and funded by the Leeds Teaching Hospitals NHS Trust and the University

of Leeds. The collection and storage of samples and information by the tissue bank and the research that can take place using them, has been reviewed and approved by the Yorkshire and the Humber (Leeds East) Research Ethics Committee.

What if I have a concern or a complaint?

If you have a question, concern or complaint about any aspect of the PNH RTB, please speak to the PNH Team in the first instance. They will do their best to address your query.

If you remain unhappy and wish to make a formal complaint, you can do this through the Leeds Teaching Hospitals NHS Trust Patient Advice and Liaison Service (PALS). PALS provides confidential advice and support and can help you raise concerns or make a formal complaint. You can find out how to contact PALS on the Leeds Teachings Hospitals NHS Trust website (www.leedsth.nhs.uk). Making a complaint will not affect your medical care, your relationship with the healthcare team, or your participation in the tissue bank.

The PNH Research Tissue Bank

GDPR

HOW WE USE YOUR INFORMATION

The PNH Research Tissue Bank will use information about you from your medical records. This leaflet explains what information may be collected and what will happen to it.

How will we use information about you?

We will need to use information from your medical records for this tissue bank to store with your samples. We will only use information that we need. We will let very few people know your name or contact details, and only if they really need it for this tissue bank.

The information about you will also include your NHS number, name, date of birth and address details. People will use this information to record that you are taking part in the tissue bank or to check your records to make sure that the research is being done properly. Only people who need to know who you are will see this information.

People who do not need to know who you are will not be able to see your name or contact details. Your health information and samples will have a code number instead.

The University of Leeds is responsible for looking after your information. We may share your tissue bank samples and related information with researchers whose project has been approved through our access process.

We will keep all information about you safe and secure by:

- Only releasing samples and data which is coded (no names or other identifiers)
- Making sure researchers sign an agreement which stops them from trying to identify a participant
- Only share information the researcher needs to do their research

International transfers

We may share or provide access to samples and data about you outside the UK for tissue bank projects if the researchers are based in other countries.

We will make sure your data is protected. Anyone who accesses your data outside the UK must do what we tell them so that your data has a similar level of protection as it does under UK law. As well as the steps we take to keep your information safe listed in the section above, we will make sure your data is safe outside the UK by doing the following:

- Some of the countries your data will be shared with have an adequacy decision in place. This means that we know their laws offer a similar level of protection to data protection laws in the UK
- Where the country does not have an adequacy decision, we use specific contracts approved for use in the UK which give personal data the same level of protection it has in the UK. For further details

visit the Information Commissioner's Office (ICO) website: https://ico.org.uk/for-organisations/uk-gdpr-guidance-and-resources/international-transfers/

- We do not allow those who access your data outside the UK to use it for anything other than what our written contract with them says
- We need other organisations to have appropriate security measures to protect your data which are consistent with the data security and confidentiality obligations we have. This includes having appropriate measures to protect your data against accidental loss and unauthorised access, use, changes or sharing
- We have procedures in place to deal with any suspected personal data breach. We will tell you and applicable regulators when there has been a breach of your personal data when this is legally required. For further details about UK breach reporting rules visit the Information Commissioner's Office (ICO) website: https://ico.org.uk/for-organisations/report-a-breach

How will we use information about you after the tissue bank ends?

Your data will be stored for as long as the tissue bank is running. Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

We will keep your tissue bank data for a maximum of 10 years after the tissue bank closes. The data will then be fully anonymised and securely archived or destroyed.

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have
- You have the right to ask us to access, remove, change or delete data we hold about you for the purposes of the tissue bank. You can also object to our processing of your data. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this

Where can you find out more about how your information is used?

You can find out more about how we use your information, including the specific mechanism used by us when transferring your personal data out of the UK:

- By visiting the HRA website to read the patient data and research leaflet (www.hra.nhs.uk/patientdataandresearch)
- By asking the PNH Team for details of the University of Leeds Data Protection Officer

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