



Healthy Volunteer Information Sheet

We would like to invite you to take part in our research tissue bank. Before you decide, we would like you to understand the purpose of the tissue bank, and what being part of it would mean for you. Our team will go through the information sheet with you and answer any questions you may have. If English is not your preferred language and you would like this information in another language, please ask and it will be provided, or an interpreter called. Take as much time as you need to decide whether or not you wish to take part. If you wish to take part, you will be asked to sign the Welsh Neuroscience Research Tissue Bank Consent Form. By signing this form, you indicate that you understand this information, and you give consent to donate samples (such as, but not restricted to, blood, saliva, urine, hair and/or nails) to the Welsh Neuroscience Research Tissue Bank. Please take time to read the following information carefully and discuss it with others if you wish.

Thank you for reading this.

What is the purpose of the tissue bank?

The aim of the tissue bank is to help research into the causes, diagnosis, and treatment of neurological diseases. Research with tissue can help find out more about what causes neurological disease, how to prevent it, and how to treat it.

What is the tissue bank?

The tissue bank is a collection of samples of human tissue and body fluids such as blood and urine. The samples are stored in a special freezer in a laboratory within Cardiff University at the University Hospital of Wales. The tissue bank is used to collect tissue for medical research.

Why have I been invited?

You have been asked to participate because you are a healthy individual who does not have one of the illnesses we are studying and are over 16 years of age. Comparison of samples between normal individuals and those with neurological disease is of considerable importance researching these illnesses.

Do I have to take part?

No, it is up to you to decide to join the research tissue bank. We will describe the research and go through this information sheet. If you agree to take part, we will then ask you to sign a consent form. If you decide not to take part, you do not have to explain your reasons and it will not affect any future medical treatment or legal rights.

You are free to withdraw your consent at any time, without giving a reason, even after signing the consent form. If requested, any unused samples will be disposed of according to locally approved procedures. Any samples used or results generated prior to the withdrawal of consent will continue to be utilised.

What will happen to me if I take part?

We will seek your consent to take, store and analyse a blood sample or other biological sample such as urine, saliva, hair or nails for research purposes into neurological diseases. If you agree to providing a blood sample, a trained phlebotomist or clinician will take a sample of no more than 50mls (or 10 teaspoons) of blood, from a vein in your arm using a standard procedure which takes place in hospital every day. Blood samples will then be processed so that serum, plasma and DNA

are extracted and stored. If you agree to providing a saliva sample, you will be asked to spit into a collection tube, containing a stabilising agent, at a time that is convenient for you. We will then use this sample to extract DNA for analysis. This is a non-invasive procedure and there are no foreseeable risks of discomfort. If you agree to provide urine, hair or nail samples, these will be collected using non-invasive procedures, overseen by a trained team member or clinician involved with the tissue bank.

If you agree to future contact, further samples may be requested, but not more than twice per year and at a convenient time agreed by you. Your consent is enduring for the duration of the tissue bank approval, however, you are free to withdraw your consent at any time, or opt out on any occasion, without giving a reason and without affecting any future medical treatment, legal rights or position within the university.

We hope that by collecting these samples we can improve the care we provide for patients with neurological conditions in the future.

Will I be paid anything for taking part?

No, you should understand that any samples you give will be as a gift and you will not benefit financially in the future should this research lead to the development of a new treatment or medical test.

How long will my tissue be stored?

Tissue placed in tissue banks are usually kept at very low temperatures, and can be stored this way for a very long time.

What type of research will be done with my tissue?

Many different types of research rely on the use of human tissues. They can be used to help understand what causes diseases, to help diagnose diseases, and can even be used to help develop new tests and new ways to treat or even cure diseases. Some of the research may lead to new medical products, such as diagnostic tests or new procedures. Research that uses the tissue in this bank includes genetic research. This can include looking at the way that diseases might be inherited in families, or how certain genes might cause disease, or how a person's genes influence the way that they respond to treatment.

Will you analyse my DNA?

On the consent form it asks that you give consent for your sample to be used in research that identifies genes or diseases that run in families, for example, disease that can be passed on (through DNA) to blood relatives. If however you are not happy for your samples to be used for research into genes, then unfortunately we will not be able to recruit you into the tissue bank.

As part of the research we intend to carry out analysis of DNA and other non-diagnostic tests. The type of analyses we will perform are for research purposes and therefore we will not be able to provide any clinical feedback.

What are the possible benefits of taking part?

There will be no direct advantages or benefits to you from taking part, but your contribution will help us understand more about the symptoms, progression and causes of neurological disorders and possibly other medical conditions.

What are the possible disadvantages and risks of taking part?

If you agree to donate tissue to the tissue bank, we will perform this at a time that is suitable for you. Blood samples will be taken by a trained phlebotomist or clinician, this will be similar to a regular blood test at your GP or hospital. Some people feel mild discomfort when giving a blood samples, sometimes there is mild bruising afterwards. The amount of blood we propose to take should not cause anaemia and we will keep a record of this in order to minimise risk. You should tell us if you have given blood (any amount) for any reason anywhere else in the past month.

At present, it is not foreseen that any cell culture of colleagues' material will occur in the vicinity of the donor. If, however, a local research study does require this, then locally approved standardised safety protocols will be adopted in order to ensure that there is no contact between donor and their own cultured material. There are no other obvious disadvantages to taking part in this study.

Will anyone look at my medical records?

We will not look at your medical records for the tissue bank. However, in order to do research with your tissue, researchers may need to know some things about you. For example: Are you male or female? What is your race or ethnic group? How old are you? Have you ever smoked? What medications are you taking? Do you have other medical problems? Is there a family history of diseases? This helps the researcher answer questions about diseases.

The information that may be given to the researcher includes but is not restricted to: your age, sex, race, medical history, and possibly some family history. This information will be collected, using the accompanying Clinical Elements Data form alongside your consent, by the tissue bank staff. All personal data will be treated as strictly confidential and only those on the research team will be able to link this data to your samples and other research data.

Under data protection law, we have to specify the legal basis that we are relying on to process your personal data. In providing your personal data for this research we will process it on the basis that doing so is necessary for our public task for scientific and historical research purposes in accordance with the necessary safeguards and is in the public interest. Cardiff University, specifically The Welsh Neuroscience Research Tissue Bank staff will collect information about you for the biobank records from the Clinical Elements form described above. The information will include your name, age, gender, race, smoking history, previous medical history etc. We will use your personal information (name, address, date of birth) to make sure we are matching the correct data to the correct donated samples. All information related to your diagnosis and treatment will be treated in strictest confidence.

Who gets to use tissue in the tissue bank?

Access to your tissue and any personal data that may be associated with your tissue is strictly controlled. Various researchers from the University Hospital of Wales/Cardiff University and elsewhere may use your tissue in research studies. However, they must make a formal request to use these samples and their research must be approved by the people who are responsible for administering the tissue bank. Samples in the Welsh Neuroscience Research Tissue Bank can only be used for research to advance the understanding of neurological diseases. Samples will not be sold for profit or used for animal research or the commercial sector. Once the study is approved, the researcher receives your tissue and when appropriate, non-identifiable data collected using the Clinical Elements Data form described above. The researcher will not receive your name, address, phone number, or any other personal identifying information. All samples will be supplied anonymously to researchers. Only the research tissue bank staff will be able to identify which samples you donated. The recipients of your samples will not be able to identify you from the samples. This is done to protect your confidential information.

Will my GP be told I am taking part in the research tissue bank?

We will not inform your GP that you are taking part.

Will my taking part in this tissue bank be kept confidential and can outside bodies like insurance companies access the research tests?

All information that is collected about you during the course of the research will be kept strictly confidential. We will code your sample, so that a number rather than a name is used in further analysis. The link between the code and your name will not leave the hospital. Coded samples (i.e. without your name) for these tests may only be shared with other research groups for analyses. Only the tissue bank team will have access to the information that can identify you and link you to your samples. Any information collected during the research will be kept confidential. We will store the information on a secure, confidential database, this will enable us to analyse the information

gathered for research. You may ask for your personal information to be removed from this database at any time, in accordance with the General Data Protection Regulation 2018.

Cardiff University is the sponsor for this study based in the United Kingdom. We will be using information from you and your Clinical Elements form 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. Cardiff University 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 at www.cardiff.ac.uk.

What happens to my samples at the end of the study?

With your consent, your samples may be retained at the end of this project for use in future research within the UK and abroad, according to ethically approved procedures. At this stage we do not know what the research will involve but some of it could include DNA analysis. Your samples will not be sold for profit and will not be used in animal research or the commercial sector.

All samples will be supplied anonymously by researchers. Only the tissue bank team will be able to identify which samples you donated. The recipients of your samples will not be able to identify you from your samples.

You may withdraw your consent for the storage and future use of your samples at any point. If you do withdraw your consent your samples will not be used in any subsequent studies and will be destroyed according to locally approved practices. Any samples already distributed will continue to be used in that study and will be destroyed at the end of the study.

What will happen to the results of research using samples from this tissue bank?

Our aim is to publish the results from these studies in academic journals and present findings at conferences. You will not be identified in any report, presentation or publication.

What if something goes wrong?

If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for legal action, but you may have to pay for it. Regardless of this, if you wish to complain, or have grounds for concerns about any aspect of the way you have been approached or treated during the course of this research; the normal National Health complaints procedure is available to you. The Complaints Officer can be contacted on (029) 20746 296 or by emailing concerns@wales.nhs.uk.

Who is organising and funding the tissue bank?

The tissue bank is organised and administered by Cardiff University, Institute of Psychological Medicine & Clinical Neurosciences, together with the University Hospital of Wales, Cardiff. The tissue bank is supported by the Neurosciences Directorate as part of its core activity.

Who has reviewed the study?

All research in the NHS is assessed by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given a favourable opinion by the Wales REC 3.

The Welsh Neuroscience Research Tissue Bank is licensed by the Human Tissue Authority (licence 12422) under the UK Human Tissue Act (2004) to store human samples for research purposes.

Contact for further information:

Should you have any further questions relating to this study, you may contact us during normal working hours:

Director: Professor Neil Robertson
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Email: robertsonnp@cardiff.ac.uk
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If you decide to take part, you will be given a copy of this information sheet and signed consent form to keep. We would like to thank you for participating in the Welsh Neuroscience Research Tissue Bank.

