



Patient 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 that you give consent to donate samples (such as, but not restricted to, blood, urine, saliva, cerebrospinal fluid (CSF), brain biopsy, peripheral nerve tissue) 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 invited to take part because you have attended the Neurology/Neurosurgery Department at your local hospital and are over 16 years of age. During your normal treatment, it is usual that samples are collected from you. We are asking your permission to take an extra sample to help study neurological diseases. There are several types of samples that might be collected, not all of which will apply to you.

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 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 CSF, urine, saliva, hair or nails for research purposes into neurological diseases.

The samples that we are able to store in the tissue bank are listed below:

- 1) Blood. If you agree to give a blood sample, a trained phlebotomist or clinician will take no more than 50mls (or 10 teaspoons) 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.

- 2) Cerebrospinal fluid (CSF). If you are having a sample of CSF collected as part of your clinical care we may ask to take surplus CSF, which will be no more than 10mls (or 2 teaspoons), for chemical analysis for research purposes if you are agreeable.
- 3) If you agree to provide a saliva sample, you will be asked to spit into a collection tube, containing a stabilising agent, at a time that is convenient to you. We will then use this sample to extract DNA for analysis.
- 4) If you agree to provide samples of urine, nails and hair, these can be collected using non-invasive procedures, over seen by a trained team member or clinician involved with the tissue bank.
- 5) Brain tissue. If you are having a brain biopsy as part of your clinical care, we may ask to keep any surplus brain tissue not used for diagnostic or clinical purposes for research if you are agreeable.
- 6) Peripheral nerve tissue. If you are having a peripheral nerve biopsy as part of your clinical care, we may ask to keep any surplus nerve tissue not used for diagnostic or clinical purposes for research if you are agreeable.

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 your medical treatment or legal rights.

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 clinical feedback.

What are the possible benefits of taking part?

There will be no direct benefits to you for 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 the same time as one of your routine clinical samples if possible. If it is not possible to take blood during your routine clinical appointment, a trained phlebotomist or clinician will collect a sample at a time that is convenient to you. You may experience some minor discomfort from having the extra blood sample taken, sometimes there is mild bruising afterwards. The amount of blood we propose to take (no more than 50mls per bleed) should not cause anaemia. We will keep records of donation dates and amounts donated in order to minimise risks. We ask you to inform us if you have given blood for any reason anywhere else over the last month. Collection of cerebrospinal fluid, brain or nerve tissue is strictly controlled and will only be taken as surplus products during your routine clinical intervention. There are no foreseeable risks of over donation and no other obvious disadvantages to taking part in this study.

Will anyone look at my medical records?

The Welsh Neuroscience Research Tissue Bank would like to collect information from your medical record, such as your age and sex, and record the details of your condition such as the diagnosis and results of various tests including results of any imaging. The tissue bank team would also like to follow your progress by looking at information that your doctor has collected from you during your routine follow up visits. You will not have to make a special trip or appointment for this. Your doctor may also record information such as what medications you take.

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 your NHS medical records. The information will include your name, age, gender, race, diagnoses, medication, disease progress for example. We will use your personal information (name, address, NHS number, date of birth) to make sure we are matching the correct medical record to the correct donated samples. All information related to your diagnosis and treatment will be treated in strictest confidence.

Why do you need information from my health records?

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.

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, including researchers from outside the UK. 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 information about you from your hospital record. The information that may be given to the researcher includes but is not restricted to: your age, sex, race, medical history, diagnosis, treatments, and possibly some family history. This information will be collected from your health records by the tissue bank staff. 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 your 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?

Yes, 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 be shared with other research groups for analyses. 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 medical records 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 may 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 to 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, Division 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 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.

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If you decide to take part, you will be given a copy of this information sheet and a signed consent form to keep. We would like to thank you for participating in the Welsh Neuroscience Research Tissue Bank.

