Bristol Biobank Information Sheet

We would like to invite you to donate to the Bristol Biobank to help researchers learn more about serious diseases such as heart disease, cancer, infectious diseases and diabetes.

Who are we?
We are a group of specialist doctors and scientists working at the University of Bristol and University Hospitals Bristol NHS Foundation Trust who carry out biomedical research into a number of different diseases and conditions.

Why have we approached you?
We are asking you to consider donating some tissue samples, because you are currently receiving medical treatment or care. This is not part of your medical care and you will not receive any results from the samples you donate. This is because the research will be done on anonymised samples.

What is the research about?
The Bristol biobank has been set up to help researchers find new ways to detect, treat and maybe even prevent or cure health problems. This research often needs samples of human tissue. Some studies may look at how genes affect risk of certain diseases or responses to treatments. The Bristol Biobank will help researchers with this research by providing tissue samples. Some diseases affect many different parts of the body (e.g. diabetes) and by sharing tissue
samples with doctors from different specialities we can work in a more coordinated manner.

**What does donation involve?**

**Left-over samples**
Depending on the reason for your medical care, you may have had, or be having, a number of test samples (blood, urine, stool etc.) taken by doctors as part of your clinical management. If you agree, we would like your permission to keep samples like this that are left over once the tests have been done.

If you have come to hospital for a planned surgical procedure, it may be possible to collect tissue that is removed during the procedure and would normally be thrown away. If you agree, and the tissue is not needed by doctors for other tests, we would like to save such samples for our biobank instead of throwing them in the bin.

**Samples collected specially for the Biobank**
We may also ask to collect additional samples from you that wouldn’t normally be taken as part of your care, but could provide us with important information. These might include samples such as saliva, blood, urine and stools, or swabs to look for bacteria and viruses in the back of the nose, throat or ear, for example. Any blood samples would be taken by specially trained individuals. Nose or throat swabs are smaller than the cotton buds you can buy and are gently inserted into the nose for a few seconds or touched against the back of your throat.

A member of the research team will explain which sample(s) we are interested in collecting from you. You can agree to donate none, some
or all of the possible samples. Any samples we get are very valuable to us.

**Repeated donation option**

Sometimes we may wish to collect several samples over a period of time, for example to compare samples from before, during and after your treatment. These may be leftovers of samples that are being taken anyway as part of your medical care or samples taken specifically for the biobank, or both. You would be asked to confirm your agreement verbally at the time of each donation, and would be able to say which samples you were happy to donate on that occasion. You would be able to withdraw your consent to further donations at any time. It is entirely up to you whether you want to donate samples once or repeatedly, or if you would prefer not to donate at all.

Any future donations would be arranged to coincide with your routine care visits/clinic appointments to minimise any inconvenience to you.

**Do I have to take part?**

No, it is entirely voluntary. You should feel no pressure to take part. If you decide to take part but then change your mind, you are free to withdraw without giving any explanation. Your decision about participation will not affect any future medical care that you may receive, or the care of any relatives already receiving treatment.

**What are the benefits of taking part?**

You will not benefit directly from the donation. Researchers will not be able to contact you to give results from your samples, even if they are...
clinically significant. This is because the samples are used anonymously and the results will not be kept in your medical records. We hope that research carried out using these samples will help us to understand, treat and prevent serious illnesses and conditions in children and adults in the future, and you may benefit from knowing that you have been involved in this. Information about the research done using samples from the bank will be available in a regular newsletter that we will send you, if you request this.

**Are there any risks involved?**

Donating samples taken during an operation should not affect the risks of the procedure itself. Donating a blood sample may be briefly painful and leave a small bruise. Whenever possible we will keep leftover blood, rather than taking a sample just for the Biobank. Having a nose or throat swab taken can be a little uncomfortable for a few seconds. The risks associated with getting most other samples, such as saliva or urine, are minimal.

**What happens to the samples?**

The samples will be stored in the Bristol Biobank. Some may be used in research that is being done now and those samples may be used up in a few weeks once the experiment is completed. Other samples will be stored securely for research in the future and may be kept indefinitely (for example, in a frozen or preserved form) until the research is ready to start. Most of the research using the samples will take place in Bristol. Some samples may also be made available to researchers working in universities, hospitals or other organisations in other parts of the UK or abroad. The samples that you donate will **not** be sold for profit and will only be used for ethically approved research.
in the field of biomedical research, although we may ask for a fee from researchers based on a cost recovery model to help cover the costs of running the biobank.

**Genetic research**

Some of the samples may be used to study the role of genes in diseases, for example, trying to understand if certain individuals or families are more at risk of certain infections because of their genetic makeup (DNA). If you do not want this to happen, you will be able to say so on the consent form.

**Cell culture**

Cells may be put into culture. This means they can be kept alive for several weeks for research. Under special conditions, ‘immortal’ cells can be made from certain types of tissue samples, which mean that the cells continue to divide in the laboratory indefinitely. Most cells die once they have been removed in only a few weeks. Generating ‘immortal’ cells allows researchers to continue working with them for longer. If you do not want this to happen, you will be able to say so on the consent form.

**Anonymity**

All samples will be processed in the laboratory anonymously. However, we will keep the consent form (with your name on it) and, separately, anonymised records of the actual samples, so that we know what has happened to all the samples that you donate to us. This way, if you decided for any reason in the future that you did not want us to use your samples, you could get in contact with us and we
could dispose of them (except any samples that were already being or had been used in experiments).

**Do the researchers need any other information?**
We would like to ask you for some general information about your health and wellbeing, as well as some information about why you are receiving medical care at this time. We will generally get this information by asking you directly, or from looking at your medical records, if you are happy for us to do this.

**Confidentiality**
Information that you provide will be held in accordance with data protection laws in the UK. Data identifying you personally will only be available to a small number of staff involved in coordinating the biobank who are professionally bound to maintain your privacy. This information will be stored securely and the biobank will not provide researchers using the tissue, or third parties, with information from the biobank to identify specific individuals. Results from the research on your individual samples will not be fed back to you, even if there are findings of clinical significant. Overall results of Biobank research will be available by newsletter to all donors who chose to receive this. Apart from this, researchers will not contact you about this tissue donation in the future.

**What happens if something goes wrong?**
The University of Bristol holds Public Liability insurance that covers the legal liability of the University in the remote eventuality of harm to a donor arising from management of the bank by the University. The University is unable to check that all clinicians taking samples for the
bank will have equivalent indemnity or insurance arrangements in place. However, NHS clinical negligence arrangements will apply as regards any negligent harm to donors caused by NHS staff or medical academic staff, and GPs and doctors in private practice should have similar legal liability cover as part of their professional role.

Who has reviewed the Biobank and how is it monitored?
The Bristol Biobank has been approved by the Wales REC 3. Tissue will be stored under license from the Human Tissue Authority who may inspect the bank to ensure it is being run in line with national recommendations. The bank may also be internally audited by the University of Bristol on whose premises the samples will be stored.

What do I do if I have got further questions or concerns?
If you would like more information from those coordinating the biobank, we would be very pleased to talk to you. Please contact:

Bristol Biobank Manager
Level 7, Bristol Royal Infirmary
Upper Maudlin Street
Bristol
BS2 8HW
Phone: 0117 342 4946
Email: Bristol-biobank@bristol.ac.uk
Alternatively, if you would like some advice about taking part in research or have any concerns or complaints about the way you have been treated, you can contact:

Patient Support & Complaints Team
University Hospitals Bristol
Welcome Centre
Queens Building
Bristol Royal Infirmary
Upper Maudlin Street
Bristol, BS2 8HW

Phone: 0117 342 1050
Email: pals@uhbristol.nhs.uk

[replace with local complaints team contact details, if applicable]

What do I need to do now?
You do not need to do anything further right now. A member of the
research team will come and see you when you have had time to
consider this information, to give you a chance to ask questions. If you
decide you would like to participate, you will be asked to sign a
consent form.

Thank you for taking the time to read this information and for
considering donating to Bristol Biobank