

NBTR - Blood & Cerebrospinal fluid (CSF) samples v 4.1

It can be very helpful to researchers if participants are prepared to give small blood and/or CSF samples which can be linked later with the donated brain tissue. This is to see whether there may be changes present during life which might help predict who may later develop dementia or other diseases. These changes are known as biomarkers. Samples would be purely for research purposes and would not be able to tell us whether you personally are at risk of developing problems. It would be completely voluntary and your decision would not affect your participation as a tissue donor.

What would blood sampling involve?

It would usually involve coming to one of our clinics where trained staff would complete a separate consent form with you and take a sample of less than 20ml of blood (four teaspoons). As with any blood sampling there is a possible risk of mild discomfort when the sample is taken and that there may be some tenderness or bruising afterwards. It is better if the sample can be taken in the clinic because it can then be processed straightaway. If you come to a clinic, we will provide a taxi (or reimburse you for any travelling expenses). If you are unable or do not wish to travel to a clinic, we may be able to arrange for the sample to be taken during a home visit.

What would CSF sampling involve?

A procedure known as lumbar puncture or spinal tap is used to obtain a sample of Cerebrospinal Fluid (CSF). This fluid cushions your brain and spinal cord and contains important bodily proteins and salts similar to blood. Because it has direct contact with the brain, it can give doctors and researchers important information about what is happening in the brain.

This procedure would only be done in the clinic. After completion of the consent form, you would be asked to lie down comfortably on one side, and a trained health professional would take a sample of CSF (

Newcastle Brain Tissue Resource

Information about
donation of additional
samples

approximately 20mls or four teaspoons) through a small needle which is placed in the lower back. The way the sample is collected is similar to how anaesthetists give pregnant women epidurals during labour. It involves lying on one side, curled up. The skin of the lower back is numbed with local anaesthetic and then a very fine needle is introduced to obtain the sample.

What are the risks of lumbar puncture?

Most people experience only mild discomfort.

Complications are rare. They include:

- Excessive discomfort during the procedure. This is more likely if the procedure is technically difficult
- Headache after the procedure (see below)
- Local infection/abscess is potentially possible but is extremely uncommon

Damage to the spine itself or the nerves are not recognised complications.

What about afterwards?

The whole lumbar puncture will only take about 30 minutes but you will be advised to rest for an hour or so afterwards before you go home. We would advise that you don't drive yourself home. We will provide taxi transport for you to get to and from the clinic.

You will have a small plaster over the needle site on your back. You need take no special precautions.

A headache is the commonest side effect following a lumbar puncture and occurs in around one in six people. It usually comes on the day following the procedure or after a few days. In most cases it is mild and settles in a couple of days. In a minority of cases, it can be severe and associated with nausea and dizziness. Even severe cases usually settle by themselves over a number of days and do not require special treatment.

If you develop a headache following your lumbar puncture, we would advise:

1. Drink plenty of fluids (aim for 2.5-3 litres over the day). Caffeine (coffee or caffeine containing soft drinks) may help.
2. Rest. Lying flat will ease the headache
3. Take conventional over the counter painkillers, if appropriate. If you are already on a painkiller, discuss options with your pharmacist.

If the headache does not settle after 48 hours or becomes intolerable, contact the research doctor who performed the lumbar puncture, your GP or your local study team.

INSERT STUDY TEAM DETAILS HERE

Do I have to give both types of sample?

No, it is completely optional. The type and number of samples you give is entirely up to you.

Where and how will they be stored?

Samples will be stored in exactly the same way as brain and spinal cord samples in secure purpose built facilities. They are subject to exactly the same degree of care and attention.

What about my preferences?

You will be asked about any preferences or restrictions on your consent. For instance, if you prefer that your samples are not used for genetic projects, by commercial organisations, in projects involving animals or sent out of the UK then these preferences will be recorded and we will abide by them.

How will we use information about you?

We will need to use information from you, and from your medical and study records for this research project.

This information will include your NHS number, name, contact details and details of your medical history. People will use this information to do the research or to check your records to make sure that the research is being done properly.

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

We will keep all information about you safe and secure.

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.

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.

We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

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

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- our leaflet available from www.hra.nhs.uk/patientdataandresearch
- by asking one of the research team
- by sending an email to nbtr@ncl.ac.uk
- by ringing us on 0191 2081231

What can I do if I have a complaint?

- Complaints or concerns can be raised with the NBTR manager on 0191 2081231 or nbtr@ncl.ac.uk or with any member of the research team
- If you prefer you can talk to the Patient Liaison Service 0800 032 0202 or NorthofTynePALS@northumbria-healthcare.nhs.uk
- If your concerns are about donated tissue the Newcastle University Quality Assurance team can be contacted via humantissueresearch@ncl.ac.uk