

INFORMATION SHEET
Lothian Birth Cohort 1936 (LBC1936) Study—Brain Tissue Bank



What is the study about?

In June 1947, almost all children living in Scotland and born in 1936 sat a verbal reasoning test that measured their mental abilities. You have kindly taken part in three waves of the LBC1936 study. The LBC1936 study aims to find out how important mental ability at age 11 years was in affecting health and mental abilities in later life. We hope that you will be willing to take part in further study waves over the coming years.

We now ask you to consider donating brain tissue after your death. This will allow us to improve the studies on the people in the LBC1936 in ways that are only possible by examining the brain directly. We aim to study the effects of the normal ageing process on the brain. We shall look at the structure of the brain to see how that relates to changes in mental ability between age 11 and later life, and the changes in thinking within the years of study in later life. We shall also measure how strongly different genes are acting in different brain tissues to see how they influence mental ability changes.

Your decision on whether or not to donate brain tissue after your death should be made after discussing it with your family. We have prepared some information for you and your family in the format of answers to questions that are often asked. It is important that you have sufficient information to make the decision of whether to become a brain tissue donor.

If, after reading all the information and discussing it with your family, you have decided to bequeath your brain tissue to research we ask that you complete and return the authorisation forms enclosed in this pack. We will keep the original forms and send you photocopies for your records.

Will the brain tissue donation cost my family anything?

No. All the costs will be met by the study.

Will my decision affect the funeral arrangements?

No, the funeral arrangements can proceed and will not be delayed or otherwise affected by your agreement to make a donation.

Can I still be an organ donor or donate my whole body to medical teaching?

If you are an organ donor, and your organs are accepted, that will take priority over brain tissue donation. However, we can arrange brain tissue donation after the organ donation process. You will not be able to donate your whole body to medical teaching.

What happens if I die at home?

In this case, your next of kin will need to call the LBC1936 study team as soon as they can. If phoning during office hours (Mon to Fri, 9am to 5pm), they will call 07913 296 845. If phoning outside office hours, they will call 07432 017 170. We will guide them through the process of what to do. We will arrange for our designated

undertaker to collect your body and take it to Edinburgh Royal Infirmary Mortuary for the limited post-mortem examination. The undertakers work 24 hours a day and can even do this during the night if necessary.

Will my family be able to view my body?

Yes. Your family would be able to view your body either before or after the limited post-mortem examination if they wish to. The procedure of limited post-mortem examination and brain tissue retrieval does not disfigure the body and should not cause your family any added distress.

What is a limited post-mortem examination?

After death your body would be taken to Edinburgh Royal Infirmary mortuary where a pathologist, assisted by skilled mortuary staff, would perform the examination. As your post-mortem examination is limited to the head, the brain would be lifted out and examined. A precisely-defined range of small brain tissue samples would be taken from the brain before it is returned to the body. These small brain samples would be retained for later examination under a microscope and be stored for research purposes.

After the limited post-mortem examination the body is carefully reconstituted by the mortuary staff. There is no disfigurement of the body and the face is not touched. The body is then released to the family for funeral arrangements with the brain replaced.

If your death occurred suddenly, or away from home, it might be that your doctor was unable to sign a death certificate because they were unsure of the cause of death. In such cases your death might be further investigated by the medico-legal authorities (Procurator Fiscal in Scotland or Coroner in England and Wales) who are likely to state that a forensic post-mortem examination will take place to establish the cause of death. Even in these circumstances, it is helpful for the legal authorities and for your family if you have stated your wishes about what you want to happen to your body.

The post-mortem examination also forms an essential contribution to the training both of young doctors who wish to specialise in Pathology and of other health care workers who require to have an in depth knowledge of the working of the human body.

What do we mean by tissue?

Tissue is the word used for a collection of specialised cells within the human body that perform a specific job. All organs, including the brain and spinal cord, are made up of tissue.

Why is brain tissue needed for research?

The donation of brain tissue is a precious gift that can advance our knowledge and understanding of many conditions. Brain tissue donation can also make an essential contribution to finding better treatments for different illnesses.

What tissue is needed?

A range of tissues from the brain will be sampled for research purposes.

What happens to my body after the brain tissue has been removed?

Following the limited post-mortem examination and removal of brain tissue samples, your body will be returned to your family's own undertaker who will be responsible for the funeral arrangements.

If I agree to donate brain tissue samples for research, how long will my brain tissue be stored?

The preservation techniques ensure that brain tissue will be usable in research studies for many years. Generally, brain tissue will be used for as long as it is feasible to do so.

If I agree to donate for research, how will my brain tissue samples be used?

The brain tissue samples will be used for ethically approved studies. Brain tissue may be used for protein, RNA or DNA analysis in future studies, and may be used for genetic studies.

What other information will be required?

In relation to any donation of tissue, it is important to have the fullest possible medical and clinical history. That is why permission to access your medical records is requested on the authorisation form.

What about confidentiality?

Your identity and that of your family is totally confidential. No identifying details will ever be made public.

All information obtained in this study will be stored securely in the Centre of Cognitive Ageing and Cognitive Epidemiology (CCACE), University of Edinburgh, and retained indefinitely. The information may be shared in an anonymised form with other researchers who are carrying out ethically approved research into cognition and ageing. Patient identifying data will be known only to core staff within the Brain Tissue Bank.

We request permission to contact your GP to let them know that you have agreed to take part in this study.

Who funds and oversees the work of the brain and tissue bank?

The Medical Research Council, which is a UK government-funded research body, funds and oversees the work of collecting post-mortem tissue and organs for research.

What if I do not wish to proceed, or if I change my mind after pre-arranging brain tissue donation for research?

We understand that deciding to make a brain tissue donation for research is not right for everyone. If you do not wish to register you need not do anything further although we would appreciate it if you returned the reply sheet. Thank you for taking the time to read through this leaflet.

If you change your mind after registering, you can make contact at any time to tell us you no longer wish to make a brain tissue donation for research. In that case, we shall

return your original Authorisation Form and remove your details from our Brain Tissue Bank register. You do not need to give any reason for changing your mind.

If you think that you have been harmed in any way by taking part in this study, you have the right to pursue a complaint and seek any resulting compensation through NHS Lothian who act as the research sponsor. Details about this are available from the research team. Also, as a patient of the NHS, you have the right to pursue a complaint to the Patient Liaison Manager, NHS Lothian Complaints Team, Waverley Gate 2nd Floor, 2-4 Waterloo Place, Edinburgh, EH1 3EG (0131 536 3370). Note that the NHS has no legal liability for non-negligent harm. However, if you are harmed and this is due to someone's negligence, you may have grounds for a legal action against NHS Lothian but you may have to pay your legal costs.

When and how will the brain tissue be retrieved?

1. Following your death, a death certificate will be issued by your GP or by the hospital doctor if you died in hospital.
2. Your next of kin will call the study team. During office hours, Mon to Fri, 9am to 5pm, call Tracey Millar, Nurse-Coordinator of the Brain Tissue Bank, on 07913 296 845. Outside office hours, call 07432 017 170.
3. Staff from the LBC1936 Brain Tissue Bank team, will guide your next of kin through the post-mortem process, step-by-step.
4. A limited post-mortem examination will be performed and your donated brain tissues will be retrieved by a pathologist.
5. Research staff from the Brain Tissue Bank will collect the donated samples and prepare them for storage.
6. Your body will be returned to your next of kin's chosen undertaker for the funeral arrangements.

It is important that we are contacted as soon as possible after your death, and we can therefore be contacted 24 hours a day. If your relatives call during office hours they are to ring 07913 296 845. If they call out of office hours they are to ring 07432 017 170. Your whole family including your immediate next of kin, and/or your legal representative, need to know that in the event of your death one of them needs to call the LBC1936 Brain Tissue Bank. We also ask you to ensure that your next of kin and/or legal representative and any healthcare professionals looking after you are aware of your bequest. In particular, it is very helpful to notify your GP of your wishes. With your permission, we will also send a copy of your signed pre-mortem authorisation form to your GP.

Who has reviewed the study?

The Tayside Committee on Medical Research Ethics B, which has responsibility for scrutinising all proposals for medical research on humans in Tayside, Fife & Forth Valley, has examined the proposal and has raised no objections from the point of view of medical ethics. It is a requirement that your records in this research, together with any relevant records, be made available for scrutiny by monitors from NHS Lothian, whose role is to check that research is properly conducted and the interests of those taking part are adequately protected.

Your agreement to take part in this study is purely voluntary and does not affect any care or treatment you receive from the health service. The study is a research project and is not part of any treatment to benefit you directly. **You can withdraw any time you like without giving any reason. Withdrawing from the study does not affect any of your treatment from the health service.** The study is co-ordinated by Professor Ian Deary BSc, MBChB, PhD, FRCPEd, FRCPsych, Professor of Differential Psychology, University of Edinburgh.

Thank you for taking the time to read this Information Sheet and for considering taking part in this study.