Information on Tissue Donation Version 4.1 – 8th December 2022

**INFORMATION ON TISSUE DONATION**

We appreciate your interest in tissue donation; although this does not benefit individuals directly, it does help to advance knowledge of brain disorders.

Please read the following information carefully. You may wish to discuss it with your family, friends or General Practitioner.

**Donating to the Queen Square Brain Bank for Neurological Disorders**

University College London (UCL) Queen Square Institute of Neurology and the National Hospital for Neurology and Neurosurgery have an international reputation for research into and treatment of neurological disorders. The Queen Square Brain Bank for Neurological Disorders (QSBB) has a unique tissue collection which is used to study a range of conditions including Parkinson’s disease, progressive supranuclear palsy, multiple system atrophy, dementia and dystonia. It has made significant contributions to understanding the causes of neurological diseases and to developing new therapies.

A tissue donation is a gift. Because the brain is a complicated organ, a whole brain is needed for diagnosis, research, developing medical and scientific tests, education and audit.

Examination of the spinal cord and samples of other tissues such as skin, muscle, peripheral nerves, dura (the brain covering) and internal organs can also contribute to diagnosis and research. Cerebrospinal fluid (CSF) bathes the brain and spinal cord, and the study of this, along with a blood sample, may provide useful information and can be obtained at the time of donation. Together the brain, spinal cord, other tissue samples, CSF and blood will be referred to as tissues in this information sheet and in the consent form.

Tissue samples are examined under a microscope by a neuropathologist to identify any disease processes. This may be supplemented by biochemical studies, analysis of DNA and other genetic material to look for abnormalities specific to some diseases. Some samples are preserved, and others are kept frozen so that they remain valuable for research for many years to come. All samples are stored in a locked facility accessible by authorised staff only.

To ensure confidentiality, each donation is given a unique code number and records are held securely. Code numbers are also used on photographs taken of specimens, microscopic slides and on clinical information. Anonymised tissues, clinical data and genetic information are released

to researchers in the UK and world‑wide for as many studies as possible, which may include genetic research, and occasionally research involving the use of animals.

The use of animals in research is not taken lightly. It is sometimes necessary in situations where other methods would not suffice. The likelihood of tissues being released to animal studies is small. Less than five percent of samples distributed for research have been used in this type of study and have typically involved mouse models to investigate fronto-temporal dementia, Alzheimer’s and Parkinson’s disease. Projects such as development of new drug treatments may also involve work with animals in the early stages.

The quality and ethical aspects of proposed research projects are assessed by a QSBB Committee set up with the purpose of ensuring tissue is used appropriately.

Results of research are published in scientific journals and are not available on an individual basis. Anonymity of donors is maintained although complete anonymity cannot always be guaranteed as it is possible donors could be recognisable to those who have known them.

Research may be carried out with the support of the commercial sector, in line with UCL Queen Square Institute of Neurology’s policy of encouraging research that can lead to new therapies. Intellectual property agreements are always set up so that neither the scientists nor the donors’ families gain a financial advantage.

The Human Tissue Act (2004) prohibits trade in human tissues for profit. To offset the considerable expense of banking tissue, cost recovery is necessary, and researchers are asked to contribute a service fee, as recommended by the UK Brain Bank Network.

**The importance of correct diagnosis**

Diagnosis of many neurological disorders can only be achieved by microscopic examination of post-mortem brain and related tissues. For research to be precise, a diagnosis made in life must be confirmed by neuropathological evaluation.

Many neurological conditions are not inherited, and often the close relatives of an affected person are at no greater risk of developing the illness than anyone else. However, in some cases problems with a particular gene can cause disease and if the neuropathological examination reveals this possibility, a diagnostic genetic test performed using stored tissue may be necessary to determine a definite diagnosis. The next of kin will always be contacted with the support of appropriate medical or nursing personnel to discuss the potential for inheritance and will be asked to give specific consent before any diagnostic genetic test is performed.

With consent, appropriate medical or nursing personnel are available to discuss the neuropathological findings with the next of kin or nominated/appointed representative. Over time research may require additional information from the next of kin, and the QSBB will seek permission to make contact in the future if necessary.

**How to become a tissue donor**

Individuals with a neurological condition and those who are without a neurological disorder can register on our donor scheme. Tissues donated from people with no neurological illness are of vital importance, providing researchers an understanding of the normal appearance and function of the brain and for comparison with disease.

A donor must be over 18 years of age, reside in the UK, and have discussed the bequest with a relative or nominated/appointed representative. The Registration and Consent to Tissue Donation forms must be completed, signed and witnessed and sent to the administrator of the QSBB at the above address. If a donor is unable to complete the consent form, it is possible for a next of kin or nominated/appointed representative to do this and sign the declaration on their behalf. Please contact QSBB if there are any queries.

When the completed Registration and Consent to Donate forms are received by QSBB, a donor is registered on our donation scheme and a donor card is issued to be carried at all times. With permission, a link to an online self-assessment questionnaire requesting medical information may also be sent to the donor. These data will be held on a highly secure web-based database, REDCap which is used in numerous similar studies within the NHS and is fully compliant with UK data security laws. Access to personal data will be protected and restricted to authorised members of the QSBB team.

Consent is sought to allow clinical information to be obtained from medical records and securely stored on a UCL computer database. A donor’s identity and the data collected and stored remain strictly confidential in accordance with the UK General Data Protection Regulation 2021 and amended UK Data Protection Act 2018.

**Steps to be taken at the time of the death of a donor**

It is important that there is as short a delay as possible between death and donation. We would be grateful if the QSBB is informed if a prospective donor becomes seriously ill.

If death occurs in the community a qualified medical practitioner (usually GP or nurse) must be contacted to confirm (verify) the death before the donor’s body can be taken into the care of a local funeral director and refrigerated. If death occurs in hospital, verification of death is usually followed by immediate transfer to the on-site mortuary. Keeping the donor’s environment cool is important to help preserve the tissue for use in research. Refrigeration at 4⁰C should happen preferably within 4 hours of the time of death.

The QSBB team should be contacted as soon as possible. Outside office hours the answer phone will give the mobile telephone number of the duty officer to contact.

QSBB staff will liaise with the GP and on confirmation that the Medical Certificate of the Cause of Death is issued, will liaise with the funeral director to arrange for the donor’s body to be transported to the nearest local hospital where the removal of tissues can be performed.

As brain donation does not require removal of the eyes or lead to disfigurement of the face, it does not prevent open casket or other traditional funeral arrangements. Skin, muscle and peripheral nerve samples can be taken discreetly from small incisions on the body. Removal of the spinal cord results in a long scar on the back of the torso. However, these procedures are not visible once the body has been prepared for the funeral. Only donated tissues are transferred to the QSBB. The donor’s body will be collected by the family’s chosen funeral director and the usual funeral arrangements can proceed without delay. All costs directly related to the tissue removal will be met by the QSBB. Funeral costs must be met by the family.

If the donor has not completed a QSBB “Consent to Tissue Donation” form during life, before the donation takes place, a QSBB "Post-Mortem Consent to Tissue Donation" form must be completed and signed by the next of kin or a nominated/appointed representative and a witness.

For this purpose, the Human Tissue Authority defines next of kin in the following order of precedence: a) spouse or partner; b) parent or child; c) brother or sister; d) grandparent or

grandchild; e) niece or nephew; f) stepfather or stepmother; g) half-brother or half-sister; h) friend of long standing.

On occasions the QSBB may be unable to accept a donation. This can be due to a number of reasons such as the donor having other conditions that may affect the brain, or if unfavourable circumstances prevail at the time of death, including the opposition of next of kin. For legal reasons some deaths require a post-mortem examination performed on behalf of the Coroner. However, it may still be possible to arrange for the transfer, examination of tissues and preparation for future research studies at the QSBB. This would require discussion between the Coroner, QSBB staff and the next of kin at the time of death.

**Important notes**

If donor registration and consent were not completed during life, the next of kin or nominated/appointed representative, with a witness, may still complete a tissue donation consent and registration form following death, in the knowledge that the donor would not have objected.

If a prospective donor’s details change, for example address, next of kin, General Practitioner, diagnosis, please notify the QSBB so that records can be amended.

As time passes it may be necessary to alert additional people to the bequest or remind others who may have forgotten.

An individual is free to withdraw consent at any time without having to give a reason. Please note that next of kin can withdraw consent after death. Samples and data will be removed from QSBB records and researchers will no longer be able to access these. However, if samples and data have already been used in the research process, complete removal may not always be possible.

When tissue is no longer suitable for research, we arrange careful disposal in a lawful and respectful manner in compliance with the Human Tissue Act 2004 and UCL policies.

The QSBB is fully licensed by the Human Tissue Authority (licence number 12198), a government regulatory body which oversees consent, storage and the use of human samples in research.

QSBB protocols have been approved by the NHS Health Research Authority, Ethics Committee London-Central. REC reference 23/LO/0044.

If you have any comments, wish to withdraw consent or make a complaint about your involvement with the QSBB, firstly please contact the Administrator, Queen Square Brain Bank, UCL Queen Square Institute of Neurology, 1 Wakefield Street, London WC1N 1PJ. Telephone: 020 7837 8370. Email: l.haddon@ucl.ac.uk

If this is not satisfactory you may wish to make a complaint through the University College London’s complaints procedure (the details of which can be obtained from University College London, Gower Street, London WC1E 6BT. Tel: +44 (0) 20 7679 2000).