



Brain and Spinal Cord donation—Participant Consent v 9.2

Please initial boxes:

I have read the NBTR Information Sheet v 9.2 on donation of brain and spinal cord tissue. I understand that by agreeing to consent to donation the tissue will be used to make a diagnosis and for ethically approved studies of neurodegenerative disease. I have had time to discuss with other family members, and opportunity to ask questions.

I understand that I, or my Nominated Representative (if applicable), can withdraw consent at any time before the donation has taken place without giving a reason, and without my medical treatment or legal rights being affected.

SECTION 1: AGREEMENT TO CLINICAL ASSESSMENT

I consent to testing of memory and thinking ability, behaviour and living skills using standard measures once a year (once every 2-5 years for non-memory impaired individuals).

SECTION 2: AGREEMENT TO REMOVAL OF TISSUE

I agree that the following may be removed after my death. I understand that in some circumstances it may only be possible to collect the brain.

Brain

Blood sample

Spinal cord

Other small samples

Note: It is very helpful to receive both brain and spinal cord but especially so in motor neurone disease, fronto-temporal dementia, ataxia and normal controls. Removal of the spinal cord entails examination of the chest and abdomen and/or back. Some studies may also wish to examine small samples of nervous, vascular and other tissues if you agree to this. You will be asked to sign a separate consent form for this. However, depending on circumstances at the time of donation, it is sometimes only possible to collect the brain.

I would like my Nominated Representative to receive a letter stating disease diagnosis only

And/or I would like a copy of the final results to be sent to my GP and referring consultant (if appropriate).

Or I would like the results to be sent to my Nominated Representative's GP:

Drat

so he/she can discuss the report with them.

Please initial boxes:

SECTION 3: USE OF RETAINED TISSUE

I agree to the use of the clinical data and tissue in any research agreed by the Management Committee of Newcastle Brain Tissue Resource. I understand that Newcastle Brain Tissue Resource will undertake custodianship of the clinical data, and donated tissue in full compliance with guidelines agreed by National Research Ethics Committee, Human Tissue Authority, and Medical Research Council. I understand that according to these guidelines, researchers will be asked to make a contribution to the cost of providing tissue samples.

I agree to the use of the clinical data and tissue by commercial/pharmaceutical companies. I understand neither I, nor my Nominated Representative nor family members will receive any financial benefit from tissue donation.

Note: Much research is carried out by commercial companies, often working in partnership with NHS and academic institutions.

I agree to the genetic analysis/study of the tissue if required.

I agree to the project data and tissue being used in research conducted outside the UK which is approved by the Management Committee of Newcastle Brain Tissue Resource.

I understand that cells may be grown in culture from my samples

I agree that clinical data and tissue retained for research may be used as a reference for other clinical cases, for medical education, audit and quality control.

I agree to the use of tissue and data in projects involving animals if necessary.

Note: It is rare that tissue will be used directly in projects with animals but many projects such as development of new drug treatments may have involved work with animals in the early stages.

SECTION 4: INFORMATION FROM MEDICAL RECORDS

I give access to my medical records, psychometric data and other research study information.

Note: The identity of the donor is not known to the researcher but it can be helpful to know more of the medical history of the person who has died. The identity of the donor is never given in publications.

SECTION 5: AFTER THE RESEARCH

I agree to the hospital disposing of the tissue in a lawful and respectful way (usually by incineration) when it can be of no further use.

Note: After completion of investigation and research, any remaining tissue or associated biological samples must be disposed of in a lawful way, according to guidelines agreed by the Royal College of Pathologists, the Medical Research Council, and the Human Tissue Authority.

OR

I agree that the NBTR will contact my Nominated Representative (*name & address*).....

.....

once the tissue is no longer required for research, who will arrange for lawful disposal. I understand this would be months or years after the funeral.

I agree to NBTR storing the clinical data for 10 years after completion of the study and thereafter subject to further ethical review.

SECTION 6: THANK YOU

The doctors and scientists who carry out research are very grateful for the tissue donation you are intending to make and would like to keep you informed about ongoing research that relies on donated brain tissue and other things we think may be of interest to you. We are not allowed to do this unless you agree. Please tell us your preferences.

I would like to receive your newsletters and information on research.

SECTION 7: OTHER REQUESTS

Please write in any other requests/concerns you have here:

SECTION 8: NOMINATED REPRESENTATIVE APPOINTMENT AND SIGNATURES

I confirm I still wish to participate in NBTR and brain donation even in the event that my capacity to make such a decision is diminished.

I appoint (*print name*) of
(*address*).....

to be my Nominated Representative with respect to brain donation
Name of donor: Date:
(*please print your name*)

Signature of Donor:
(*Please sign*)

Name of Witness: Date:.....
(*please print*)

Witness Signature:
Note: the witness needs to be someone other than the Nominated Representative

Witness Address.....

Name of Second Witness..... Date.....

Second Witness Signature
(*Only if consent is taken verbally*.....)

Second Witness Address:

SECTION 9: CONTACT INFORMATION

DONOR

Name

Address (Home/Nursing Home/Hospital):
.....
.....

Telephone: Date of birth:

Neuropsychiatric diagnosis (if known/applicable):.....

Contact name (if donor is in nursing home/hospital).....

Consultant caring for donor (if applicable):

Consultant telephone:

NOMINATED REPRESENTATIVE

Name:

Address:

Relationship to donor:

Telephone:

GENERAL PRACTITIONER

Name:

Address: Telephone:.....

SECTION 10: SIGNATURE OF MEMBER OF STAFF SEEKING CONSENT

I confirm that:

- I have explained to the person giving consent what taking part in the project involves.
- I have ensured there are no known objections to donation of the tissue specified (in section 2).
- I have offered the information leaflet on brain donation
- I have discussed the case (if applicable) with Prof/Doctor

.....

Signature: Print name:

Date: Position:

Organisation Address:

.....

Telephone:

SECTION 11: CONSENT TO BRAIN DONATION (TO BE COMPLETED AFTER DEATH)

I am the Consultee/Representative of

I confirm that to the best of my knowledge, the consent to donate the tissue specified in Section 2 is still valid and that I wish the donation to Newcastle Brain Tissue Resource to go ahead. I understand that in some circumstances it may only be possible to collect the brain.

Signature: Date:.....

Print Name:.....

If you are not the person who completed Section 8 please let us know the following details:

Relationship to donor:

.....

Address:

Contact phone number:

.....

IS PERSON CONFIRMING BRAIN DONATION DIFFERENT TO PERSON IN SECTION 8? IF YES, PLEASE TELL US YOUR PREFERENCES BELOW

THANK YOU

The doctors and scientists who carry out research are very grateful for the gift of tissue donation at such a difficult time, and would like to write to you to express their thanks. Please tell us your preferences.

I would like to receive a letter of thanks

I would like to receive your newsletter which contains information on the types of research doctors and scientists are involved in. This will be sent to the address above unless you give a different address or an email address here:

INFORMATION FOR DONORS' FAMILIES

We need to ensure that your wishes to donate can be carried out when the time comes. We will hold a copy of the consent form at the Newcastle Brain Tissue Resource (NBTR) and send copies to your nominated representative, General Practitioner, and the Nursing Home/hospital (if that is where the donor is receiving care). We recommend that the relatives closest to the donor, the executor(s) of their Will and solicitors also be informed of the decision to donate.

CONTACTING THE BRAIN BANK

In the event of death of the donor please telephone **0191 208 1345 as soon as possible** so the NBTR can make the appropriate arrangements. A death certificate needs to have been issued by the GP/hospital doctor before the body can be temporarily transferred (at our expense) to the mortuary for removal of consented tissue.

Outside office hours, at weekends, or during public holidays please telephone **0191 208 1345**. Please give your name, message and telephone number where you can be reached and someone will call you back. In the event of a death outside normal hours the NBTR advises that the body should be taken to the mortuary (if in hospital) or funeral directors, and be kept cold. We apologise for the fact that post mortem arrangements for removal of consented tissue cannot be made until the next working day due to circumstances beyond our control.

We appreciate the effort you are making, at a time you least feel like it. If you do not hear from the NBTR and are wondering what to do, please continue with your plans. We will fit in with your arrangements.