



MRC Prion Unit at UCL, Institute of Prion Diseases  
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## Using your sample for research into prion disease and related disorders

We would like to invite you (or your relative) to donate a sample for this research. We are conducting research projects to understand more about prion disease and related disorders including its' causes and effects and how it could be diagnosed and treated. Please take time to read the following information carefully. Talk to others about the study if you wish.

*The particular projects we would like you to help us with are:*

### Development of new diagnostic tests for prion disease

Prion disease is caused by abnormal prion proteins in the brain. The abnormal protein is also found elsewhere including in the blood and we are developing new ways to detect this. There are several types of abnormal prion protein whose presence and abundance we are investigating.

### Biochemical studies: characteristics and prevention of prion disease

These studies look more closely at prion proteins and how they are made up. We are using this basic knowledge to assist in the design of methods of diagnosis and treatment of prion disease. We are also using this work to find the best ways to remove prion proteins from medical instruments to reduce the risk of infection being passed on by them.

### Genetic studies: causes and risk factors in prion disease

Differences in our genes affect which diseases we are susceptible to. We are studying which genes increase risk of prion diseases and how genes affect patterns of prion disease. As we do not yet know what effect some of these genes have on diseases we do not inform participants of individual results.

Full details of our studies are available from the address below or from our website: [www.nationalprionclinic.org](http://www.nationalprionclinic.org) Samples donated for research are very valuable to us and can be stored for future studies at the MRC Prion Unit at UCL, UCL Institute of Prion Diseases (IoPD) and other collaborating organisations. All research projects are approved by a Research Ethics Committee before any samples are taken and used. Your sample would be de-identified and used anonymously by researchers; any published results would not identify you in any way. Research projects may ultimately lead to tests and treatments for disease being developed commercially which would benefit future patients. Those donating samples would not benefit financially from such development. As samples will be used in a research study you will not receive individual feedback from any testing performed.

If you (or your relative) agree to help with our research we will, depending on the sample(s) being donated:

- take some extra blood (up to 70ml, about 15 teaspoons) from a vein in your arm/hand in the usual way, this can be collected at the same time as blood is being taken for other tests.
- use any residual cerebral spinal fluid (CSF – fluid surrounding your central nervous system) once diagnostic tests have been completed.
- collect urine via a sample pot or from your catheter bag should you have one.
- take a small amount of extra tissue, for example skin, muscle or bone marrow, if possible at the same time as the tissue is taken for other tests.
- collect other specified tissue or bodily fluids ie saliva, breast milk freely donated by you.

It is entirely up to you whether you agree to your sample being used for research: neither a diagnostic test, if performed nor your medical care or legal rights will be affected by your decision. You can change your mind about taking part in this research at any time and ask that your sample be disposed of. Please ask your doctor if you have any further questions. UCL is the sole Data Controller for personal data collected, held and processed. Further information can be obtained following website: [www.prion.ucl.ac.uk/welcome/privacy/](http://www.prion.ucl.ac.uk/welcome/privacy/) Appropriate measures will be taken to ensure your data is secure and to prevent unauthorised access, disclosure and loss. Requests for access to your information should be referred to [data-protection@ucl.ac.uk](mailto:data-protection@ucl.ac.uk) or the National Prion Clinic: [www.nationalprionclinic.org](http://www.nationalprionclinic.org).

### Information relating to research samples

For confidentiality, your sample will not have your name on it, simply an identifying number. If you agree we will keep some data about you at the Institute of Prion Diseases, including your name and clinical details. Professor Collinge is responsible for access to your data. Access is only granted to authorised clinical and support staff involved in your clinical care and authorised research staff and administrators directly involved in ethically approved projects.

## Research into prion disease and related disorders

I agree that my sample may be used for research into prion and related diseases. I understand that this research will not necessarily provide information that will be of direct benefit to me. A relative, carer or nominated consultee can sign this form if the patient is unable to take their own decisions and if they do not believe that the patient would have objected to taking part in this research.

**Please tick box to indicate agreement to each part:**

- I have read and understood the information sheet (v3.0, 08/10/18) and have had the chance to ask questions about it.
- I understand that donating my sample for research use is voluntary and that I can withdraw my permission at any time, without having to give a reason and this will not affect my medical care in any way or my legal rights..
- I agree that my sample is a gift and can be used for research into prion and related diseases including genetic analysis and other tests. I understand that the results of such research will not be available to me on an individual basis and that any published results will not identify me.
- I agree that relevant sections of my medical records can be looked at by senior responsible individuals from the MRC Prion Unit at UCL, Institute of Prion Diseases (IoPD) and the clinical staff at the National Prion Clinic. I understand this would only be done if it was relevant to the sample or associated data being used in research and also that my confidentiality will be respected.
- I agree that information about me that is relevant to the research may be held on a secure confidential database that is kept in accordance with the Data Protection Act 2018, as amended. I understand that UCL is the Data Controller of my personal data and that I can request to see what information is held about me or to have it removed. Requests for access should be referred to: data-protection@ucl.ac.uk or through the National Prion Clinic.
- I understand that the sample I give for research could be used in the development of diagnostic tests and treatments with academic or commercial collaborators in the UK or worldwide. I understand that neither I, nor my legatees will benefit financially in this case.
- I understand that decisions about future use of my donated sample and data generated will be made by Prof Collinge and that my sample may be used in future studies in the UK or worldwide and that my identity will not be revealed. After the research has been completed, if the sample is not retained, the IoPD will arrange lawful and respectful disposal of the sample(s).

**Please tick to confirm which sample(s) you are donating:      I consent to my sample(s) being used in the following research (please tick):**

- |  |                                 |   |
|--|---------------------------------|---|
| <input type="checkbox"/> CSF                         | <input type="checkbox"/> Tonsil | <input type="checkbox"/> Development of new diagnostic tests for prion disease                  |
| <input type="checkbox"/> Blood                       | <input type="checkbox"/> Brain  | <input type="checkbox"/> Biochemical studies on characteristics and prevention of prion disease |
| <input type="checkbox"/> Urine                       |                                 | <input type="checkbox"/> Genetic causes of prion and brain diseases                             |
| <input type="checkbox"/> Other (please specify)..... |                                 |   |

I consent to the use of my sample for research and have read the information overleaf relating to this **or** The patient cannot give consent for themselves. I do not believe s/he would object to the sample being kept for research use

Signature.....Relationship to patient.....  
 Name (PRINT).....Date.....  
 Person taking consent.....Signature.....  
 Position:.....Date.....

**Statement of interpreter (if used)**

I have interpreted the information given to the patient to the best of my ability and in a way which I believe s/he can understand.

Signed.....Date.....  
 Name (PRINT).....Contact details.....

**patient label or details**

Name.....  
 Address.....  
 .....  
 .....  
 .....  
 DoB.....Hosp no.....

**notes**

**lab use only**

Sample ID.....  
 Specimen type:    Blood    DNA  
 other.....  
 Received: date ..... / ..... / ..... time.....