Simplified Patient Information Sheet:

National Prion Monitoring Cohort

(Note: this simplified information sheet is for the first strata – symptomatic patients with confirmed disease)

Version: 3.0 Date: 20 April 2010

A longitudinal observational study of all patients diagnosed with or at high risk of developing human prion disease

You are being invited to take part in a research study. Please take time to read the following information carefully and discuss it. Ask us if there is anything that you do not understand or if you would like more information.

WHAT IS THE STUDY ABOUT? WHY IS IT BEING DONE?

The National Prion Monitoring Cohort is a study for people with human prion disease, like CJD. It is trying to collect information about prion disease that may help us to better understand how this disease affects people. No treatment will be given specifically as part of this study, but it will collect information from people taking and not taking any treatment.

WHAT HAPPENS IN THE STUDY?

You will have clinical assessments at least every 6 months and at most every 6 weeks – it would be up to you how often you would be willing to be seen. Study visits are normally carried out in London but if you live a long way from London and travel is difficult, we can arrange for a study doctor to visit you at home.

WHY HAVE I BEEN CHOSEN?

You have been asked to join this study because you have a prion disease. You will have already had some investigations for this.

WHAT DOES THE STUDY INVOLVE?

CLINIC VISITS

Before you start the study you will have a detailed assessment by a doctor and a nurse. Some of the tests will be repeated from time to time during the study - many will already be familiar to you. We would like to visually record some of these assessments if you are happy for us to do this. This will enable your progress to be reviewed by doctors who are not involved with your care so that they can assess any changes independently.

You will need to be seen by study staff every 3 weeks – 6 months.

We would also like to make telephone contact at 1-2 weeks following our first visit to enquire about clinical changes, thereafter we will contact at 1-2 weekly intervals until the first review visit. After the first review the frequency of telephone contact will be altered according to changes in symptoms. If there are only minor changes in symptoms at this point the use of telephone contact may be reduced or stopped completely.

We would also like to do some special tests, and store a blood sample in case any new blood test becomes available during or after the study that would be useful to work out exactly what is happening to you. We will discuss with you at each visit which of these assessments you feel you will be able to manage. **We appreciate not everybody will want to have all the different tests and you will be free to refuse any test you do not want.** Separate information sheets are available about these tests.

WHAT ARE THE POSSIBLE RISKS OF TAKING PART?

As no drugs are prescribed as part of this study, the only potential risks are those associated with investigations, which are minimal. You will have a number of additional tests and hospital visits in addition to those necessary for normal care.

CONFIDENTIALITY

All information, including blood samples, collected about you during this study will be confidential, but it will not be completely anonymous This means information about you will be stored only by a study number, your date of birth and initials, and not by your name. Names will not be used in any of the study records or samples.

PARTICIPATION

It is up to you and your family to decide whether you want to be part of this study. If you do not want to be in this study that is OK. You can stop during the study at any time without giving a reason. Your doctor will still look after you as normal. We hope, though, that you will tell us why you wish to stop the study and will let us continue to follow how you are doing.

Thank you for taking time to consider this study. Please ask any questions and let us know if there are things that you do not understand, or would like more information about.

Please address any further questions to Simon Mead, Consultant Neurologist and Clinical Co-ordinator; or Professor John Collinge, Clinical Director, at the National Prion Clinic:

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Thank you for taking the time to read this information sheet