HD-CSF: Studying cerebrospinal fluid
to understand key CNS pathobiological targets
in Huntington’s disease

Information and Consent Form

Version date: 2015-12-08

What is HD-CSF?

HD-CSF is a research study. The main purpose of HD-CSF is to collect cerebrospinal fluid
(CSF), the fluid that surrounds the brain and spinal cord. We will use this CSF to study
Huntington’s disease (HD). CSF can be used to provide information about the brain and the
nervous system that is impossible to obtain in any other way. CSF is collected by a
procedure called a lumbar puncture or spinal tap. This is a commonly performed procedure
that takes around 30 minutes.

Who is organising HD-CSF?

The Principal Investigator is Dr Edward Wild, MRC Clinician Scientist at UCL Institute of
Neurology and Honorary Consultant Neurologist. The Sponsor of HD-CSF is University
College London. HD-CSF is funded by the Medical Research Council (MRC).

Why am I being invited to take part?

We are inviting you to participate in HD-CSF because you have tested positive for the
genetic mutation that causes HD, or because you are a healthy control. A healthy control is
a person who does not carry the genetic mutation that causes HD.
What is the purpose of HD-CSF?

The CSF collected will be used to study HD and to identify and evaluate biomarkers and pathways for HD. It may be used to understand other conditions relevant to HD as well. A biomarker is something we can measure that helps us to better understand a disease. A pathway is a series of chemical reactions in a cell that play an important biological function.

Understanding how HD affects the brain, having better biomarkers for HD and identifying pathways relevant to HD may help the development of new treatments for HD. In addition, biomarkers may help design and guide future research studies and clinical trials as well as help us better understand who will most likely benefit from a particular treatment.

Two examples of biomarkers and pathways we intend to study in the CSF are (1) the huntingtin protein, which causes HD, and (2) chemicals of the kynurenine pathway – a group of chemicals produced by the brain which are thought to be involved in HD.

Blood samples will also be collected, in order to make a collection of blood products matching the CSF collection. The blood sample collection will be used for the same purposes as the CSF sample collection.

In addition to the CSF and blood samples, certain information will be collected from you during this study. And, because you must first be a participant in the Enroll-HD study to participate in this study, we will also use information collected from you through your participation in the Enroll-HD study to help understand the findings from analysis of the CSF and blood samples and information collected from you in this study.

You will also be invited to have MRI scans of the brain. An MRI scan uses a powerful magnet to obtain images of the brain. MRI scans have been shown to be helpful in tracking the progression of HD, and we intend to see how these scan changes relate to the chemical changes in the CSF and blood. The MRI scan is optional – you can still participate in the rest of the study if you prefer not to undergo it, or if you cannot complete the scan.

Many other important aspects of HD can be studied using these samples and information, so we will share them with other researchers for research relevant to HD.

We are asking you to donate up to 20 ml of CSF and approximately 50 ml of blood for the purposes described above and more fully described below. And, we are asking you to donate up to another 15 ml of blood for routine safety tests.

HD-CSF is a longitudinal study. You will be asked to go through the procedures described here twice – once at the study baseline and again after about two years.

Please read this consent form carefully. Ask the person who presents this consent form to you any questions you have before deciding whether to participate in this study. You will be given a copy of this consent form.

Do I have to take part in this study?

Your participation in this study is completely voluntary. You are completely free to choose whether or not to participate in this study. If you decide to participate, you can change your mind and withdraw from this study at any time for whatever reason. You are not required to give any reason for your decision on whether or not to participate in this study or, if you decide to participate, for your decision to withdraw from this study. Deciding not to participate in this study or deciding to withdraw from this study will not affect the current or future care that you would otherwise expect to receive. Nor will any such decision affect your participation in the Enroll-HD study.
Will my information be kept confidential?

We will not put your name, address or any other information that could directly identify you on the information and biological samples you allow us to collect from you. All information and biological samples collected from you during this study will be coded with a Huntington's disease identifier (HDID), the unique 9 digit number created for you as part of your participation in the Enroll-HD study. As you may recall, the HDID is used to protect your identity and connect your clinical information and biological samples to other HD studies in which you may participate. Only the study site staff will be aware of your identity and be able to link the information and biological samples collected from you during this study. All information and biological samples collected from you during your study visits will be stored in secure databases and repositories where they will be available now and in the future to researchers who are trying to develop new tests for, and ways to treat HD and similar diseases, as well as other relevant biomedical research.

How many participants will be involved?

Approximately 80 participants will be included in this study – 60 people with the HD genetic mutation and 20 healthy controls.

What procedures are involved in HD-CSF?

HD-CSF is a longitudinal study consisting of a core baseline assessment, then a core follow-up assessment about two years later. The visits and procedures at the baseline and follow-up are the same, except that you don’t have to sign the consent form again at the follow-up visit.

Each assessment (baseline and follow-up) consists of 2 study visits, the Screening Visit and the Sampling Visit, not more than 30 days apart. All participants will also be contacted by telephone 1 to 3 days after the Sampling Visit to see how they are doing.

Some participants may be asked to return for additional study visits, the Optional Sampling Visits, within 8 weeks of the baseline and/or follow-up Sampling Visits, in order to understand how the CSF changes over short periods of time. Therefore participants consenting to the Optional Sampling Visits may undergo a maximum of 4 sampling visits. All participants who return for an Optional Sampling Visit will also be contacted by telephone 1 to 3 days after the Optional Sampling Visit to see how they are doing.

Screening Visit

We will discuss the details of this study with you. You will have the opportunity to ask any questions you may have about this study. If you decide to participate, you will have to sign this form to give your informed consent to participate in this study.

In order to check if you are eligible to participate in this study, a researcher will ask you questions regarding any illnesses or medical conditions you may have, and about any medications that you have been using within the last month. A brief physical examination and a neurological examination will be performed, you will be asked questions regarding your mental and emotional wellbeing and, if you are an HD participant, your symptoms of HD will be assessed.

Since you are a participant in the Enroll-HD study, some of the above examinations and assessments may have been done as part of your most recent Enroll-HD study visit. If any of such examinations and assessments have been conducted within 2 months of your Screening Visit, they will not be repeated, and the information collected from you during
your most recent Enroll-HD study visit will be used instead. Otherwise, in addition to the examinations described above, you will be asked to complete the clinical, behavioural and cognitive assessments that form the core of the Enroll-HD study as part of the HD-CSF study. You will need to be fluent in English to complete the cognitive assessments. Your height and weight will also be measured. You may be familiar with these from previous Enroll-HD study visits, and they will take between 45 and 90 minutes. Information about the genetic mutation that causes HD, if applicable, will be collected from the Enroll-HD study.

Approximately 15 ml of blood (about 3 teaspoonsfuls) will be taken for tests to help ensure it is safe to collect the CSF. The entire procedure of collecting blood should take about 10 minutes.

**Optional MRI scan.** If you agree to have an MRI scan, this will be carried out at the screening visit. An MRI safety assessment will first be performed. The assessment is to flag any potential problems that may arise if you were to undergo a scan. Some things can create a health risk or interfere with imaging, such as medical implants, some permanent cosmetics or tattoos.

Female participants: If you are pregnant or think that you could be pregnant, you must notify the MRI operator or radiologist during the safety assessment. Depending on the outcome of the safety assessment, you may not be able to have the scan.

The MRI scanner is like a tunnel about 1.5 metres long, surrounded by a large circular magnet. You lie on a couch which then slides into the scanner. The scanner will produce loud noises; this is normal and should not worry you. However, you will be provided with earplugs and/or headphones. During the MRI, the operator will be able to speak to you, hear you, and observe you at all times through a window and a 2-way microphone communication system.

The scan lasts a total of 45 minutes but takes place in several parts, up to 15 minutes each. You will need to keep still during each part of the scan but can move a little between them.

The entire Screening Visit will last about 1 to 3 hours since, depending on when your most recent Enroll-HD visit was conducted, some of the above examinations and assessments may have been done as part of your most recent Enroll-HD study visit procedures and will not have to be repeated during the Screening Visit.

If you are eligible for study participation, you will be scheduled for the Sampling Visit, which will need to be done within 30 days of your Screening Visit.

If we find that you are not eligible for study participation, but might become eligible within a reasonable period of time after your Screening Visit, you may be invited to return to repeat some or all of the above examinations and assessments. If you are asked to return, you may decline to do so. If after repeating those examinations and assessments, we find that you have become eligible for study participation, you will be scheduled for the Sampling Visit, which will need to be done within 30 days of the date of the initial part of your Screening Visit.

**Sampling Visit**

You will be asked to arrive at the study site in the morning so that the CSF collection can be done between 8:00 and 10:30 am. If it is more convenient for you, you may choose to stay at a hotel close to the study site the evening before your Sampling Visit. You will be provided with help to arrange your travel and hotel accommodations for your Sampling Visit.

You will be asked not to eat anything from midnight on the day of your Sampling Visit until after the CSF and blood sample collection is completed. You are permitted to drink water.
If you forget and eat something by mistake, your Sampling Visit will have to be rescheduled.

The study physician will confirm that you are still willing to participate in this study. If so, a neurological examination and a brief physical exam and a motor examination will be performed, and the results of the blood testing done at your Screening Visit will be reviewed. If the study physician confirms that you still meet all eligibility requirements for this study, the study site staff will prepare you for the CSF collection.

**Lumbar puncture.** You will be asked to lie on your side with your knees pulled up and your chin tucked downward. A pillow will be placed between your knees. After cleaning the skin of your lower back, local anaesthetic will be injected. This stings for a couple of minutes, then the skin goes numb. A very thin needle will be inserted into your lower back and up to 20 ml of CSF will be collected. Occasionally it may be necessary to try again in a different spot, or for you to sit upright, to find the right place and collect the fluid.

**Blood sample collection.** Once the CSF collection has been completed, approximately 50 ml of blood (the same volume as 10 teaspoons) will be taken from a vein in your arm. You will then be asked to lie flat for up to an hour. The entire procedure of collecting CSF and blood should take about 20-45 minutes, not including the resting period.

The study site staff will check to see how you are doing during the resting period. When you are ready to leave, you will be given instructions on follow-up care.

This entire Sampling Visit will last about 3-5 hours.

**Follow-Up Call: 1 to 3 Days after Sampling Visit**

We will call you 1 to 3 days after your Sampling Visit to see how you are doing. You will be asked how you are feeling and if you have experienced any medical conditions or symptoms since your Sampling Visit.

**Visit 3: Optional Sampling Visit**

Should you be asked to participate in the Optional Sampling Visit, you may decline to do so. If you do agree to participate, you will be asked to undergo a second CSF and blood sample collection as described above under ‘Sampling Visit’. You are free to change your mind at any time without affecting your participation in the rest of the study.

**Follow-Up Call: 1 to 3 Days after Optional Sampling Visit**

A member of the study site staff will call you 1 to 3 days after your Optional Sampling Visit to see how you are doing. You will be asked how you are feeling and if you have experienced any medical conditions or symptoms since your Optional Sampling Visit.
# HD-CSF: Studying cerebrospinal fluid to understand key CNS pathobiological targets in Huntington’s disease

## Visit Number

<table>
<thead>
<tr>
<th>Visit Type</th>
<th>CORE BASELINE ACTIVITIES</th>
<th>OPTIONAL BASELINE ACTIVITIES</th>
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<tr>
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<td>CORE BASELINE ACTIVITIES</td>
<td>OPTIONAL BASELINE ACTIVITIES</td>
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<tr>
<td>Visit Type</td>
<td>Screening</td>
<td>Sampling</td>
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<tr>
<td>Days</td>
<td>-30 to -1</td>
<td>Day 0</td>
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- **Informed Consent**: ✓
- **Inclusion/Exclusion Criteria review**: ✓ ✓ ✓ ✓
- **Confirm Enroll-HD core assessments completed within last two months; if not, complete Enroll-HD core assessments**: ✓
- **UHDRS motor assessment, diagnostic confidence score, total functional capacity and Independence Scale (if applicable)**: ✓
- **Short Problem behaviours assessment (PBA-S) (if applicable)**: ✓
- **Symbol-digit modality test (if applicable)**: ✓
- **Stroop word reading (if applicable)**: ✓
- **Stroop colour naming (if applicable)**: ✓
- **Categorical verbal fluency (if applicable)**: ✓
- **Brief Physical Exam**: ✓ ✓ ✓ ✓
- **Medical History update**: ✓ ✓ ✓ ✓
- **Previous Medication update**: ✓ ✓ ✓ ✓ ✓ ✓
- **Standard Neurological Examination**: ✓ ✓ ✓ ✓
- **Total Motor Score (TMS)**: ✓ ✓ ✓ ✓
- **Vital Signs (Blood Pressure, pulse, body temperature)**: ✓ ✓ ✓
- **Safety Laboratory Assessments**: ✓
- **Optional MRI scan**: ✓
- **Recording of side effects (Adverse Events)**: ✓ ✓ ✓ ✓ ✓ ✓
- **Final Eligibility Check**: ✓ ✓ ✓
- **Spinal fluid collection (Lumbar CSF Collection)**: ✓ ✓
- **Blood sampling**: ✓ ✓ ✓
<table>
<thead>
<tr>
<th>Visit Number</th>
<th>4</th>
<th>5</th>
<th>6</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Visit Type</strong></td>
<td>Screening</td>
<td>Sampling</td>
<td>Telephone Follow-Up</td>
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<tr>
<td><strong>Time window</strong></td>
<td>Upto 30 days before follow-up sampling</td>
<td>21 to 27 months after baseline sampling</td>
<td>Follow-up sampling + 1-3 days</td>
</tr>
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</table>

- Inclusion/Exclusion Criteria review
- Confirm Enroll-HD core assessments completed within last two months; **if not, complete Enroll-HD core assessments**
- UHDRS motor assessment, diagnostic confidence score, total functional capacity and Independence Scale (if applicable)
- Short Problem behaviours assessment (PBA-S) (if applicable)
- Symbol-digit modality test (if applicable)
- Stroop word reading (if applicable)
- Stroop colour naming (if applicable)
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- Brief Physical Exam
- Medical History update
- Previous Medication update
- Standard Neurological Examination
- Total Motor Score (TMS)
- Vital Signs (Blood Pressure, pulse, body temperature)
- Safety Laboratory Assessments
- Optional MRI scan
- Recording of side effects (Adverse Events)
- Final Eligibility Check
- Spinal fluid collection (Lumbar CSF Collection)
- Blood sampling
Tell me more about the optional MRI scans

MRI is a non-invasive technique that can provide detailed pictures that can show for example, tissues, organs and other structures inside your body; differences between healthy and unhealthy tissue. MRI is routinely used to generate pictures of the brain. It uses a magnetic field and radio waves, together with an advanced computer system to build up a series of images, each one showing a thin slice of the area being examined.

MRI does not use any ionizing radiation or x-rays and there are no known side-effects or cumulative risks. In general, the MRI procedure produces no pain and causes no known short-term or long-term tissue damage of any kind. However, the powerful magnetic field of the MRI scanner can attract certain metallic objects, causing them to move suddenly and with great force towards the centre of the MRI machine. This may pose a risk to anyone in the way of the object. Therefore, great care is taken to prevent such objects e.g. such as watches, jewellery, hair pins and items of clothing that have metallic threads or fasteners from entering the MRI room. The MRI facility safety assessment requires MRI staff and radiologist to ask about the presence of metallic implants and tattoos etc. Research suggests that heating and pulling can occur with older tattoos, which may contain small quantities of metal. Therefore, participants with tattoos are sometimes excluded from MRI scans unless special precautions are taken.

What must I keep in mind during this study?

During the time of this study, you are being asked to follow all instructions that the study physician and study team give you, including those regarding restricted medications that were given to you at your Screening Visit. You should also follow instructions regarding follow-up care after your Sampling Visit or Optional Sampling visit.

On the day of your Sampling Visit or Optional Sampling visit you will be asked to not eat anything from midnight until the CSF and blood collection have been completed.

If you are not feeling well or if you have had medications since your Screening Visit you should inform the study team

How will my samples and information be stored?

The information collected about you during this study will be entered via secure internet connections into a confidential database that is located at a data storage facility selected for this study. This facility, called a hosting facility, follows security procedures to make sure the information is safe and secure. The biological samples collected about you during this study will be stored in a biological samples repository at UCL Institute of Neurology.

The information collected from you and entered in the database will not be associated with, or identified by, your name or other information that could directly identify you. Only the study site staff will be aware of your identity and have the key to the code that links your information and biological samples to you.
How will my samples and information be used and shared?

The coded information and/or coded biological samples collected from you during this study may be used by Dr Wild, his research team members, his appointed service providers, and his appointed partners from academic, not-for-profit and/or commercial research organisations, for the following purposes:

- To generate a CSF sample collection and a blood products sample collection for identifying and evaluating biomarkers and pathways that will enable the development of new treatments for HD.
- To check the quality of the information and biological samples collected from you during this study.
- To see how different possible medicines influence biological and chemical processes that might be important in HD or other diseases.
- To design and guide future research studies and clinical trials.
- To support and enable scientific discussion and research as follows: (1) to better understand HD or other diseases being studied, (2) that furthers the development of treatments for HD or other diseases or (3) that furthers biomedical research.

Dr Wild may also share the coded information and/or coded biological samples collected from you during this study with the following third parties:

- Representatives of organisations providing services in connection with this study, such as 2MT Software, the organisation contracted to collect, maintain, and manage the information collected in this study; service providers engaged to check the accuracy of the information collected; and such other service providers as may be designated from time to time.
- Research Ethics Committees and other independent review boards overseeing the ethical conduct of this study.
- Representatives of governmental and regulatory agencies such as the European Medicines Agency (EMA).

Dr Wild, the study sponsor (UCL) and each of the organisations, researchers and services providers referred to above, may publish the results of their research, including coded information, in medical journals or present such results at meetings. However, your name, address or any other information that could directly identify will not be published.

Dr Wild or his partners may also submit coded information to be included in one or more other electronic databases for use by Dr Wild and the organisations, researchers and services providers referred to above for scientific discussion and research as follows: (1) to better understand HD or other diseases being studied, (2) that furthers the development of treatments for HD or other diseases or (3) that furthers biomedical research.

The information and biological samples collected from you during this study will be used only for research purposes and will not be sold.

Your coded information and a portion of your coded biological samples will be shared with CHDI Foundation Inc. (CHDI), an appointed partner of Dr Wild, to supplement CHDI's HDClarity study, an international study that, like HD-CSF, aims to study CSF to better understand HD and related conditions with the purpose of helping to develop new treatments. CHDI is a not-for-profit foundation that only works on Huntington's disease (HD). Dr Wild is the global Chief Investigator of the HDClarity study and UCL is its sponsor. Samples donated to CHDI will be stored in a biological samples repository that is located at a biological samples storage facility selected for the HDClarity study. Information and samples donated in this way may be used at the direction of CHDI Foundation, Inc., for the purposes stated above.
You can change your mind at any time about the storage and use of the biological samples collected from you during this study. Just contact Dr Wild or a member of his research team, and let him or her know that you no longer want the biological samples collected from you during this study stored and such biological samples will be removed from the storage facility and destroyed. If any of the biological samples collected from you during this study have already been distributed for use, we may not be able to locate and destroy such biological samples.

Any of the uses and activities described above may involve sending coded information and coded biological samples to other countries that may not have the same or as strict privacy laws as this country. However, given that only coded information or coded biological samples are sent, the risk of unintended disclosure of identifying information is low.

The information collected from you and entered in the database as well as the biological samples collected from you and stored in the biological sample repository will not be associated with, or identified by, your name or other information that could directly identify you. Only the study site staff will be aware of your identity and have the key to the code that links your information and biological samples to you.

**What discomforts and risks are involved?**

Any adverse medical events arising from your participation in this study will be followed up and treated as necessary by the study team.

**Lumbar puncture to collect CSF**

Before the procedure, you will be assessed for any medical factors that would increase risks of injury from a lumbar puncture.

At the start of the procedure, local anaesthetic is injected into the skin of the lower back. This causes stinging pain that fades after a few minutes. The local anaesthetic makes the area go numb, but some people still experience pain during the procedure. Sometimes it is necessary to try more than one different site, and this may involve experiencing more pain. You are free to ask for the procedure to be stopped at any time.

As with blood tests, some people feel faint during the procedure. After the procedure, you may experience back pain, swelling or rash at the puncture site. Pain after the procedure is usually mild and fades within a couple of days.

About 5% of people get a headache after a lumbar puncture. If it does occur, it is usually mild and lasts less than 2 days. If you get a headache, you are advised to take paracetamol and rest. Occasionally a ‘low pressure headache’ may develop, due to spinal fluid leakage. These headaches are more severe, worse when standing up and better when lying down. They usually get better with bed rest, hydration and caffeine intake (e.g. coffee, tea or cola) plus painkillers. If a low-pressure headache lasts longer than a week, it can be treated with a procedure called a ‘blood patch’. This is only necessary very rarely, with less than 1% of patients requiring a ‘blood patch’ after having a lumbar puncture. Blood is taken from the arm and put into the lumbar puncture site to patch the leak. This relieves the headache within a few hours.

You could have an allergic reaction to the local anaesthetic or skin cleanser used. This is very unlikely. It is important that you tell us if you have ever had a reaction to a local anaesthetic or skin cleanser. Other very rare side effects are infection and bleeding into the spinal fluid space. Theoretically, this could cause damage to the nervous system. The chance of any serious complications causing lasting disability is very low – less than one in...
Precautions are always taken to minimise these risks during the screening period and lumbar puncture procedure.

The lumbar puncture will be done by an experienced doctor trained to perform the procedure using a sterile technique. You will be given instructions on how to contact the study team if you have any problems or concerns after the procedure.

**Blood sampling**

Giving a blood sample causes brief pain but is very safe. There is a risk include bruising and, rarely, infection where the needle was inserted. There is a risk of feeling faint or fainting.

**Optional MRI scan**

Some subjects find MRI scanning uncomfortable because of the enclosed space and the need to stay still during the scanning process. Appropriate steps will be taken to make you feel as comfortable as possible. A 2-way communication system will also allow you to speak to the MRI operator during the scan.

A safety assessment will be performed by trained personnel to ensure that it is safe to perform an MRI. As long as this questionnaire is correctly completed, MRI is safe.

**Assessments and questionnaires**

If you are required to complete the clinical, behavioural and cognitive assessments that form the core of the Enroll-HD study as part of this study, you may experience anxiety or psychological discomfort (such as stress or fatigue) while completing these assessments. If at any time you feel you could benefit from treatment or support, you may request to be referred for appropriate care. In the course of doing questionnaires or tests you may feel tired and/or irritable. If this happens please tell your doctor or a member of the research staff and ask them to allow you time to rest or stop the testing all together.

**Collection of private / personal information**

We take great care to protect your personal information and all procedures are in compliance with the Data Protection Act 1998. However, there is a slight risk of accidental disclosure of information, or breach of computer security.

**Unexpected findings**

This is a research study looking for new biomarkers, and we do not expect to find anything of medical significance for individual research participants. The results of the tests will not routinely be conveyed to you. However, occasionally, an MRI scan, blood tests or a lumbar puncture can reveal an unexpected finding of possible medical importance. If this happens, we will let you know and, with your permission, inform your GP who will be able to take any necessary action through the usual NHS care pathways.

**What are the benefits of taking part in HD-CSF?**

You will not have any direct benefits from participating in this study. The results of this study may contribute to new knowledge of HD.
What are the alternatives to taking part?

You do not have to participate in this study. Choosing not to participate will not affect your current or future medical care at the National Hospital for Neurology and Neurosurgery.

Is there any payment or cost?

Your expenses, including meals and hotel (if applicable) incurred within the scope of your participation in this study will be covered. You will need to provide receipts for your expenses. We can usually help book travel and accommodation so you don't have to pay upfront. Please consult the study team before spending your own money, to make sure the expense will be refunded, as some items like train fares and hotel accommodation have limits on how much can be reimbursed. HD positive gene carriers will not receive any direct payment for taking part. If you are a healthy control you will be offered £40 to compensate for your time and discomfort in taking part in the study.

What happens if I am injured or something goes wrong?

If you wish to complain, or have any concerns about the way you have been approached or treated as part of this study, you should contact Dr Wild or a member of his team, who will do their best to address your concerns. The National Health Service or UCL complaints mechanisms are available to you. Please ask Dr Wild or a member of his team if you would like more information on this.

UCL Hospitals Foundation Trust will provide medical care for any emergency medical problem that you may experience as a direct result of your participation in this research. You will not have to pay for this emergency care.

We will notify your GP that you are taking part in this study, unless you have told us that you would prefer that your GP is not made aware of your participation.

If you have health insurance, it is up to you to find out whether participation in this study may affect your insurance cover.

In the unlikely event that you are harmed by taking part in this study, compensation may be available. If you suspect that the harm is the result of the Sponsor's (University College London) or the hospital's negligence then you may be able to claim compensation. After discussing with Dr Wild, you can make the claim in writing to Dr Wild as Principal Investigator for the study. He will then pass the claim to the Sponsor's Insurers, via the Sponsor's (Joint Research Office) office. You should note that you may have to bear the costs of the legal action initially, and you should consult a lawyer about this.

If you have concerns about any aspect of this study, you should call 020 3448 3774 and ask to speak to the researchers who will do their best to answer your questions.

If you remain unhappy and wish to complain formally, you can do this by contacting the Patient Advice and Liaison Service on 020 3448 3237 or write to UCLH Patient Advice and Liaison Service at the following address; PALS, Box 25, National Hospital for Neurology and Neurosurgery, Queen Square, London WC1N 3BG, or email: pals@uclh.nhs.uk

Will my information or samples be used for commercial purposes?

Successful research by us and others using your coded information and coded biological samples collected in the course of this study could result in a commercial test or
therapeutic product with significant value, such as a product for the treatment of HD. You will not receive any financial benefit from such a result.

Who has reviewed this study?

This study has been reviewed by the UCL/UCLH Research and Development office and the Research Ethics Committee.

Insurance

The study is insured under UCL’s insurance policy which provides liabilities (negligence) of UCL and its employees or agents. The policy will be renewed annually until the end of the study.

University College London holds insurance against claims from participants for harm caused by their participation in this clinical study. Participants may be able to claim compensation if they can prove that UCL has been negligent. However, if this clinical study is being carried out in a hospital, the hospital continues to have a duty of care to the participant of the clinical study. University College London does not accept liability for any breach in the hospital’s duty of care, or any negligence on the part of hospital employees. This applies whether the hospital is an NHS Trust or otherwise.

Funding and organisation

Funding for this study is provided by a Clinician Scientist Fellowship grant awarded to Dr Edward Wild by the Medical Research Council. Study procedures are carried out at the Leonard Wolfson Experimental Neurology Centre at the National Hospital for Neurology & Neurosurgery.

Could the study end early?

You may be withdrawn from this study if you do not follow the directions of this study or if your medical condition changes so that staying in this study might risk your health or this research. Your participation in this study may also end if the sponsor (UCL) or Principal Investigator (Dr Wild) decides to terminate the study for safety or other reasons.

How do I get in touch with the study team?

For more information concerning this research or if you believe that you have suffered a research related injury, please contact:

Dr Edward Wild
Box 104
National Hospital for Neurology & Neurosurgery
Queen Square
London WC1N 3BG