Huntington’s Disease Young Adult Study

Information Sheet and Informed Consent Form

Young Adult Gene Carrier
Version 2.1, 1st May 2017 (IRAS number: 208997)

I. Part I

1. Invitation Paragraph

You are being invited to participate in a research study named Huntington’s Disease Young Adult Study (HD-YAS). Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information.

2. What is the purpose of the study?

The purpose of this research study is to determine whether any HD related changes can be identified in young adult HD gene carriers who are decades from developing the disease. This will help us to guide the use of any potential future treatments, so that they can be given at the earliest and most effective time in order to prevent or treat HD disease progression.

To study whether these changes can be identified, we will carry out a number of assessments. We will look at images of the brain using a safe and non-invasive technique called Magnetic Resonance Imaging (MRI). We will examine your cognitive and emotional function through a series of questionnaire and simple computer based tasks to examine the way you process, store and apply information, including about other people and social situations (cognitive and emotional tasks). We will also collect biological samples, such as blood and DNA (the genetic material in your blood) to look for potential biomarkers – a biomarker is something we can measure to help us better understand a disease.

As an optional part of the study we will also collect cerebrospinal fluid (CSF), the fluid that surrounds the brain and spinal cord that can be used to provide information about the brain and the nervous system that is impossible to obtain in any other way. In this study we will see if there are any
changes in HD CSF biomarkers which relate to any early changes we see in the brain and functioning. An additional blood sample 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.

This information sheet describes the research study and what you can expect if you decide to participate. Please read this information sheet carefully. Ask the person who presents the form to you, or contact the study team (details on page 14), with any questions you may have before deciding whether to participate in this study.

3. **Why am I being invited to take part?**

   We are inviting you to participate in the HD-YAS study because you have tested positive for the faulty gene that causes HD but you do not show clinical signs of the disease.

4. **Do I have to take part in this study?**

   Your participation in this study is completely voluntary. You are 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.

5. **What will happen to me if I take part in this study?**

   If you agree to take part, you will be asked to attend a one-off study visit at the National Hospital for Neurology and Neurosurgery (NHNN) London which will last a whole day. We will collect a blood sample from you, perform an MRI scan of your brain and you will complete a number of questionnaire and computer based tasks. The visit may involve an overnight stay, depending on how far you have to travel and/or whether you choose to take part in the optional CSF and matching blood collection. There will be plenty of time for refreshments, lunch and breaks. After the visit, at home, we will ask you to complete some more questionnaires either online or on paper, depending on your preference.

   If you chose to take part in the optional CSF collection we are asking you to donate up to 20 ml (the same volume as 4 teaspoons) of CSF and 50 ml (the same volume as to 10 teaspoons) of blood for the purposes described above and more fully described below. And, we are asking you to donate up to another 15 ml (the same volume as 3 teaspoons) of blood for routine safety tests.

   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), a unique 9 digit number created for you. 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.

6. Who is organising HD-YAS?

This research is being organised by Professor Sarah Tabrizi (Principal Investigator), Professor of Clinical Neurology, Honorary Consultant Neurologist and Director of UCL Huntington’s Disease Centre and is sponsored by University College London (Sponsor). The HD-YAS is funded by the Wellcome Trust as part of the Collaborative Award in Science presented to Professor Tabrizi as part of the TREAT-HD project. CSF collection is funded by CHDI Foundation Inc., a not-for-profit foundation that only works on HD.

Part 2 below gives you more information about the conduct of HD-YAS

II. PART 2

1. How many participants will be involved?

120 participants will be included in this study – 60 people who carry the HD gene, but do not show any signs of the disease, and 60 control participants. A control participant is a person who does not carry, and is not at risk of carrying the genetic mutation that causes HD.

2. Procedures and Study Visits

The main study consists of a one-off study visit at the National Hospital for Neurology and Neurosurgery (NHNN) London which will last a whole day. You may be offered an overnight stay in a nearby hotel depending on how far you have to travel and there will be plenty of time for refreshments, lunch and breaks.

Day 1 – Main Study Visit

At the study visit, you will have a number of assessments, performed by experienced professionals.

- 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.

- We will collect a blood sample from you.

- You will have a medical interview asking about your health, your medical history, medications and Huntington’s disease in you and your family. Information about the genetic mutation that causes HD will be requested from your doctor/clinical care team with your permission.

- You will have an interview and a questionnaire asking about your mood and behaviour.

- A brief neurological examination will be performed.

- Your thinking and cognitive-emotional function (the way you process, store, and apply information about other people and social situations) will be assessed by a series of cognitive tasks.
- An MRI brain scan will be performed, lasting approximately 60 minutes.

You will need to be fluent in English to complete the cognitive assessments. Your height and weight will also be measured. At the end of the study visit, you will be instructed to complete a set of self-administered questionnaires at home either on paper or online within 7 days.

A schedule of the study visit and estimated times are shown below:

**Day 1**

<table>
<thead>
<tr>
<th>Estimated Time</th>
<th>Assessment Type</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>09:30</td>
<td>Informed Consent for HD-YAS, including the optional CSF collection.</td>
<td>30-45 min</td>
</tr>
<tr>
<td>10:15</td>
<td>Blood sample collection</td>
<td>30 min</td>
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<tr>
<td></td>
<td>Clinical review for CSF collection (optional)</td>
<td></td>
</tr>
<tr>
<td>10:45</td>
<td>Cognitive and Emotional Assessments</td>
<td>110 min</td>
</tr>
<tr>
<td>13:00</td>
<td>LUNCH</td>
<td></td>
</tr>
<tr>
<td>14:00</td>
<td>MRI scan</td>
<td>60 min</td>
</tr>
<tr>
<td>15:15</td>
<td>BREAK</td>
<td></td>
</tr>
<tr>
<td>15:30</td>
<td>HD core assessment battery</td>
<td>60 - 75 min</td>
</tr>
<tr>
<td>16:45</td>
<td>END OF STUDY VISIT</td>
<td></td>
</tr>
</tbody>
</table>

Within one week of completing study visit. Questionnaires to complete on paper or online about your health and wellbeing. 40 mins

**Day 2 - Participant arrives fasted**

<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>8:00-10:30</td>
<td>Optional CSF and Blood Collection</td>
</tr>
<tr>
<td>10:30</td>
<td>BREAKFAST</td>
</tr>
</tbody>
</table>

1-3 days after CSF collection. Telephone follow-up to check for adverse events following the optional CSF and Blood collection.
Blood Sample Collection

We will collect up to 50 ml of blood (approximately 4 tablespoons) from a vein in your arm in the usual way. A portion of your blood will be used to obtain your DNA (the genetic material in your blood) for genetic analysis. You have already undergone a predictive genetic test to show the presence of the HD causing gene. We will repeat the test to obtain information about the size of the genetic abnormality by a standardised protocol. This information is used in our statistical analysis but does not reveal anything of clinical significance to you. The result of the test will not be made available to you.

DNA may also be used for epigenetic analysis – looking at chemical modifications and mutations in the DNA that might be useful for understanding future disease progression. The analysis may be performed in the UK or overseas. The analysis will have no clinical significance to you and will be returned to Professor Tabriz but not reported to you.

Your blood will also be used to look for biomarkers – a biomarker is something we can measure that helps us to better understand a disease. We intend to relate any changes we may see in biomarkers to any early changes we may see in the brain and functioning.

Cognitive and Emotional Tasks

You will spend about an hour and 50 minutes doing some thinking tasks, which will include for example, trying to remember the location of shapes on the screen or find a pattern in a sequence. As well as emotion tasks like detecting emotions on faces in pictures or rating your feelings in response to a set of moral scenarios. There will be a number of different tasks to assess different areas of thinking and emotion. The tasks are performed using a computer but you do not need to have any knowledge of computers in order to do them. You should bring reading glasses if you require them.

MRI scan

MRI is a painless and safe technique that can provide detailed 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.

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.

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.

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 scan lasts up to 60 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 parts.

**HD Core Assessment Battery**

During your study visit we will ask questions about your medical history, your current health and treatments (including medications) you are then taking. We will measure your height and weight. We also will conduct tests to see how well you move, think, remember things, perform daily tasks, and behave – all behaviors which may be affected by HD. The examination should take about 60-75 minutes.

**Questionnaires Completed at Home**

You will be asked to complete 10 self-administered, short questionnaires at home between 1 and 7 days after the study visit. These questionnaires will take approximately 4 minutes each to complete and they will gather information about a collection of symptoms including sleep, mood, motivation, anxiety and depression. These are common symptoms that can occur in anyone in the population at any time. We will ask you to complete these questionnaires on paper or online, whatever is your preference. You will be provided with information on how to answer these questionnaires and return them to us.

Please continue to next page
In addition to the main part of this study, as described above, there is an optional part to the study where we will collect cerebrospinal fluid (CSF), the fluid that surrounds the brain and spinal cord. 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. In this study we will see if there are any changes in HD CSF biomarkers decades from any clinical signs of HD. A biomarker is something we can measure that helps us to better understand a disease. We intend to relate any changes we may see in CSF biomarkers to any early changes we see in the brain and functioning.

An optional blood sample 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.

What Will Happen to Me if I Take Part?

We will ask you to donate up to 20ml of CSF (approximately 4 teaspoons) through a procedure called a lumbar puncture. 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.

Do I Have to Take Part?

You can choose whether or not you want to take part in the CSF collection, it is entirely optional and you can choose to take part in one, both or neither aspects of the study. If you do not want to participate in the CSF collection, or it is not possible for you to undergo a lumbar puncture you can still participate in the rest of the study if you choose, and your participation in HD-YAS will not be affected. If you choose to participate in the optional CSF collection you will be asked to provide specific consent.

Procedures and Study Visits

The study will occur over two days instead of one and you will be offered an overnight stay in a nearby hotel.

Day 1- Main Study Visit

The same assessments and procedures will occur as for the main study visit, as detailed above, but an additional blood sample will be taken from you on the first day. Approximately 15 ml of blood (about 1 tablespoon) will be taken for tests to help ensure it is safe to collect the CSF. The entire procedure of collecting blood will take about 10 minutes.

Day 2 - CSF Collection

The CSF collection will occur on the second day. We will ask you to arrive at the study site in the morning so that the CSF collection can be done between 8:00 and 10:30 am. You will be asked not to
eat anything from midnight on the day of the CSF collection 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 CSF and blood sample collection will have to be cancelled.

The study physician will confirm that you are still willing to participate in this part of the study. If so, the results of the blood testing done the previous day will be reviewed. If the study physician confirms that you still meet all eligibility requirements for the CSF collection, the study site staff will prepare you for the procedure.

**Lumbar Puncture**

A lumbar puncture is a medical procedure where a very thin needle is inserted into the lower back in order to collect CSF fluid from the spine. It is a very common procedure that typically takes around 30 minutes to perform.

At the start of the procedure 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. The skin around your lower back area is cleaned and local anaesthetic will be injected, this stings for a couple of minutes, then the skin goes numb. After a couple of minutes a very thin needle will be inserted into your lower back to collect the CSF, 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. Although the local anaesthetic makes the skin go numb some people can still experience some pain during the procedure. You are free to ask for the procedure to be stopped at any time.

Following the sample collection you will 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.

**Blood 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. The skin around the injection site will be cleaned and a small needle will be inserted to draw blood. This procedure is quick, typically taking just a few minutes to do and will be performed by an experienced and trained member of the research team.

**Follow-Up Call: 1 to 3 Days after optional CSF Collection**

We will call you 1 to 3 days after the CSF and Blood collection 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 visit.

**What discomforts and risks are involved?**

Some of the possible **discomforts of CSF collection** include:

- The anaesthetic will sting when first injected.
- You may feel a pressure sensation when the needle is inserted.
- Some people experience brief pain, either in the back or down one leg, when the needle is close to the spinal fluid. This pain usually stops after a few seconds.
- You may experience some back pain following the CSF collection.
You may experience a headache following the CSF collection. You will be given instructions on how to manage this if it occurs. The risk of headache is about 5%. Occasionally the headache doesn't go away on its own and a second hospital procedure called a "blood patch" may be recommended to help it resolve. This is rare – the chance is less than 1% overall.

Some of the possible **discomforts of blood collection** include:

- Blood collection may cause some pain and discomfort and a bruise may form at the site of the puncture with the needle.
- Fainting or feeling lightheaded may occur during or shortly following the blood collection.

Possible **risks of CSF collection** include:

- Hypersensitivity (allergic) reaction to the anaesthetic.
- Infection caused by the needle going through the skin. This is very rare; the risk is much less than 1 in 1,000.
- Damage to the nerves in the lower back, which could cause numbness, pain or altered function in the legs, bowels, bladder or genitals. This may be caused directly by the needle or by blood leaking into the fluid. It is very rare (much less than 1 in 1,000).

Possible **risks of blood collection** include:

- A clot may form at the site of needle puncture and infections may occur, but these are rare.

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

Please continue to next page
3. **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. If you choose to partake in the optional CSF and blood collection you should also follow instructions regarding follow-up care after the CSF and blood collection which will be explained to you by the study doctor.

On the day of optional CSF and blood sampling visit you will be asked to not eat anything from midnight the night before until the CSF and blood collection has been completed.

If you are not feeling well or if you have had medications since your referral to us for the study or the telephone call to arrange your study visit you should inform the study team as soon as possible.

4. **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 on a secure server through the study sponsor, University College London. In addition, data will be held at a data storage facility selected for this study. Access will be restricted to authorised personnel. 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 for which Prof Tabrizi is the custodian.

The information collected from you and entered in a secure 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.

5. **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 Prof Tabrizi, her research team members, her appointed service providers, and her 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.
Prof Tabrizi or her partners may also submit your coded information to be included in one or more other electronic databases for use by Prof Tabrizi 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.

Your coded information and a portion of your coded biological samples will be shared with CHDI Foundation Inc. (CHDI), a not-for-profit foundation that only works on HD. CHDI will store your coded biological samples in a biological samples repository (storage facility) and your coded information in one or more electronic databases. CHDI may also share your coded information and coded biological samples with other researchers and service providers for the purposes already stated above.

To meet regulations or for reasons related to this study, Prof Tabrizi may also share this consent form and records that identify you and biological samples collected from you during this study with the following third parties:

- Representatives of organisations providing services in connection with this study, the organisation contracted to collect, maintain, and manage the information collected in this study alongside UCL; 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).

Prof Tabrizi, the study sponsor (UCL), CHDI 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.

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

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 Prof Tabrizi or a member of her 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 biological samples collected from you during this study have already been distributed for use, it may not be possible for us to locate and destroy them.

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.

Whilst we do not want to cause alarm, we are required by the body governing Research Ethics Committee to let participants know what will happen to their samples and/or data if they were to lose capacity during the course of the study (or thereafter). Should you lose the capacity to consent during your participation, you will be withdrawn from the study by the research team, and we would like to ask your permission in advance to retain any CSF and/or blood samples collected prior to your withdrawal for use in HD research.

6. 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.

Blood Collection

There is a small risk of discomfort, bruising or bleeding associated with having a blood sample taken. Sometimes people can feel faint or light-headed during or shortly following blood collection. You will be given plenty of time to rest if you feel unwell, until you feel better.

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

When completing the clinical, behavioural and cognitive assessments for HD-YAS, you may experience low mood or psychological discomfort (such as stress or anxiety). 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 these questionnaires or tests you may also 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

We do not expect to find anything of medical significance for individual research participants as part of this study. 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 General Practitioner (GP) who will be able to take any necessary action through the usual NHS care pathways.

7. **What are the benefits of taking part in HD-YAS?**

You will not have any direct benefits from participating in this study. The results of this study may contribute to new knowledge of HD.

8. **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.

9. **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.

10. **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 Prof Tabrizi or a member of her team, who will do their best to address your concerns. The National Health Service or UCL complaints mechanisms are available to you. Please ask Prof Tabrizi or a member of her 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. University College London (UCL) 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.
If you have concerns about any aspect of this study, you should call 020 3108 7480 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

**11. 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.

**12. Who has reviewed this study?**

HD-YAS has been reviewed by the UCL/UCLH Research and Development office and the London Bloomsbury Research Ethics Committee.

**13. 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.

**14. 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 (Prof Tabrizi) decides to terminate the study for safety or other reasons.

**15. 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

Professor Sarah Tabrizi
Box 104
HD-YAS

(IRAS number: 208997)

Huntington’s Disease Identification number __ __ __ - __ __ __ - __ __ __

Informed Consent Form (GENE CARRIER)

I have read and understood Gene Carrier Information Sheet and Informed Consent Form version 2.1 1st May 2017, for the above study. I have had the opportunity to consider the information and ask questions, and have received satisfactory answers. I understand I will receive a signed copy of this informed consent document.

Please initial if you agree

I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.

I agree to undergo the MRI scan and its use for research.

I understand that sections of my medical notes, and data collected during the study, may be looked at by people from Prof Tabrizi’s research team, appointed service providers, regulatory authorities or the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.

I understand that my data will be stored with a coded research identifier to protect my identity. I understand that my coded samples and coded data will be shared with Prof Tabrizi’s appointed partners from academic, not-for-profit and/or commercial research organisations and other HD researchers for research purposes. I understand that my coded samples and coded data will be shared with CHDI and by CHDI with other researchers and service providers for research purposes. I give permission for my coded data and coded samples to be shared in this way.

I agree to my General Practitioner being informed of my participation in the study.

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Should I lose the capacity to consent during the study, I agree to any data, DNA, blood and CSF samples (if relevant) collected prior to my withdrawal being retained and used for research purposes.
I give permission for the study team to contact me after HD-YAS visits to inform me of any future potential research studies or clinical trials in HD.

I agree that a sample of my DNA can be used for genetic and epigenetic analysis. I understand that the results of this analysis will have no clinical implications for me.

Consent to optional CSF and Blood sample collection

I wish to participate in the optional CSF collection part of this study and agree to provide blood samples and to undergo the lumbar puncture to collect spinal fluid.

For Study Site Staff

**Person Obtaining Consent.** I have read this form to the participant and/or the participant has read this form. An explanation of this study was given and questions were solicited and answered to the participant’s satisfaction. In my judgement, the participant has understood the information.

HD-YAS Gene Carrier PIS/ICF v2.1  IRAS: 208997  1st May 2017