University College London Hospitals NHS
NHS Foundation Trust

The National Hospital for Neurology and Neurosurgery
Multidisciplinary Huntington's Disease Clinic
Consultants: Professor S J Tabrizi, Dr E Rosser,
Professor T Warner, Dr T Andrews, Dr E Chu, Dr E Wild
HD Specialist Care Advisers: Alison Heavey, Mandy Ledbury,
Helen Santini, Anna Gardner
NHNN Box 104, Queen Square, London WC1N 3BG
Nurse Consultant: Rachel Taylor 020 3108 7471
Specialist Nurse: Desiree Salanio 020 3448 3776
Secretary: 020 3448 3420
Appointments: Mohammad Hussain: 020 3448 8960
Email: UCLH.NHNN-HDSecs@nhs.net
Fax: 020 3448 4786
Websites: www.hdresearch.ucl.ac.uk
www.uclh.nhs.uk

PART 1

1. **Document heading**
   Enroll-HD Participant Information Sheet for Adults

2. **Study Title**
   Enroll-HD:
   A Prospective Registry Study in a Global Huntington's Disease Cohort
   A CHDI Foundation Project

3. **Invitation Paragraph**

   You are being invited to participate in a research study named "Enroll-HD". 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.

   Part 1 tells you the purpose of this study and what will happen to you if you take part. Part 2 gives you more detailed information about the conduct of the study.

4. **What is the purpose of the study?**

   The purpose of this research study is to collect clinical information about you and your health. We will also collect biological samples, such as blood and DNA (the genetic material in your blood). Your clinical information and biological samples are sensitive data and will be coded so that an identification number will be assigned to your data. Researchers will use this information and samples to learn more about HD and to try to find new treatments for the disease. People from many countries contribute to Enroll-HD. Because of the size of the study we hope to get answers to many research questions faster than in the past. This consent form describes the research study and what you can expect if you decide to participate. Please read this consent form carefully. Ask the person who presents the form to you any questions you have before deciding whether to participate in this study.

5. Why have I been invited?

We are inviting you to participate in Enroll-HD because you are affected by HD or from an HD family.

We plan to include all individuals affected by HD or who come from an HD family who are eligible and willing to participate in Enroll-HD. Each site will be able to enrol as many such participants as possible. "Community controls" may be required for some sub-studies of certain aspects of HD. A community control is a person who does not carry the HD genetic mutation that causes Huntington's disease and is not part of an HD family. The number of community controls to be enrolled will be based on the needs of those sub-studies.

6. Do I have to take part?

You are completely free to choose whether or not to participate in this research study. If you decide to participate, you can change your mind and withdraw from the research study at any time; you are not required to give any reasons for your decision. Deciding not to participate will not affect you or your family's current or future clinical care. You do not need to know (or learn) whether you carry the genetic mutation responsible for HD to participate in this study.

7. What will happen to me if I take part?

Enroll-HD is a continuation of the European-based Registry study and North American-based COHORT study (Cooperative Huntington Observational Research Trial). It is an ongoing longitudinal study. A longitudinal study is one where participants are assessed regularly over a period of time. For Enroll-HD we will invite you to undergo the research procedures about once a year for as long as you are willing to participate.

Enroll-HD has several parts, five of which are core parts of the research study and others which are optional. If you consent to participate in Enroll-HD we will:

1. Assign/confirm a 9-digit unique identifier (HDID)
2. Conduct a clinical evaluation of your current medical status and wellbeing.
3. Collect a sample of your blood to study your DNA.
4. If you participated in the Registry study, include any data and samples collected from you in that study in the database along with the data from the Enroll-HD study.
5. Store the data and biological materials we collect from you (including any data and samples from Registry) in a secure place and make them available for future research.

For the **optional** parts, we will also:

1. Collect information about your family history.
2. Collect other biological samples from you.
3. Link clinical information about you collected in research studies other than Registry to the clinical information about you collected in this study.
4. Offer you the opportunity to participate in sub-studies.
5. Contact you between study visits to provide information about future HD research studies or find out information about your health status or wellbeing.

We will also ask for your permission to discuss post-mortem tissue donations with you.

In order to participate in Enroll-HD you must agree to take part in the five core parts of the study. Your decision to participate in the optional parts of Enroll-HD will have no impact on your participation in the rest of the study.

Each of the parts of Enroll-HD is described in more detail below.

1. ASSIGNING THE HDID (9-Digit Unique Identifier) – CORE

All information collected about you will be coded with a Huntington's disease identifier (HDID) that is a unique 9 digit number used to protect your identity and connect your clinical information to other HD studies in which you may participate. If you do not already have an HDID or you have lost your HDID, at the initial visit you and a member of the site research staff will go to a secure website and generate a HDID. Four data elements (date of birth, birth name, place/town of birth and mother's maiden name) are required to create the HDID. The information used to generate this HDID is never stored and resides on a dedicated, secure server only for the split-second needed to generate the HDID.

2. CLINICAL EVALUATIONS – CORE

At the initial visit as well as at your follow-up visits (about every 12 months), 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 behaviours which may be affected by HD. We hope that these examinations will help give a better understanding of HD symptoms and the factors that determine how fast or how slow HD progresses. If you bring a companion to the research study visits, with your permission, we may ask that person questions about your ability to do day-to-day activities and your behaviours. At your initial visit, the examination should take about 60-75 minutes; at follow-up visits it should take about 45 minutes.

3. **COLLECTING BLOOD TO STUDY YOUR DNA – CORE**

At the initial visit, we will collect one tube of blood (approximately 2 teaspoons or 10ml) from a vein in your arm and store it using standard procedures. This will take about 5 minutes. All blood samples are shipped and stored in a central storage facility 'BioRep S.r.l.',

which is in Milan, Italy, or such other facility designated by CHDI Foundation, Inc. from time to time. This storage facility is an independent organisation that has expertise in storing biological samples to ensure quality and safety. It will then be linked to a unique lab identification number once it is sent to a research facility selected for Enroll-HD (BioRep, Srl in Milan, Italy or such other facility designated by CHDI Foundation, Inc. from time to time). The blood will be used to obtain your DNA (the genetic material in your blood). The DNA will then be analysed or "**genotyped**". As part of this genotyping, the number of cytosine-adenosine-guanine (CAG) repeats in your HD gene will be counted. This is the genetic mutation that determines whether or not you have, or will develop HD. Genotype information will also be used as described below under the heading "5. STORING AND SHARING INFORMATION AND BIOLOGICAL MATERIALS FOR RESEARCH PURPOSES – CORE." Because this genotyping is being done as a part of this research study, the results are experimental data and normally the results will not be reported to you or to anyone at your research centre.

If you had HD genetic testing in the past (other than as part of Registry) and your CAG number is entered into the Enroll-HD database, that CAG number and the one determined as part of the research genotyping will be compared by a Data Safety Monitoring Committee (DSMC). If there is a difference in the two numbers and the DSMC is concerned about the difference, the research staff and your doctor will be contacted. Your doctor may talk to you about this difference depending on your medical condition.

If you would like to find out if you carry the HD gene mutation while participating in this study, you may do so through available HD genetic testing centres in your area. Ask the site staff for additional information.

Note- If you were a participant in the Registry research study and you already had your DNA genotyped, you will not need to do that again for this study.

4. INCLUDING YOUR INFORMATION AND SAMPLES FROM REGISTRY– CORE

For those who participated in Registry: If you were a participant in the Registry research study your consent will enable us to obtain a copy of the information collected about you in that study and combine it with the new information being collected about you in Enroll-HD and treat it as if it were information collected in this research study. Your consent will also enable us to treat any biological samples collected from you in Registry as if they were samples collected in Enroll-HD.

5. STORING AND SHARING INFORMATION AND BIOLOGICAL MATERIALS FOR RESEARCH PURPOSES – CORE

The clinical information collected about you will be entered via secure internet connections into a confidential computer database that is created, maintained and protected by an IT company, 2mt Software GmbH, based in Germany, or such other facility designated by CHDI Foundation, Inc. from time to time, who specialise in developing IT systems to record clinical

information obtained from research studies and clinical trials. The database system has been created to ensure that your information is safe and secure. **The clinical information that is entered into the database will not contain your name or other information that could identify you.**

Only the site research staff will be aware of your identity and have the key to the code that links your clinical information and biological samples to you.

To meet regulations or for reasons related to this research study, the site research staff may share a copy of this consent form and records that identify you with the following people/oversight entities:

- CHDI Foundation, Inc. (the organization funding this study).
- Outcome Sciences, Inc. and its agents, the Organization contracted for Enroll-HD who will maintain, manage, and monitor the information collected in the study.
- Professor Sarah Tabrizi and this research study research staff at University College London, Institute of Neurology.
- Representatives of national and foreign governmental and regulatory agencies and health authorities, such as the United States Food and Drug Administration (FDA) and the European Medicines Agency (EMA).
- The ethics committees/review boards (committees that make certain your rights as a research subject are protected) that reviewed Enroll-HD.
- BioRep, Srl in Milan, Italy (or such other entity designated by CHDI Foundation, Inc. from time to time, representatives who may store your samples for future research and conduct the research genotyping for the study).
- 2MT Software in Ulm, Germany (or such other entity designated by CHDI Foundation, Inc. from time to time, representatives who receive and store the clinical data, maintain the Enroll-HD database and prepare all the data for transfer for future use by CHDI Foundation, Inc. and other qualified researchers).
- Data Safety Monitoring Committee (a committee that periodically reviews coded data for any safety concerns and genotyping results for any discrepancies).
- Other agents designated by CHDI Foundation, Inc.

CHDI Foundation, Inc. may **use** and make available for use by other service providers or researchers the **coded** clinical information collected about you for the following purposes:

- To check the quality of the clinical information and biological samples we collect from you.
- To better understand HD or other diseases being studied.
- To better understand how new treatments may influence HD or other diseases being studied.
- To improve the design of future research studies.
- To support scientific discussion and research that furthers the development of treatments for HD and other disorders.

CHDI Foundation, Inc. may **use** and make available for use by other service providers or researchers the **coded** biological materials collected from you for the following purposes:

- To look at the DNA and see if there are special "markers" that help explain things about HD.
- To measure the amount of proteins and other molecules found in the biological samples that also might help explain things about HD.
- To see how different possible medicines influence biological and chemical processes that might be important in HD.

CHDI Foundation, Inc. may **share coded** clinical information and **coded** biological samples with the following third parties:

- Representatives of organizations providing services to CHDI Foundation, Inc. in connection with Enroll-HD, such as laboratories, 2MT Software and Outcome Sciences, Inc. and their agents, which organizations are contracted for Enroll-HD to collect, maintain, manage, and monitor the information collected in the study.
- Representatives of national and foreign governmental and regulatory agencies and health authorities, such as the United States Food and Drug Administration (FDA) and the European Medicines Agency (EMA).
- The ethics committee/review board at the site that is overseeing the ethical conduct of the study.
- Doctors at other sites that are taking part in Enroll-HD and the ethical review boards at those sites.
- Third parties working with or providing services to CHDI Foundation, Inc. as part of scientific discussions. For example, CHDI Foundation, Inc. may share coded information from Enroll-HD about the progression of a specific symptom of HD in order to discuss the best way to design a study to treat that symptom.
- Researchers (including researchers at companies) that wish to use the coded clinical information and coded biological samples for research that furthers the development of treatments of HD or other disorders.

CHDI Foundation, Inc. or these third parties, including Enroll-HD investigators, may publish the results of their research, including coded clinical data, in medical journals or present such results at meetings. Because your name, address or other identifying information are never given to CHDI Foundation, Inc. and these third parties, this information will not be disclosed.

CHDI Foundation, Inc. may also submit coded clinical information to be included in one or more other electronic databases for use by researchers conducting studies to further the development of treatments for HD, other disorders or the purposes of other bio-medical research.

The biological materials collected from you 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 your biological materials. Just contact the site investigator and let him or her know that you no longer want your biological materials stored and they will be removed and destroyed. If your biological materials have already been distributed to a researcher for use, we may not be able to locate and destroy those biological materials. At the end of the study, all biological materials will continue to be stored in the BioRep s.l.r. biorepository in Milan (or such other

facility designated by CHDI Foundation, Inc. from time to time)for at least 50 years or more after the study end date. The samples may be used for research as described in this form.

Any of the uses and activities described above may involve sending coded clinical data and coded biological samples to other countries that may not have the same or as strict privacy laws as this country, including the United States. However, each recipient will be required to enter into an agreement under which the recipient will be required to comply with local laws applicable to their use of the data, and given that only coded clinical data or coded biological samples are sent, the risk of unintended disclosure of identifying information is low.

Throughout the study, you have the right to ask what kind of data is recorded about you, who keeps your data, and who has access to it. You also have the right to review or ask that your data be corrected or deleted in accordance with your country's data protection laws. You understand and approve that access and corrections of data may be limited in order to ensure scientific accuracy and responsibility in accordance with applicable laws and regulations. If you choose to stop your participation in the study, no new information about you will be collected or added to the study database; however, data that was previously collected will not be removed and will be used and disclosed as set forth above.

A description of this research study will be available on http://www.clinicaltrials.gov. This website will not include information that can identify you. At most the website will include a summary of the results of the research study. You may search this website at any time.

The following parts of Enroll-HD are optional. You will be asked to decide whether or not you wish to participate in each of these parts of the study on a one-by-one basis. Deciding not to participate in any of these optional parts of Enroll-HD will not affect your participation in the rest of the study, or your current or future clinical care.

1. COLLECTION OF FAMILY HISTORY INFORMATION – OPTIONAL

An **optional** part of Enroll-HD is the collection of family history information. If you

- have been clinically diagnosed with HD,
- do not have a clinical diagnosis of HD but are known to carry the genetic mutation responsible for HD because you took a genetic test, or
- are at risk for HD due to a family history of HD

you will be invited to participate in this optional procedure.

If you agree to participate, you will be asked questions about members of your extended family, both living and deceased, in order to make a family tree. Information collected about each family member will include their year of birth, sex and if applicable, year of death. For those family members who have HD, you will be asked about their HD symptoms. At subsequent visits, you will be asked to provide updates. This information will help us to better understand whether family members have similar HD symptoms and to link the

coded clinical information and samples of family members who have agreed to participate in Enroll-HD at different sites.

The information you provide about the family history will **NOT** include your name or your family members' names – the computer will automatically assign a random number code to the family members entered in the system. The family history information will be entered into the computer and stored in the same secure database with the rest of your coded clinical information. We will never contact your family members because you told us about them in this part of the study.

2. ADDITIONAL BIOLOGICAL MATERIAL COLLECTION/STORAGE/RESEARCH USE – OPTIONAL

Another **optional** part of Enroll-HD involves collecting blood samples to process and store for future research.

The purpose of collecting, processing and storing these blood samples is to make them available in the future to researchers who are trying to develop new tests for, and ways to treat HD as well as other diseases. We hope that making these biological materials available for this purpose will provide information that will help HD research and lead to treatments for HD.

If you agree to participate in this part of Enroll-HD, at each annual visit we will collect a blood sample (about 8 teaspoons or 40ml) from a vein in your arm and store it using standard procedures. We will send your blood sample to a research facility selected for Enroll-HD where it will be processed so that different parts of your blood can be analysed and stored for future research. These parts include DNA and white blood cells (the cells in blood that fight infections). Because these analyses are being done for research purposes, the results are experimental data. Individual results will not be reported to you or to anyone at your research centre.

CHDI Foundation, Inc. will store the biological materials collected from you and may use and share them in the way described above under the heading "**5. *STORING AND SHARING INFORMATION AND BIOLOGICAL MATERIALS FOR RESEARCH PURPOSES – CORE***".

3. LINKING CLINICAL INFORMATION FROM PREVIOUS STUDIES TO ENROLL-HD – OPTIONAL

Another **optional** part of Enroll-HD involves linking clinical information about you collected in other HD studies (other than the Registry study) to the clinical information collected about you in Enroll-HD.

The purpose of this part of Enroll-HD is to give us the opportunity to track the progression of your HD over an extended period of time or through different tests that are conducted in other HD studies. If you agree to participate in this part of Enroll-HD you will be asked to

provide the name(s) of other HD studies you have participated in. If you cannot remember the study name, you can provide any information that may help to identify it such as the approximate year(s) you took part in the study(s), your subject identifier associated with the study(s) and/or the name of the drug under study. We will use this information to request that the clinical information collected about you in other HD studies be linked into the Enroll-HD database. This information will be captured electronically and will provide the opportunity to track your data across multiple studies.

4. PARTICIPATION IN SUB-STUDIES – OPTIONAL

The last **optional** part of Enroll-HD involves collecting information in sub-studies. A sub-study is added on to a regular Enroll-HD visit and involves a specific sub-population of the participants in Enroll-HD. In general, a sub-study will end once the number of research participants needed to answer the specific research question has done so.

The purpose of a sub-study is to rapidly evaluate a new or improved test, questionnaire or rating scale that may help measure HD better than those currently available. A sub-study will always be non-invasive and will never involve tools that break the skin or physically enter the body. Tests are usually paper and pencil or computerized, or involve movements like walking, getting up from a chair, and so forth. A sub-study could also involve an interview during which a member of the site research staff asks you questions about how you feel or how you are doing at home or at work. The addition of a sub-study to your usual Enroll-HD visit should not increase the total length of your visit past 2½ hours. Even if you agree to participate in the process of developing and qualifying new tests as part of a sub-study a member of the site research staff will always explain the specific study to you and give you the option to participate or not.

CONTACTING YOU

A member of the site research staff will need to contact you to schedule your yearly study visits. We will work with you to determine the best way to contact you to set up these visits. We recognize that there may be reasons you are not able to come in for a study visit. If this happens, you can still continue your participation in the research study and we will make arrangements to reschedule your appointment.

Contact Between Study Visits

Although we will contact you regarding your study appointments, you have the **option** of being contacted between visits to collect additional information or to provide you with study updates. If you allow us to do this, we will not identify ourselves as having any connection with a medical facility, so as to preserve your privacy.

Contact Regarding Other Research Studies

While Enroll-HD is ongoing we may participate in other HD research studies. If you agree, we will contact you about studies we think you may be eligible to participate in. This may

involve your doctor or a member of the staff at the research centre contacting you about a clinical trial involving an investigational medicine or other treatment related to HD. This may help your doctor identify potential research participants for future clinical trials and may help improve participant recruitment in those HD studies. This information would be kept confidential and will be stored at University College London, Institute of Neurology.

Contact Regarding Post-Mortem Tissue Donation

Studying biological materials from people with HD may help find treatments for the disease. For example, because HD is a neurological disease brain tissue is particularly important but, for all practical purposes, brain tissue cannot be accessed and examined during life. Talking about donating tissues for research after death is not easy – many people and families have feelings about this – and we do not want to impose unless you and your family are comfortable discussing this topic. We would therefore like to ask you whether you are willing to be approached by your doctor to discuss options for post-mortem tissue donations.

8. Expenses and payments

You will not receive payment for participating in Enroll-HD. There is also no cost for the research evaluations performed during this research study. Study participants are eligible for a payment to defer the cost of travel. The payments are based on how far you need to travel from your home to the Enroll-HD site.

If you travel:

Less than 40 km; you receive £ 20.00

40- 80 km; you receive £ 30.00

Greater than 80 km; you receive £ 50.00

Since this payment is to defer your travel expenses and is voluntary you may refuse the payment.

9. What will I have to do?

Apart from attending yearly study visits, we will not require any further participation from you, unless you have consented to additional Optional Parts, e.g. participation in Sub-studies, in which case you may be invited to participate in additional visits.

10. What are the possible disadvantages and risks of taking part?

Your chance of developing HD will not be influenced by participating in Enroll-HD. However, if you have inherited the HD genetic mutation, there is a chance that you may develop

clinical signs of HD during the course of this research study. If you have HD or are diagnosed with HD during the course of Enroll-HD, there may come a time when you are no longer able to understand the future activities that are planned as part of this research study. Therefore, we recommend that you identify an individual to act as your "research proxy." This individual will help you decide whether it is a good idea for you to continue to participate in Enroll-HD. You will identify your research proxy on a separate form when you begin the study or if you are diagnosed with HD during the study.

During the course of this research study it is possible that we may develop concerns that you could be of harm to yourself or to others. If this takes place, we may need to disclose information about you without your consent to protect you or others around you. If possible, we will discuss this with you before making such disclosures.

You may experience anxiety or psychological discomfort (such as stress or fatigue) while completing the clinical evaluation and family history questions. If at any time you feel you could benefit from treatment or support, you may request to be referred for appropriate care.

During the collection of blood samples you may experience pain and/or bruising at the site where blood is taken. A clot may form at the site and infections may occur, but these are rare. Fainting or feeling lightheaded may occur during or shortly after having blood drawn. If you experience this, you should lie down immediately to avoid possible injuries and notify study personnel.

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.

As with the collection of any personal (private) information, there is also a slight risk of accidental disclosure of information or breach of computer security. Loss of confidentiality could have a negative impact on you, your family, or other individuals or groups, including insurability, employability and/or family relationships. Safeguards are in place to minimize this potential risk.

You will not receive direct health benefit from participating in Enroll-HD study. However, your participation may provide information that is useful to our understanding of HD and our efforts to find treatments for HD.

11. What happens when the research study stops?

You may be withdrawn from Enroll-HD if you do not follow the directions of this research study or if your medical condition changes so that staying in this research study might risk your health or this research. You participation in the study may also end if CHDI Foundation, Inc. discontinues funding for the study or discontinues the study site's participation in the study.

12. What if there is a problem?

Detailed information is given in Part 2 about (i) how to make a complaint about the way you have been dealt with during the study and (ii) treatment for any injuries you might suffer during the study.

13. Will my taking part in the study be kept confidential?

Yes. We will follow ethical and legal practice and all identifying information about you will be handled in confidence. The details are included in Part 2.

If the information in Part 1 has interested you and you are considering participation, please read the additional information in Part 2 before making any decision.

PART 2

1. What if relevant new information becomes available?

If relevant new information becomes available about the study or the study is stopped for any reason, we will tell you.

2. What will happen if I don't want to carry on with the study?

Your participation in this research study is completely voluntary. You are free not to participate or to withdraw at any time, for whatever reason, without risking loss of present or future care you would otherwise expect to receive. In the event that you do withdraw from this research study, the information you have already provided will be stored, used, and disclosed in the manner described in this form.

3. What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions 020 3108 7480/020 3108 7483. If you remain unhappy and wish to complain formally, you can do this via the National Health Service or UCL complaints mechanisms. Details can be obtained from your research doctor.

In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against University College London Hospitals NHS Foundation Trust but you

may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

You will be provided with 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, but reimbursement for this care may be sought from the National Health Service.

4. Will my taking part in this study be kept confidential?

Yes. We will not put your name, address or any other information that could directly identify you on the clinical information and biological samples you allow us to collect from you. Only the site research staff will be aware of your identity and be able to link the information collected from your study visits to you. All information collected for the study 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.

CHDI Foundation, Inc. will store and may use and share coded information in the ways described above under the headings "***1. ASSIGNING THE HDID (9-Digit Unique Identifier) – CORE****", and* "**5. *STORING AND SHARING INFORMATION AND BIOLOGICAL MATERIALS FOR RESEARCH PURPOSES – CORE***".

5. Involvement of GP?

With your permission, your GP will be informed that you are taking part in this study.

6. What will happen to the results of the research study?

Successful research by CHDI Foundation, Inc. and other organizations using your coded clinical information and coded biological samples collected in the course of Enroll-HD could result in a commercial 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.

The results of this study will be subject to peer review either in professional forums or published journal articles. You will not be identified in any report/publication.

Because Enroll-HD is a research study you will not be told the results of any of the tests performed in the study. However, your doctor will have access to the clinical information and may use it to help with your care.

7. Who is organising and funding the research?

Enroll-HD and the storage of coded clinical information and coded biological materials collected in the course of Enroll-HD are supported by CHDI Foundation, Inc., a not-for-profit foundation that funds a variety of research activities aimed at finding treatments for HD.

8. Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and has been approved by the Wales REC1.

9. Further information and contact details

For more information concerning this research or if you believe that you have suffered a research related injury, please contact: Professor Sarah Tabrizi on 020 3108 7469 or s.tabrizi@ucl.ac.uk.

If you have questions about your rights as a research subject, you may call the Patient Advisory and Liaison Service (PALS) on **020 3448 3237** or PALS@uclh.nhs.uk

University College London Hospitals NHS
NHS Foundation Trust

The National Hospital for Neurology and Neurosurgery
Multidisciplinary Huntington's Disease Clinic
Consultants: Professor S J Tabrizi, Dr E Rosser,
Professor T Warner, Dr T Andrews, Dr E Chu, Dr E Wild
HD Specialist Care Advisers: Alison Heavey, Mandy Ledbury,
Helen Santini, Anna Gardner
NHNN Box 104, Queen Square, London WC1N 3BG
Nurse Consultant: Rachel Taylor 020 3108 7471
Specialist Nurse: Desiree Salanio 020 3448 3776
Secretary: 020 3448 3420
Appointments: Mohammad Hussain: 020 3448 8960
Email: UCLH.NHNN-HDSecs@nhs.net
Fax: 020 3448 4786
Websites: www.hdresearch.ucl.ac.uk
www.uclh.nhs.uk

Enroll-HD Consent Form for Adult Participants

TITLE: Enroll-HD:

A Prospective Registry Study in a Global Huntington's Disease Cohort

A CHDI Foundation Project

Name of researcher:_____

Please initial box

I confirm that I have read and understood the information sheet Enroll-HD Participant Information Sheet for Adults, V1.2, 22 MAR 2016 for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

I agree to participate in the Core ENROLL-HD assessments, and to participate in yearly follow-up visits. ☐

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

I understand that relevant sections of my medical notes and identifying data collected during the study, may be looked at by individuals from Outcome Sciences Inc., from regulatory authorities, from the NHS Trust or others as described in the information sheet for this study, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records. ☐

I agree to the uses and disclosures of my personal information as described in the information sheet for this study. ☐

I agree to my General Practitioner (GP) being informed of my participation in this study. ☐

My decisions regarding participation in the ENROLL-HD Optional Parts are provided below:

Optional Part 1: Collection of Family History Information

I agree to participate in the collection of family history information as part of this research study. Yes ☐ No ☐

Optional Part 2: Additional Biological Material Collection/Storage/Research Use

I consent to give additional blood samples that may be processed and stored for future research and shared with other researchers for the purpose of biomedical research. Yes ☐ No ☐

Optional Part 3: Linking Clinical Information from Previous Studies to ENROLL-HD

I consent to have clinical information collected from other HD studies that I have knowledge of participating in linked to this research study. Yes ☐ No ☐

Optional Part 4: Participation in Sub-studies

I consent to participate in sub-studies for which I am eligible as part of my participation in Enroll-HD and agree that clinical information collected about me in Enroll-HD may be used in those sub-studies. I understand that my doctor or the staff at the research centre will explain each sub-study to me and give me the option not to participate. Yes ☐ No ☐

My decisions regarding Contact During ENROLL-HD Participation are provided below:

Contact Between Study Visits

I consent to being contacted between visits to provide additional information or receive study updates.

Yes ☐ No ☐

Contact Regarding Other Research Studies

I am willing to be contacted in the future about participation in future HD studies, including clinical trials that involve investigational treatments.

Yes ☐ No ☐

Contact Regarding Post-Mortem Tissue Donation

I am willing to be contacted in the future about post-mortem tissue donation.

Yes ☐ No ☐

_____	_____	_____
Name of patient	Date	Signature

_____	_____	_____
Name of person taking consent	Date	Signature