**[FORM TO BE ON LOCAL HEADED PAPER]**

**Summary of Patient Information Sheet (PIS) for HDClarity**

HDClarity is a research study of Huntington's disease (HD). It is designed to collect cerebrospinal fluid (CSF), the fluid that surrounds the brain and spinal cord. You are being invited to participate because you are an Enroll-HD participant and have tested positive for the genetic mutation that causes HD or because you are a healthy control (you do not carry this genetic mutation).

The samples and information collected from you will be available in the future for use by researchers who are studying HD and other conditions. They will also be used to identify and evaluate biomarkers for HD, which may help researchers to better understand the disease. In the future, these biomarkers could be used to help design clinical trials of new treatments. You will not have any direct benefits from participating in this study, but the results may contribute to new knowledge of HD.

HDClarity is an open-ended study (i.e. there is no set end date for this study). HDClarity consists of 2 annual visits: an Annual Screening Visit and an Annual Sampling Visit, up to 30 days apart. Each Annual Screening Visit takes 1-2 hours and each Annual Sampling Visit takes 3-5 hours. There is also an Optional Sampling Visit which you may be asked to attend 4-8 weeks after the Annual Sampling Visit during your first year of participation in this study. You will be encouraged to complete all annual visits, but you are under no obligation to do so and you can skip any year. If you skip three consecutive years, you will be withdrawn from this study, however, you may join again at a later date.

At the first **Annual** **Screening Visit**, the details of this study will be discussed with you, and you will have the opportunity to ask any questions. You will be invited to sign a consent form and your eligibility for the study will be confirmed. Every four years you will be asked to sign a new consent form to confirm that you still wish to take part in this study.

At each Annual Screening Visit, a brief physical and neurological examination will be performed, and you will be asked to donate 15 ml (3 teaspoons) of blood for routine safety tests.

At each **Annual** **Sampling Visit**, up to 20ml CSF (4 teaspoons) will be collected by a procedure called a lumbar puncture or spinal tap. This procedure is usually done under local anaesthetic and takes about 30 minutes. 50 ml of blood (10 teaspoons) will also be taken to be used for the same purposes as the CSF samples. During the procedure you may experience stinging, pressure or other discomforts. Afterwards, you may experience some back pain or headache or more serious complications. More information can be found on page 9 of the PIS. Medical care will be provided for any emergency medical problem that you may experience as a direct result of your participation in this study - more information can be found on page 10 of the PIS.

You may be asked to avoid certain medications before the Annual Sampling Visit. You will also be asked not to eat anything, and drink only water, for six hours before the scheduled time of your Annual Sampling Visit. All costs for hotel accommodations, travel and meals are covered within specified guidelines which will be provided to you. After every Annual Sampling Visit, you will be contacted by phone, to see how you are doing.

The information and samples collected from you will be linked to a code-number, and stored in secure databases and repositories. They will be shared with groups and individuals, including researchers (some of whom work outside the UK) to help study and develop treatments for HD and similar diseases. More information can be found on page 7 of the PIS. Please see page 11 of the PIS for details on protection of identifying information about you.

You are free to choose whether or not to participate in the HDClarity study, and you can change your mind and withdraw from this study at any time. If you decide not to take part or withdraw, it will not affect your care, or your participation in the Enroll-HD study. Before you decide to participate, it is important that you read the complete PIS.

The HDClarity study is sponsored by University College London, UK and funded by CHDI Foundation, Inc.

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****(Form to be on local headed paper)

**HDClarity Participant Information Sheet for Adults**

1. **PART 1**
	1. **Study Title**

HDClarity: a multi-site cerebrospinal fluid collection initiative to facilitate therapeutic development for Huntington's disease

* 1. **Introduction**

HDClarity Study, a research study, is sponsored by University College London, UK (Sponsor). The chief investigator for this study is Professor Edward Wild (Chief Investigator), who leads the Sponsor's Central Coordination team.

Funding for this study is being provided by CHDI Foundation, Inc. (CHDI), a not-for-profit foundation that only works on Huntington's disease (HD) and funds a variety of research activities aimed at developing treatments for HD.

The use and sharing of the information collected from you that can identify you will be done in compliance with the UK data protection laws and regulations (Data Protection Laws). This information falls within the following categories of personal data: personal details, family details, lifestyle and social circumstances, genetic data, and employment and education/training details. And, such information also falls within the following sensitive categories of personal data: physical or mental health details, sexual life, racial or ethnic origin and genetic data.

For purposes of the Data Protection Laws, both CHDI and the Sponsor are joint data controllers in respect of information that can identify you. CHDI has engaged CHDI Management, Ltd. as a local agent/representative. CHDI has an address c/o CHDI Management, Inc., 350 Seventh Ave., Suite 200, New York, NY 10001. CHDI Management, Ltd. has an address c/o CHDI Management, Inc., 350 Seventh Ave., Suite 200, New York, NY 10001. The Sponsor has an address of University College London (UCL), Gower St, Bloomsbury, London WC1E 6BT. CHDI's mission is to undertake research to understand, and to rapidly develop therapeutics that slow the progression of, HD. The Sponsor, UCL, is a University and its Privacy notice can be found at <https://www.ucl.ac.uk/legal-services/privacy/participants-health-and-care-research-privacy-notice>. In order to fulfill their respective legitimate interests, CHDI and the Sponsor need to process your personal information.

This study's clinical procedures and assessments as well as the day-to-day management of this study will be carried out at the study sites including [\_\_\_\_\_] **[INSERT NAME OF INSTITUTION]**. The study site investigator is [\_\_\_\_\_] **[INSERT NAME OF PI]**.

* 1. **Invitation Paragraph**

You are being invited to participate in HDClarity, a research study. 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. Please ask questions 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.

* 1. **What is This Study About?**

The main purpose of this study is to 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.

The CSF will be used to study HD and other conditions and to identify and evaluate biomarkers and pathways for HD and other conditions. A biomarker is something that is related to the course of an illness and can be measured which helps researchers better understand a disease. A pathway is a series of chemical reactions in a cell that play an important biological function. An increased understanding of how HD affects the brain, having better biomarkers for HD and identifying pathways relevant to HD may help in, as well as speed up, 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 researchers better understand who will most likely benefit from a particular treatment.

Two examples of biomarkers and pathways that are planned for 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.

A blood sample will also be taken 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, information collected from you through your participation in the Enroll-HD study will be used to help understand the findings from analysis of the CSF and blood samples and information collected from you in this study.

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

You are being asked to donate up to 20 ml of CSF (the same volume as 4 teaspoons) and 50 ml of blood (the same volume as 10 teaspoons) at each Annual Sampling Visit for the purposes described above and more fully described below. And, you are being asked to donate up to another 15 ml (the same volume as 3 teaspoons) of blood for routine safety tests at each Annual Screening Visit.

Please read this participant information sheet and consent form carefully. Ask the person who presents this participant information sheet and consent form to you any questions you have before deciding whether to participate in this study. If you choose to join this study, you will be asked to sign and date a consent form to confirm that you consent to participate in this study and explicitly consent to the use and sharing of the information collected about you during this study. You will be given a copy of this participant information sheet and a signed copy of the consent form.

* 1. **Why I Have Been Invited?**

You are being invited to participate in this study because you are a participant in Enroll-HD and 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.

* 1. **Do I Have to Take Part?**

**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.**

* 1. **What Will Happen to Me if I Take Part?**

You are being asked 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 at each Annual Sampling Visit for the purposes described above and more fully described below. And, you are being asked to donate up to another 15 ml (the same volume as 3 teaspoons) of blood for routine safety tests at each Annual Screening Visit.

As data controllers for this study, CHDI and the Sponsor are responsible for ensuring that they use information that can identify you in compliance with the Data Protection Laws. Each of CHDI and the Sponsor have appointed a Data Protection Officer to assist with their respective responsibilities. As part of their obligations under the Data Protection Laws, CHDI and the Sponsor are required to provide you with information about how they process information that can identify you. This information is outlined in detail in Part 2, Section 4 and Section 12 below. Please take the time to read and understand this section and, if you have any questions, please direct them using the details set out in Section 15 below.

The information collected from you includes information which directly identifies you (for example your name) as well as other information from which you may be indirectly identifiable (for example your date of birth and place of birth, which when taken together may enable you to be identified). Information that could directly identify you will not be sent outside of the study site. All information and biological samples collected from you that are sent outside of the study site will be coded with one or more unique identification numbers (codes), including your "Huntington's Disease Identifier" (HDID). These codes are used to protect your identity and to connect your information and/or biological samples to other studies in which you may participate. The study site staff will be aware of your identity and have the key that links your coded information and/or coded biological samples to you. In addition, the people and groups listed in Section 12 below may also have access to information that could identify you (including your identity and the key that links your coded information to you). Your coded information and/or coded biological samples 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 biomedical research.

Your General Practitioner (GP) will be notified that you are taking part in this study, unless you have advised that you would prefer that your GP is not made aware of your participation.

If, during the course of this study, the study site investigator learns information related to your health from the study procedures, the study site investigator may discuss this information and your options with you, including the option of providing the information to your GP.

Part 2 below gives you more detailed information about the conduct of the HDClarity study.

1. **PART 2**
	1. **How Many People Will Be in This Study?**

HDClarity aims to recruit a minimum of 2,500 participants, which includes HD participants at different stages of disease, and healthy controls. There will be multiple study centres including, but not limited to, locations in North America, South America, Australasia and Europe.

* 1. **What Will I Be Asked to Do?**

HDClarity is an open-ended study - there is no set end date for this study. This study consists of 2 annual study visits: an Annual Screening Visit followed by an Annual Sampling Visit within 30 days. Each year you will be asked to return as close as possible (within 2 months) to the anniversary date of the first Annual Screening Visit.

Inorder to understand how the CSF changes over short periods of time, some participants may be asked to return for an additional Optional Sampling Visit. If a participant returns for the Optional Sampling Visit, it will take place within 4-8 weeks of the participant's Annual Sampling Visit during the first year of their participation in this study.

After each Sampling Visit, you will be contacted by telephone 1 to 3 days after the visit to see how you are doing.

**You will be encouraged to complete all annual visits, but you are under no obligation to do so and you can skip annual visits.** However, during each year, you cannot complete an Annual Sampling Visit without first completing an Annual Screening Visit within the previous 30 days. Also, if you skip the Annual Sampling Visit for three consecutive years, you will be withdrawn from this study, however, if you wish to start participating in this study again you may join again at a later date.

All costs for hotel accommodations, travel and meals are covered within specified guidelines which will be given to you prior to your visit(s).

**Annual Screening Visit (up to 30 days prior to Annual Sampling Visit)**

Each Annual Screening Visit must take place within 3 months of your annual Enroll-HD visit. At the first Annual Screening Visit, the study site investigator or designated study site staff 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 a consent form to give your informed consent to participate in this study.

Every four years, the details of this study will again be discussed with you at the Annual Screening Visit to ensure that you remain informed about the nature and risks of this study and to confirm that you are still willing to participate in this study. At this time, you will be asked to again sign a consent form to confirm your consent to participate in this study.

At each Annual Screening Visit, the study site investigator will ask you questions regarding any concurrent diseases you may have and about any medications that you have been using within the last month, in order to check if you are eligible to continue to participate in this study. A brief physical exam and a neurological examwill be performed and your weight will be measured if it has changed since your last Enroll-HD visit.

Since you are a participant in the Enroll-HD study, the information collected from you during your most recent Enroll-HD visit will be used. Information about the genetic mutation that causes HD, if applicable, will also be collected from the Enroll-HD study.

Approximately 15 ml of blood (about 3 teaspoons) 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.

If you are female you will need to have a urine pregnancy test unless you are post-menopausal or not sexually active.

Each Annual Screening Visit will last about 1 to 2 hours.

If the study site investigator finds you eligible for study participation, you will be scheduled for an Annual Sampling Visit which will need to be done within 30 days of your Annual Screening Visit. If the study site investigator finds you not eligible to participate in this study, you may be re-screened as long as this is within 3 months of your Enroll-HD visit. You may decline repeat screening.

**Annual Sampling Visit**

Each Annual Sampling Visit will occur within 30 days of each Annual Screening Visit.

If it is more convenient for you, you may choose to stay at a hotel close to the study site the evening before each Annual Sampling Visit. You will be provided with help to arrange your travel and hotel accommodations for each Annual Sampling Visit.

You will be asked not to eat anything, and drink only water, for six hours before the scheduled time of your Annual Sampling Visit. You will be able to eat and drink straight after the CSF and blood sample collection is completed. You may also be asked to avoid certain medications prior to your appointment. If you have not followed the fasting or medication instructions, or if you are not feeling well, your Annual Sampling Visit will need to be rescheduled.

The study site investigator will confirm that you are still willing to participate in this study. If so, a neurological exam and a brief physical exam and a motor exam will be performed, and the results of the blood testing done at your Annual Screening Visit will be reviewed. If you are female, the urine pregnancy test will be repeated unless you are post-menopausal or not sexually active. If the study site investigator confirms that you still meet all eligibility requirements for this study, the study site staff will prepare you for the CSF collection.

You will be asked to either lie on your side with your knees pulled up and your chin tucked downward with a pillow placed between your knees or to sit upright leaning forward over a pillow placed on your lap. After cleaning the skin of your lower back, local anaesthetic may be injected to make the area go numb. This stings for a couple of minutes, then the skin goes numb. A thin needle will be inserted into your lower back and up to 20 ml (the same volume as 4 teaspoons) of CSF will be collected. Occasionally it may be necessary to try again in a different spot to find the right place and collect the fluid.

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 a resting period of 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.

Each Annual Sampling Visit will last about 3-5 hours.

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

A member of the study site staff will call you 1 to 3 days after each Annual 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 Annual Sampling Visit.

**Optional Sampling Visit**

Should you be asked to participate in the Optional Sampling Visit after the Annual Sampling Visit during your first year of participation in this study, 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 Annual Sampling Visit.

**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.

* 1. **What Must I Keep in Mind During This Study?**

During the time of this study, you are being asked to:

* Follow all instructions, including those regarding restricted medications that were given to you at your Annual Screening Visits.
* Not eat anything, and drink only water, for six hours before the scheduled time of your Annual Sampling Visits or Optional Sampling Visit.
* Inform the study site staff if you think you may be pregnant, of any illnesses you have had, or medications you have been taking since your Annual Screening Visit.
* Follow all instructions regarding follow-up care after your Annual Sampling Visits or Optional Sampling Visit.
	1. **How Will My Coded Information and Coded Samples Be Shared for Research?**

The coded information collected about you during this study will be entered via secure internet connections into a confidential database that is created, maintained and protected by an IT company, Webspirit Systems GmbH, based in Germany, or such other facility designated 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 coded biological samples collected from you during this study will be stored in a biological samples repository that is located at a biological samples storage facility selected for this study. The coded information and coded biological samples collected from you during this study will be used only for research purposes and will not be sold.

The coded information and coded biological samples collected from you during this study may be used, and made available for use, by CHDI, its service providers, other organizations and researchers and their service providers 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.

CHDI may also share the **coded** information and/or **coded** biological samples collected from you during this studywith the following other third parties:

* Representatives of national and foreign governmental and regulatory agencies and health authorities such as the United States Food and Drug Administration (FDA), Health Canada, the Medicines and Healthcare products Regulatory Agency (MHRA) and the European Medicines Agency (EMA).
* The National Health Service Trust (NHS Trust).
* The ethics committee/review board at the site that is overseeing the ethical conduct of the study.

CHDI and these third parties and the Sponsor are entitled to store, process, transfer, disclose and use, as applicable, your coded information for the purposes outlined above because it is necessary for their legitimate interests. Where your coded information contains sensitive information about you, CHDI and these third parties and the Sponsor are entitled to store, process, transfer, disclose and use, as applicable, your coded information for the purposes outlined above because it is necessary for scientific research purposes.

If the use and sharing of your coded information by either CHDI or the Sponsor is based on legitimate interests for the purposes outlined above, CHDI and/or the Sponsor will consider the need for such use and sharing and how it will impact your privacy. On balance, each of CHDI and the Sponsor has independently determined that the use and sharing of this information is necessary and does not adversely affect your privacy rights. You can request further information about these determinations by following the instructions set out in Section 15 below.

If your coded information from this study is published or presented at meetings, your name, address or any other information that could directly identify you will not be published or presented.

The uses and activities described above will involve sending your coded information and/or biological samples outside of the United Kingdom (UK) to countries that may have different or less strict privacy laws than this country, including the United States. However, anybody receiving your coded information and/or biological samples must sign an agreement in which they agree to follow all applicable local laws when they use your coded information and/or biological samples. If your coded information is sent outside the UK, steps will be taken to ensure that your coded information remains protected in a manner that is consistent with how your coded information will be protected in the UK. These steps include only transferring your coded information to third parties approved by the UK regulatory authorities or third parties located in countries approved by the UK regulatory authorities or requiring the third party to agree in writing to certain standard data protection clauses.

In addition, the Data Protection Laws may, under other circumstances, allow the transfer of your coded information outside the UK (for example, for reasons related to national security or law enforcement). Since only coded information and/or biological samples are sent, the risk of unintended disclosure of information that can directly identify you is low. You can obtain more details about the steps taken to protect your information when it is transferred outside the UK (including obtaining a copy of the standard data protection clauses referred to above) by following the instructions set out in Section 15 below.

Your coded information and coded biological samples will be stored for 50 years after the end of this study or longer if no effective treatment has been developed for HD during that time.

Your coded information and/or biological samples may be stripped of all identifiers and used for the research, and distributed to persons and groups, described above without additional informed consent.

A description of this 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 this study. You may search this website at any time.

* 1. **Are There Any Risks from Being in This Study?**

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. Analysis performed on data collected in the first two years of HDClarity shows that the risk of a moderate headache after an HDClarity lumbar puncture is about 6% and a mild headache occurs after about 9% of procedures. Severe headaches have occurred in less than 0.2% of HDClarity lumbar punctures. Occasionally a second hospital procedure called a "blood patch" may be recommended to help resolve the headache. 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.

Possible risks of personal (private) information collection include:

* As with the collection of any identifying or private information, there is a risk your information could be given out by mistake or stolen. If that happens, this could cause problems for you, your family, or other individuals or groups. These problems may include making it harder for you to get or keep insurance and employment as well as effects on family relationships. Safeguards are in place to minimize this potential risk.

You may experience anxiety or psychological discomfort (such as stress), or feel tired and/or irritable while completing the study procedures. If this happens please tell your study site investigator or the study site staff and ask them to allow you time to rest or stop the procedures altogether. If at any time you feel you could benefit from treatment or support, you may request to be referred for appropriate care.

* 1. **Are There Any Benefits to Taking Part in This Study?**

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

* 1. **What are My 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 [\_\_\_\_\_] **[INSERT NAME OF INSTITUTION]**.

* 1. **Will I Receive Any Money for Being in this Study?**

You will receive assistance arranging travel for the study – ask your study site investigator or the study site staff for information about this. The expenses that you incur for travel, hotel and meals resulting from your participation in the study will be covered or reimbursed in accordance with the policies provided to you by your study site investigator or the study site staff.

In addition, you will receive compensation in the amount of GBP 200 after each Annual Sampling Visit and also after the Optional Sampling Visit, if applicable. This is to compensate you for the invested time and discomforts arising within the scope of this study.

* 1. **What if I Am Injured from Being in This Study?**

The Sponsor holds insurance in case you are harmed by your participation in this study. You may be able to claim compensation if the Sponsor has been negligent. However, [\_\_\_\_\_] **[INSERT NAME OF INSTITUTION]** continues to have a duty of care to you as a participant in the study. The Sponsor does not accept liability for any breach of the duty of care owed by [\_\_\_\_\_] **[INSERT NAME OF INSTITUTION]**, or any negligence on the part of the employees of [\_\_\_\_\_] **[INSERT NAME OF INSTITUTION]**.

The [\_\_\_\_\_] **[INSERT NAME OF INSTITUTION]** will provide medical care for any emergency medical problem that you may experience as a direct result of your participation in this study. This care, may be provided by the NHS or a private provider. If you have health insurance, [\_\_\_\_\_] **[INSERT NAME OF INSTITUTION]** may seek reimbursement from your insurance provider, but you will not personally have to pay for this care.

* 1. **Where Does the Study Funding Come From?**

This study and the storage of coded information and coded biological samples collected in the course of this study are supported by CHDI, a not-for-profit foundation that only works on HD and funds a variety of research activities aimed at developing treatments for HD.

* 1. **What If My Information is Used for Commercial Purposes?**

Successful research 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.

* 1. **How Will Information That Identifies Me Be Protected and How Will This Information Be Shared?**

All information collected about you during this study that could directly identify you will be kept in a separate secure file located at the study site. Efforts will be made to securely store and handle this information but data security cannot be guaranteed. You can request access to this information as outlined below.

To meet regulations or for reasons related to this study, your study site investigator may share a copy of the consent form signed by you, your coded information and information that directly identifies you with the following people/oversight entities:

* Representatives of the United States, Canada and other governmental and regulatory agencies such as United States Food and Drug Administration (FDA), Health Canada, the Medicines and Healthcare products Regulatory Agency (MHRA) and the European Medicines Agency (EMA).
* The NHS Trust.
* The study site staff at [\_\_\_\_\_]. **[INSERT NAME OF INSTITUTION]**
* The ethical committees/review boards at study sites and other independent review boards overseeing the ethical conduct of this study (committees that make certain your rights as a participant are protected) that reviewed this study.
* CHDI.
* Other agents and service providers chosen by the Sponsor or CHDI (for example auditors and monitors).

While these people/oversight entities normally protect the privacy of information, they may not be required to do so by law.

CHDI and these people/oversight entities and the Sponsor are entitled to store, process, transfer, disclose and use, as applicable, this information for the purposes outlined above because it is necessary for their legitimate interests. Where your coded information contains sensitive information about you, CHDI and these people/oversight entities and the Sponsor are entitled to store, process, transfer, disclose and use, as applicable, this information for the purposes outlined above because it is necessary for scientific research purposes.

If the use and sharing of this information by either CHDI or the Sponsor is based on legitimate interests for the purposes outlined above, CHDI and/or the Sponsor will consider the need for such use and sharing and how it will impact your privacy. On balance, each of CHDI and the Sponsor has independently determined that the use and sharing of this information is necessary and does not adversely affect your privacy rights. You can request further information about these determinations by following the instructions set out in Section 15 below.

The study site staff will keep a copy of this signed consent form indefinitely, for as long as the coded information and coded samples are in use. Other information that could directly identify you will be stored in study-related documents that are accessible only to the study site staff and will only be kept until the end of the study after which they will be destroyed.

* 1. **Can I Choose Not to Take Part?**

**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.**

**In the event that you do withdraw from this study, the samples collected from you during this study will continue to be stored, used, and shared in the manner described in this participant information sheet, unless you request that the samples 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, it may not be possible to locate and destroy them.**

**In the event you withdraw from this study, no new information about you will be collected or added to the study database; however, the information that was previously collected will not be removed and will continue to be stored, used, and disclosed in the manner described in this participant information sheet.**

**You have the right to ask what kind of information is recorded about you, who keeps your information, and who has access to it. You also have the right to access and review your information and ask that it be corrected or deleted according to the Data Protection Laws. Some of these rights in relation to your information may be limited in accordance with applicable laws and regulations. You also have the right to withdraw your consent for the use and sharing of your information at any time. You will not need to give a reason.**

**If you withdraw your consent for the use and sharing of your information you will be removed from this study and no new information about you will be collected and the information that has already been collected will be deleted, however, your coded information will not be deleted if:**

* **It is not possible to identify you from this information.**
* **The information is needed to preserve the integrity of this study or for scientific research purposes.**
* **The information is needed in order to establish, investigate, exercise or defend a legal claim.**

**Other than being removed from this study, you will not be penalized if you decide to withdraw your consent for the use and sharing of your information. Nor will such decision affect the current or future care that you would otherwise expect to receive or affect your participation in the Enroll-HD study.**

**You also have the following rights in relation to the information held about you:**

* **The right to lodge a complaint with the data protection regulator.**
* **In some circumstances, the right to restrict or object to the use and sharing of your information.**
* **In some circumstances, the right to request that some of the information you provided be sent to a third party. Please note that this right only applies to information which you have provided.**

**If you have any questions or would like further information about your rights please direct them using the details set out in Section 15 below. You can exercise your rights by following the instructions set out in Section 15 below.**

**You can find out more information about your rights by contacting the Information Commissioner's Office, or by searching their website at https://ico.org.uk/.**

* 1. **Can My Participation in This Study End?**

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 study. Also, if you skip the Annual Sampling Visit for three consecutive years, you will be withdrawn from this study, however, if you wish to start participating in this study again you may join again at a later date.

Your participation in this study may also end if funding for this study is discontinued or the Chief Investigator elects to discontinue the study.

You will be removed from this study if you withdraw your consent for the use and sharing of your information.

* 1. **Who Do I Contact if I Have a Question?**

If you wish to complain about your treatment by study site staff due to your participation in the study, National Health Service or UCL complaints mechanisms are available to you. Please ask your study site investigator if you would like more information on this.

In the event that you are harmed by taking part in this study, or if you have concerns about any aspect of this study, you should ask to speak to a member of the study site staff who will do their best to answer your questions. If you remain unhappy or wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from the Patient Advice and Liaison Service.

For more information concerning this research or if you believe that you have suffered a research related injury, please contact: [\_\_\_\_\_]. **[INSERT NAME AND PHONE NUMBER OF CONTACT PERSON FOR STUDY INFORMATION \*NOTE: THIS PERSON IS USUALLY THE SITE'S PI]**

If you have questions about your rights as a participant, you may call [\_\_\_\_\_]. **[INSERT NAME AND PHONE NUMBER OF CONTACT PERSON FOR PARTICIPANT'S RIGHTS]**

If (1) you have any questions or would like further information on the collection, storage, processing, transfer, disclosure and use of your information or the exercise of any of your rights related thereto or (2) you would like to contact CHDI's or the Sponsor's Data Protection Officer, please address questions, comments and requests to [\_\_\_\_\_] **[INSERT SITE SPECIFIC CONTACT INFORMATION].**

If you are still not satisfied you have the right to lodge a complaint with the Information Commissioner's Office.

* 1. **Who Has Reviewed This Study?**

This study was designed jointly by the Chief Investigator (Professor Edward Wild) and CHDI with input from expert colleagues. It has been reviewed by the Sponsor (University College London). 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 London Camberwell St Giles Research Ethics Committee.

**(Form to be on local headed paper)**

**HDClarity Consent Form for Adult Participants**

**Study Title:** HDClarity: a multi-site cerebrospinal fluid collection initiative to facilitate therapeutic development for Huntington's disease

A CHDI Foundation Project

**Name of Study Site Investigator**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Please initial box**

I have read (or have had read to me) the contents of the participant information sheet for the above study. I have been encouraged to ask questions and have had my questions answered.

I understand that my participation in the study 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 consent to the storage, processing, transfer, disclosure and use of my identifying information as described in the participant information sheet.

I consent to the storage, processing, transfer, disclosure and use of my coded information and coded biological samples as described in the participant information sheet. I understand that my coded information and/or coded biological samples will be available now and in the future to researchers for the uses as described in the participant information sheet including (1) gaining a better understanding of HD or other diseases being studied, (2) furthering the development of treatments for HD or other diseases and (3) furthering biomedical research.

I understand that my coded information and records that identify me may be looked at by the study site staff, individuals from regulatory authorities, appointed service providers, the NHS Trust and others as described in the participant information sheet, where it is relevant to my taking part in the study. I agree that these organizations may have access to such information and records.

I understand that my General Practitioner will be informed of my participation in this study unless I’ve informed the study site staff that I do not wish for them to be contacted.

I agree to participate in the study. I understand that I will be given a signed copy of this consent form for my records and future reference.

Signature of Participant Printed Name Date

**For Study Site Staff:**

**Person Obtaining Consent**

I have read the participant information sheet (including information about the use and sharing of the information collected about the participant and biological samples collected from the participant) for this study and this consent form to the participant and/or the participant has read the participant information sheet for this study and this consent form. An explanation of this study and the use and sharing of the information collected about the participant and biological samples collected from the participant was given and questions from the participant were solicited and answered to the participant's satisfaction. In my judgment, the participant has demonstrated comprehension of the information.

Signature of Person Obtaining Consent Printed Name and Title Date

**---------------------------- Use this witness section only if applicable -------------------------**

***If the participant information sheet and this consent form is read to the participant because he/she is unable to read, or is able to read and understand but is unable to sign, an impartial witness must (1) be present while the participant is being consented and (2) read and affirm the statement below by signing where indicated.***

I confirm that the information in this participant information sheet for this study and this consent form and any other written information was accurately explained to, and apparently understood by, the participant. The participant freely consented to participate in this study and the use and sharing of the information collected about the participant and biological samples collected from the participant.

Signature of Witness Printed Name Date