[FORM TO BE ON LOCAL HEADED PAPER]

Summary of Patient Information Sheet (PIS) for Consultees 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. Your relative or friend is being invited to participate because they have tested positive for the genetic mutation that causes HD.

The samples and information collected from them will be used to study 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. Your relative or friend will not have any direct benefits from participating in this study, but the results may contribute to new knowledge of HD.

HDClarity consists of a Screening Visit and a Sampling Visit, up to 30 days apart. The Screening Visit takes 1-3 hours and the Sampling Visit takes 3-5 hours. After the sampling Visit, you and/or your relative or friend will be contacted by phone, to see how they are doing. They may be asked to attend a further, Optional Sampling Visit, but you or they may decline to do so.

At the **Screening Visit**, the details of this study will be discussed with you both, and you and they will have the opportunity to ask any questions. You will be invited to sign a consultee declaration form and your relative or friend's eligibility for the study will be confirmed. A brief physical and neurological examination will be performed, and they will be asked to donate 15 ml (3 teaspoons) of blood for routine safety tests. Since they are a participant in the Enroll-HD study, the results from the examinations performed at their most recent Enroll-HD study visit may be used instead, depending on the timing of their last visit.

At the **Sampling Visit**, up to 20ml CSF (4 teaspoons) will be collected by a procedure called a lumbar puncture or spinal tap. This procedure is 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 they may experience stinging, pressure or other discomforts. Afterwards, they may experience some back pain or headache or more serious complications. More information can be found on page 10 of the PIS. Medical care will be provided for any emergency medical problem that they may experience as a direct result of their participation in this study - more information can be found on page 11 of the PIS.

They may be asked to avoid certain medications before the Sampling Visit. They will also be asked not to eat anything from midnight on the day of their Sampling Visit, although they may drink water. All costs for hotel accommodations, travel and meals are covered within specified guidelines which will be provided to you.

The information and samples collected from your relative or friend will be linked to a code-number, and stored in secure databases and repositories. They will be shared with companies and individuals, including researchers (some of whom work outside Europe) 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 12 of the PIS for details on protection of identifying information about your relative or friend.

You are free to choose whether or not your relative or friend would have any objection to taking part in HDClarity, and you can change your mind and withdraw them from this study at any time. Deciding not to take part or withdraw will not affect your relative or friend's care, or their participation in the Enroll-HD study. Before you decide whether they may participate, it is important that you read the complete PIS.

HDClarity 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 Consultees

I. PART 1

1. Study Title

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

2. Sponsor/Chief Investigator/Funding Organization

HDClarity Study, a research study, is sponsored by University College London, UK (Sponsor). The chief investigator for this study is Dr. 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.

For purposes of the General Data Protection Regulation (GDPR), both CHDI and the Sponsor are joint data controllers in respect of information that can identify your friend or relative. 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. In order to fulfill this legitimate interest, CHDI needs to process your relative's or friend's personal information. 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.

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]**.

3. Invitation Paragraph

Your relative or friend appears to be unable to decide for themselves whether to participate in this research. To help decide if they should join the study, you are being asked for your opinion as to whether or not they would want to be involved. They are already participating in Enroll-HD and have expressed an interest in participating in further HD research by consenting to contact regarding other studies. You are asked to consider what you know of their wishes and feelings,

and to consider their interests. Please also advise of any advance decisions they may have made about participating further in research. These should take precedence.

If you decide your relative or friend would have no objection to taking part, you will be asked to read and sign the consultee declaration on the last page of this information leaflet. You will be given a copy to keep. You will be kept fully informed during the study so you can advise whether you have any concerns or you think that your relative or friend should be withdrawn.

If you decide that they would not wish to take part, it will not affect the standard of care they receive in any way. If you are unsure about taking the role of consultee you may seek independent advice. It is understandable if you do not want to take on this responsibility.

The following information is the same as would have been provided to your relative or friend.

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

4. What is the Purpose of the Study?

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 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 your relative or friend during this study. And, because they must first be a participant in the Enroll-HD study to participate in this study, information collected about them through their 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 them 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.

Your relative or friend is 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) for the purposes described above and more fully described below. And, they are being asked to donate up to another 15 ml (the same volume as 3 teaspoons) of blood for routine safety tests.

Please read this information sheet and consultee declaration carefully. Ask the person who presents this information sheet and consultee declaration form to you any questions you have before deciding whether your relative or friend should participate in this study. You will be given a copy of this information sheet and consultee declaration.

5. Why Has My Relative or Friend Been Invited?

Your relative or friend is being invited to participate in this study because they have tested positive for the genetic mutation that causes HD.

6. Do They Have to Take Part?

Their participation in this study is completely optional. You are completely free to choose whether or not they would have any objection to taking part in this study. If you decide that they would have no objection to taking part, you can change your mind if you think they should be withdrawn from this study at any time for whatever reason. You are not required to give any reason for your decision on whether or they should participate in this study, or if you later decide they should be withdrawn 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 they would otherwise expect to receive. Nor will any such decision affect their participation in the Enroll-HD study.

If, at any time, your relative or friend indicates in any way that they do not wish to take part, they will be withdrawn from study immediately, and you will be informed.

What Will Happen to My Relative or Friend if They Take Part?

Your relative or friend is 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 for the purposes described above and more fully described below. And, they are being asked to donate up to another 15 ml (the same volume as 3 teaspoons) of blood for routine safety tests.

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 GDPR. 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 GDPR, CHDI and the Sponsor are required to provide you with information about how they process information that can identify your relative or friend. This information is outlined in detail in Section 4 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 your relative or friend includes information which directly identifies them (for example his or her name) as well as other information from which your relative or friend may be indirectly identifiable (for example their date of birth and place of birth, which when taken together may enable your relative or friend to be identified). Their name, address or any other information that could directly identify them will not be linked to the information and biological samples that are collected from them and sent outside of the study site. All information and biological samples collected from them and sent outside of the study site will be coded with a Huntington's disease identifier (HDID), the unique 9 digit number created for them as part of their participation in the Enroll-HD study. As you may know, the HDID is used to protect their identity and connect their clinical information and biological samples to other HD studies in which they may participate. Only the study site staff and the people/oversight entities identified in Section 12 below will be aware of their identity and be able to link the information and biological samples collected from them during this study. All information and biological samples collected from them during their 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 biomedical research.

Your relative or friend's General Practitioner (GP) will be notified that they are taking part in this study, unless you have advised that they would prefer that their GP is not made aware of their participation.

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

II. PART 2

1. Number of Participants

HDClarity aims to recruit a minimum of 1,200 participants, which includes HD participants at different stages of disease, and approximately 200 healthy controls. There will be multiple study centres including, but not limited to, locations in North America, South America, Australasia and Europe.

2. Procedures and Study Visits

This study consists of 2 study visits, the Screening Visit (Visit 1) and the Sampling Visit (Visit 2), not more than 30 days apart. All participants will also be contacted by telephone 1 to 3 days after the Sampling Visit to see how they are doing. Some participants may be asked to return for an additional optional study visit, the Optional Sampling Visit (Visit 3), within 8 weeks of the first Sampling Visit, in order to understand how the CSF changes over short periods of time. All participants who return for the Optional Sampling Visit will also be contacted by telephone 1 to 3 days after the Optional Sampling Visit to see how they are doing.

When your relative or friend has completed the Sampling Visit, and Optional Sampling Visit, if relevant, their participation in HDClarity will be considered completed. However, because we are also interested in understanding how the CSF changes over long periods of time, if you agree to be contacted, by initialing the relevant box below, your relative or friend may be invited to participate in this study again and repeat the sequence of study visits described above. If your relative or friend are to be invited to participate in this study again, there must be at least 11

months between Screening Visits and the study site staff will contact you approximately one month before this time to ask if you still think your relative or friend would want to return to participate in this study again. Please note you are under no obligation to agree to your relative or friend participating in this study again or taking part in further study visits.

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

Visit 1: Screening Visit (up to 30 days prior to Visit 2)

The study site investigator or designated study site staff will discuss the details of this study with you and your relative or friend. You and they will have the opportunity to ask any questions you may have about this study. If you decide that your relative or friend would have no objection to taking part, you will have to sign the consultee declaration to confirm and record this opinion.

In order to check to see if your relative or friend is eligible to participate in this study, the study site investigator will ask them and you questions regarding any concurrent diseases they may have and about any medications that they have been using within the last month. A brief physical exam and a neurological exam will be performed, they and you will be asked questions regarding their mental and emotional wellbeing and their symptoms of HD will be assessed.

Since your relative or friend is a participant in the Enroll-HD study, some of the above examinations and assessments may have been done as part of their most recent Enroll-HD study visit. If any of such examinations and assessments have been conducted within 2 months of their Screening Visit, they will not be repeated, and the information collected from them during their most recent Enroll-HD study visit will be used instead. Otherwise, in addition to the examinations described above, they will be asked to complete the clinical, behavioural and cognitive assessments that form the core of the Enroll-HD study as part of this study. You may be asked to help provide information for these assessments. Their height and weight will also be measured. These assessments will probably be familiar from previous Enroll-HD study visits and they will take between 45 and 90 minutes. Information about the genetic mutation that causes HD, if applicable, will be collected from the Enroll-HD study.

Approximately 15 ml of blood (about 3 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.

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

If the study site investigator finds them eligible for study participation, they will be scheduled for the Sampling Visit which will need to be done within 30 days of their Screening Visit.

If the study site investigator finds they are not eligible for study participation, but might become eligible within a reasonable period of time after their Screening Visit, they may be invited to return to repeat of some or all of the above examinations and assessments. If they are asked to return, you or they may decline to do so. If after repeating those examinations and assessments, the study site investigator finds they have become eligible for study participation, they will be

scheduled for the Sampling Visit, which will need to be done within 30 days of the date of the initial part of their Screening Visit.

Visit 2: Sampling Visit

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

Your relative or friend will be asked not to eat anything from midnight on the day of the Sampling Visit until after the CSF and blood sample collection is completed. They are permitted to drink water. They may also be asked to avoid certain medications prior to the appointment. If they have not followed the fasting or medication instructions, or if they are not feeling well, the Sampling Visit will need to be rescheduled.

The study site investigator will confirm with you that your relative or friend still has no objections to participate in this study. A neurological exam and a brief physical exam and a motor exam will be performed, and the results of the blood testing done at their Screening Visit will be reviewed. If the study site investigator confirms that they still meet all eligibility requirements for this study, the study site staff will prepare them for the CSF collection.

They will be asked to lie on their side with their knees pulled up and their chin tucked downward. A pillow will be placed between their knees. After cleaning the skin of their 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 very thin needle will be inserted into their 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, or for them to sit upright, 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 their arm. They 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 they are doing during the resting period. When they are ready to leave, they and you will be given instructions on follow-up care.

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

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

A member of the study site staff will call you and/or your friend or relative 1 to 3 days after the Sampling Visit to see how they are doing. You will be asked how they are feeling and if they have experienced any medical conditions or symptoms since their Sampling Visit.

Visit 3: Optional Sampling Visit

Should your relative or friend be asked to participate in the Optional Sampling Visit, you or they may decline to do so. If you think they would have no objections to participating further, they will be asked to undergo a second CSF and blood sample collection as described above under Visit 2: Sampling Visit.

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

A member of the study site staff will call you and/or your friend or relative 1 to 3 days after the Optional Sampling Visit, to see how they are doing. You will be asked how they are feeling and if they have experienced any medical conditions or symptoms since your Optional Sampling Visit.

3. What Must I Keep in Mind During My Relative or Friend's Participation in This Study?

During the time of this study, your relative or friend is being asked, with your help, to:

- Follow all instructions, including those regarding restricted medications that were given to them at the Screening Visit.
- Not eat anything on the day of the Sampling Visit or Optional Sampling Visit from midnight until the CSF and blood collection have been completed.
- Inform the study site staff of any illnesses they have had or medications they have been taking since the Screening Visit.
- Follow all instructions regarding follow-up care after the Sampling Visit or Optional Sampling Visit.

4. Procedures for Storing and Sharing Coded Information and Biological Materials for Research Purposes

The information collected about your relative or friend during this study will be entered via secure internet connections into a confidential database that is created, maintained and protected by an IT company, 2MT Software, 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 their information is safe and secure. The biological samples collected from them 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 information collected from them and entered in the database as well as the biological samples collected from them and stored in the biological sample repository will not be associated with, or identified by, their name or other information that could directly identify them. Only the study site staff and the people/oversight entities identified in Section 12 below will be aware of their identity and only the study site staff and the people/oversight entities identified in Section 12 below have the key to the code that links their information and biological samples to them. Such coded information and coded samples will be retained, shared and used as provided in this consent form.

CHDI may **use,** and make available for **use** by its service providers and other organizations/researchers and their service providers, the **coded** information and/or **coded** biological samples collected from them during this study, 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 them 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 study with the following other third parties:

- Representatives of organizations providing services in connection with this study, such as 2MT Software, the organization contracted to collect, maintain, and manage the information collected in this study and BioRep SRL, the organization contracted to store the samples collected in this study (or such other services providers as may be designated from time to time).
- Researchers at other study sites that are taking part in this study, the ethical review boards at those study sites, and other independent review boards overseeing the ethical conduct of this study.
- Representatives of national and foreign governmental and regulatory agencies and health authorities such as the United States Food and Drug Administration (FDA), Health Canada 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, information that can identify your relative or friend for the purposes outlined above because such storage, processing, transfer, disclosure and use of your information is necessary for reasons of public interest in the area of scientific research.

The Sponsor, CHDI and each of the organizations, 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, their name, address or any other information that could directly identify them will not be published.

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

The information and biological samples collected from your relative or friend 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 them during this study. Just contact the study site investigator and let him or her know that you no longer want the biological samples collected from them during this study stored and such biological samples will be removed from the storage facility and destroyed. If any of the biological samples collected from them during this study have already been distributed for use, it may not be possible to locate and destroy them.

Any of the uses and activities described above may involve sending, storing and processing coded information and coded biological samples outside of the European Economic Area (EEA) to 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 information. If coded information and/or coded biological samples are sent outside the EEA, steps will be taken to ensure that your relative's or friend's information remains protected in a manner that is consistent with how such information will be protected in the EEA. These steps include only transferring their information to third parties approved by the European Commission or third parties located in countries approved by the European Commission or requiring the third party to agree in writing to certain standard data protection clauses. In addition, the GDPR may, under other circumstances, allow the transfer of information outside the EEA (for example, for reasons related to national security or law enforcement). Given that only coded information or coded biological samples are sent, the risk of unintended disclosure of identifying information is low. You can obtain more details about the steps taken to protect information when it is transferred outside the EEA (including obtaining a copy of the standard data protection clauses referred to above) by following the instructions set out in Section 15 below.

The information and biological samples collected from your relative or friend will be stored for 50 years after the end of this study or longer if no effective treatment has been developed for HD at the expiry of that time period.

If you or they choose to stop their participation in this study, no new information about them will be collected or added to the study database; however, information that was previously collected will not be removed and will continue to be stored, used and disclosed in the manner described in this consent form.

The rights to access, change or move information held about your friend or relative are limited, as the information needs to be managed in specific ways in order for the scientific research to be reliable and accurate. To safeguard these rights, the minimum information possible will be used.

These rights can be exercised by following the instructions set out in Section 15 below.

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

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

5. What are the Possible Disadvantages, Discomforts and Risks in Taking the Part?

Some of the possible discomforts of CSF collection include:

- The anaesthetic will sting when first injected.
- Your relative or friend 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.
- They may experience some back pain following the CSF collection.
- They 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 relative or friend's 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 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.

If they are required to complete the clinical, behavioural and cognitive assessments that form the core of the Enroll-HD study as part of this study, they may experience anxiety or psychological discomfort (such as stress or fatigue) while completing these assessments. If at any time you or they feel they could benefit from treatment or support, you or they may

request to be referred for appropriate care. In the course of doing questionnaires or tests they may feel tired and/or irritable. If this happens please tell their study site investigator or the study site staff and ask them to allow them time to rest or stop the testing all together.

6. What are the Possible Benefits in Taking Part?

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

7. What are the Alternatives to Taking Part?

Your relative or friend does not have to participate in this study. Choosing not to participate will not affect their current or future medical care at [_____] **[INSERT NAME OF INSTITUTION]**.

8. Travel Expenses/Payments

Your relative or friend 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 and they incur for travel, hotel and meals resulting from their 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, they will receive compensation in the amount of GBP 200 after the Sampling Visit and after the Optional Sampling Visit for the invested time and discomforts arising within the scope of this study. You will be asked to ensure that this compensation is used in accordance with their wishes.

9. Insurance and Compensation For Injury

The Sponsor holds insurance in case your relative or friend are harmed by your participation in this study. They 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 your relative or friend 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 your relative or friend may experience as a direct result of their participation in this study. They will not have to pay for this emergency care, but the [_____] **[INSERT NAME OF INSTITUTION]** may seek reimbursement for this care from their private health insurance carrier or government health service.

10. Who is Funding This Study?

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.

11. Commercial Uses

Successful research using your relative's or friend's 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. Neither you or your relative or friend will not receive any financial benefit from such a result.

12. Confidentiality

To meet regulations or for reasons related to this study, your relative or friend's study site investigator may share a copy of this consent form and records that identify them 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 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 relative or friend's rights as a participant are protected) that reviewed this study.
- Representatives of organizations providing services in connection with this study, such as 2MT Software, the organization contracted to collect, maintain, and manage the information collected in this study and BioRep SRL, the organization contracted to store the samples collected in this study (or such other services providers as may be designated from time to time).
- CHDI
- Other agents designated by the Sponsor or CHDI

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 your relative or friend 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.

13. Optional Participation

Your relative or friend's participation in this study is completely optional. You are completely free to choose whether or not they would have any objection to participating in this study. If you decide that they would have no objection to taking part, you can change your mind if you think they should be withdrawn from this study at any time for whatever reason. You are not required to give any reason for your decision on whether or they should participate in this study, or if you later decide they should be withdrawn 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 they would otherwise expect to receive. Nor will any such decision affect their participation in the Enroll-HD study.

If, at any time, your relative or friend indicates in any way that they do not wish to take part, they will be withdrawn from study immediately, and you will be informed.

In the event that your relative or friend is withdrawn from this study, the samples collected from them during this study will continue to be stored, used, and shared in the manner described in this consent form, unless you request that the samples be removed from the storage facility and destroyed. If any of the biological samples collected from them during this study have already been distributed for use, it may not be possible to locate and destroy them. In the event that your relative or friend is withdrawn from this study, no new information about them 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 consent form. Your rights to access, change or move information held about your relative or friend are limited, as the information needs to be managed in specific ways in order for the scientific research to be reliable and accurate. To safeguard your relative or friend's rights, the minimum information possible will be used.

14. Early Discontinuation of This Study

Your relative or friend may be withdrawn from this study if they do not follow the directions of this study or if their medical condition changes so that staying in this study might risk their health or this study. Their participation in this study may also end if funding for this study is discontinued or the Chief Investigator elects to discontinue the study.

15. What if There is a Problem or You Would Like More Information?

If you wish to complain about the treatment of your relative or friend by study site staff due to their 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 they are harmed by taking part in this study, or if you have concern 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 your relative or friend has 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 their rights as a participant, you may call [_____]. **[INSERT NAME AND PHONE NUMBER OF CONTACT PERSON FOR PARTICIPANT'S RIGHTS]**

If (1) you would like further information on the collection, storage, processing, transfer, disclosure and use of your information, 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.

16. Who Has Reviewed This Study?

This study was designed jointly by the Chief Investigator (Dr 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 NHS Health Research Authority Wales Research Ethics Committee 1.

(Form to be on local headed paper)

HDClarity Consultee Declaration Form

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 been consulted about [name of participant]'s participation in this study and have read (or have had read to me) the contents of this participant information sheet and declaration form and have been encouraged to ask questions.	☐
I have received answers to my questions.	☐
In my opinion they would have no objection to taking part in the above study consisting of a Screening Visit and Sampling Visit, with the possibility of an Optional Sampling Visit within 8 weeks.	☐
I give permission to be contacted regarding my relative or friend participating in this study again and repeating the sequence of study visits described above.	☐
I agree to the uses and disclosures of the participant's identifying information as described above.	☐
I give permission for their coded information and coded samples to be stored and shared for research purposes as described above.	☐
I understand that coded information and records that identify the participant may be looked at by the study site staff, individuals from regulatory authorities, appointed service providers, the NHS Trust and others as described above, where it is relevant to their taking part in this study. I give permission for these organizations to have access to such information and records.	☐
I agree to their General Practitioner being informed of their participation in this study.	☐
I understand that I will be given a signed copy of this form for my records and future reference.	☐

Name of Consultee	Printed Name	Date

Relationship to participant

For Study Site Staff:

Person Undertaking Consultation

I confirm that the participant lacks capacity to give or withhold consent to this study because of an impairment of the mind or brain associated with Huntington's disease. The participant is unable to (please tick all that apply):

Understand information about the procedures involved in the study	☐
Retain that information in their mind	☐
Use or weigh that information as part of the decision-making process, or	☐
Communicate their decision (by talking, using sign language or any other means).	☐

I have read this form to the consultee and/or the consultee has read this form. An explanation of this study was given and questions from the consultee were solicited and answered to the consultee's satisfaction. In my judgment, the consultee has demonstrated comprehension of the information.

Signature of Person Obtaining Consent	Printed Name and Title	Date

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

If this consent form is read to the consultee because the consultee is unable to read the form, an impartial witness not affiliated with the research or investigator must be present for the consent and sign the following statement:

I confirm that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the consultee. The consultee freely gave their opinion that the participant would have no objection to taking part in the above study.

_____ _____

Signature of Impartial Witness Date

Note: This signature block cannot be used for translations into another language. A translated consent form is necessary for enrolling participants who do not speak English.