

**CLINICAL SITE ASSESSMENT**

# Contact Information

Please add contact information for all relevant personnel at the site. If anyone serves more than one role, or if multiple people use the same address, information does not need to be repeated.

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| --- | --- |
| Site details | |
| Site Name: |  |
| Enroll-HD Site ID: |  |
| Address: |  |
| City: |  |
| State/Province: |  |
| Zip/Postal Code: |  |
| Country: |  |

|  |  |
| --- | --- |
| PrincipAL investigator contact details | |
| Name: |  |
| Position: |  |
| Email: |  |
| Telephone: |  |
| Address (if different from above): |  |

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| Is this person also the Enroll-HD PI at the site? | Yes |  | No |  |
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| Study coordinator contact details | |
| Name: |  |
| Position: |  |
| Email: |  |
| Telephone: |  |
| Address (if different from above): |  |

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| Is this person also the Enroll-HD study coordinator at the site? | Yes |  | No |  |

Please provide the following information for site personnel who will be working on HDClarity

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| Research staff |

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| Name | Position AT SITE | Role in the study  **(Use Legend #)** |
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| Legend (role in study)   1. Recruitment 2. Informed consent 3. Urine pregnancy testing 4. Lumbar puncture 5. CSF processing | 1. Blood draw 2. Serum/plasma processing 3. UHDRS motor and functional scales 4. PBA-s 5. Adverse event responsibilities | 1. Other (PI) 2. Other (Study Coordination) 3. Other (\_\_\_\_\_\_) 4. Other (\_\_\_\_\_\_) |  |
| (b) Refers to a role that the staff member is trained in but only performs as backup | |  |  |

# Approvals

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| 2.1 Ethical approval | | | | |
| Please indicate whether you will use a local or central ethics committee (e.g. NHS REC, WIRB) for approval of HDClarity: |  | | | |
| Name of ethics committee: |  | | | |
| Frequency of meetings: |  | | | |
| Is a contract required before ethical approval can be sought: | Yes |  | No |  |
| Details of any additional review required, e.g. public/patient: | Yes |  | No |  |
| If yes, provide details including the frequency of these other meetings, if applicable: |  | | | |
| On average for your institution how long does it take from receipt of a final clinical study protocol to both a fully executed contract and EC/IRB/ERB review and approval: |  | | | |
| Estimated earliest start date: |  | | | |

# Recruitment

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| --- | --- | --- | --- | --- |
| 3.1 Estimated recruitment | | | | |
| Total number of Enroll-HD participants: |  | | | |
| Number of Enroll-HD participants active in past 12 months: |  | | | |
| Total estimated recruitment for HDClarity: |  | | | |
| Total number estimated in each group: |  | | | |
| * Control |  | | | |
| * Early premanifest |  | | | |
| * Late premanifest |  | | | |
| * Early HD |  | | | |
| * Moderate HD |  | | | |
| * Advanced HD |  | | | |
| * Juvenile manifest HD |  | | | |
| * Incomplete penetrance (CAG 36-39) |  | | | |
| In addition to Enroll-HD, how else will participants be recruited: |  | | | |
| Is the site currently participating in any clinical trials in HD? | Yes |  | No |  |
| If Yes, insert name of trial and target number of participants: |  | | | |
| If planning to recruit advanced HD patients, please give details of how the site will handle   * ethical approval * consent / assent * practical aspects (where will the procedures be done and how will samples be processed) |  | | | |
| If planning to recruit juvenile HD patients, please give details of how the site will handle   * ethical approval * consent / assent * practical aspects (where will the procedures be done and how will samples be processed) |  | | | |

# Study Procedures

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| 4.1 PREGNANCY TESTING | |
| Does the site have access to urine pregnancy tests? | Yes  No |
| Will the site be able to perform urine pregnancy tests as required by the protocol? | Yes  No |

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| 4.2 Lumbar puncture | | | | |
| Approximately how many LPs have been performed by each HDClarity staff member proposed to undertake the procedure? |  | | | |
| Do the LP administrators have experience collecting CSF using the following: | Delete as necessary | | | |
| 22G atraumatic needle | Yes / No | | | |
| 24G atraumatic needle | Yes / No | | | |
| Introducer | Yes / No | | | |
| Gentle suction | Yes / No | | | |
| Does the site usually use lidocaine for LP: | Yes / No | | | |
| If No, would the site be willing to learn and apply this technique? | Yes / No | | | |
| Describe the facility where LP will take place: |  | | | |
| How frequently would this facility be available for HDClarity LPs: |  | | | |
| What time of the day will be preferable for the LP be performed? (after a fast of at least 6 hours) | Morning  Afternoon | | | |
| Describe the resources available for investigating and managing complications of LP: |  | | | |
| Does the site have access to the resources necessary for administering a blood patch: | Yes  No | | | |
| 4.3 sample processing and storage | | | | |
| Is the sample processing lab that will be used for CSF processing located in the same building as the clinical room? | Yes | | No | |
| Please provide the name of the lab and details of the lab certification, e.g. UKAS, CPA, ISO 15189 or equivalent: |  | | | |
| If you will be using an external lab then can you please provide details of that lab: |  | | | |
| Will your centrifuge accommodate the 50ml polypropylene CSF collection tube?  12cm length  3cm Diameter  9.5cm Circumference  cid:image002.png@01D278AD.21A87850 | Yes | No |  |  |
| Will blood samples be processed at same or different location as CSF? | Same |  | Different |  |
| If different, provide details: |  | | | |
| What is the estimated time and method for transferring the CSF and blood samples to your lab? |  | | | |
| Can CSF processing begin within 15 minutes of sample collection? | Yes | | No | |
| Can blood processing start within 15 minutes of blood draw? | Yes | | No | |
| If using a different lab for CSF cell counts, what is the estimated time and method for transferring CSF for cell counts? |  | |  | |
| Is microscopic cell count manual or automatic: | Manual |  | Auto |  |
| If automatic, is a manual count routinely carried out to check high counts: | Yes | | No | |
| Has your lab confirmed that they can perform the triplicate cell count in 200 µl CSF as per the protocol p25-27 (please note differential cell counts are not required)? |  | |  | |
| What is the experience of the personnel undertaking the CSF microscopic cell count e.g. how often do they perform this type of analysis? |  | | | |
| **STORAGE** | | | | |
| Can samples be stored for at least 3 months at -80C: | Yes | | No | |
| Which alarm system does your -80 freezer have? |  | | | |
| How will staff be notified (specifically overnight and weekends), when the freezer temperature has deviated? |  | | | |
| What is the standard operating procedure if there is a power failure? |  | | | |
| Does the freezer have a backup generator in case of power failure, and how long will the generator last? |  | | | |

# Equipment

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| 5.1 equipment available at the site | |
| Refrigerated centrifuge (4 oC) | Yes  No |
| A 2nd centrifuge to spin the serum samples at room temperature | Yes  No |
| Freezer storage (-80  oC) | Yes  No |
| Vortex | Yes  No |