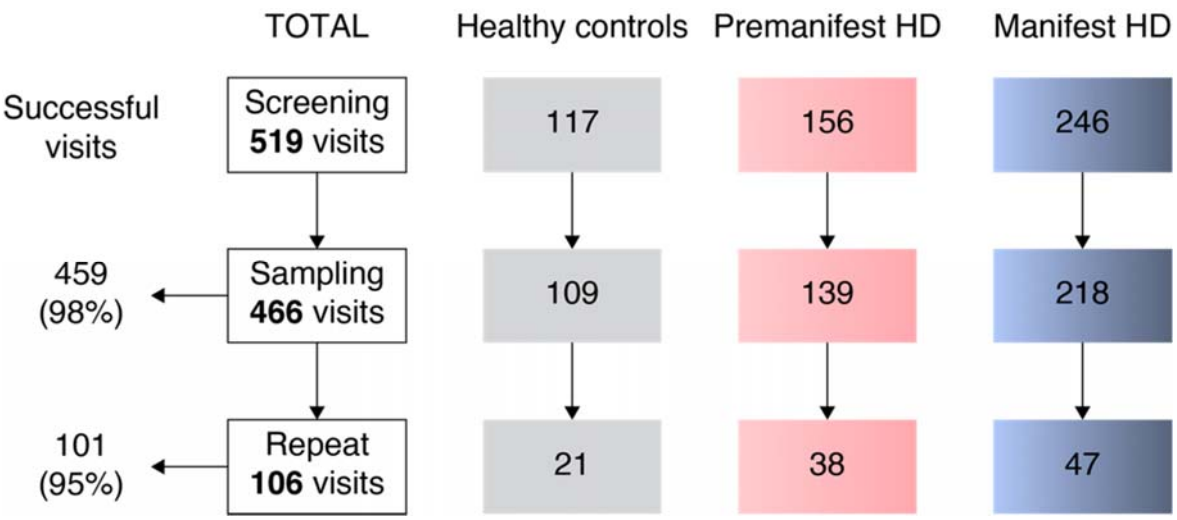
Supplementary Material

Safety and Feasibility of Research Lumbar Puncture in Huntington's Disease: The HDClarity Cohort and Bioresource



Supplementary Figure 1. Visit disposition from screening to sampling and short-term repeat sampling visit, by disease group. Successful visits were defined as when dura was pierced and CSF was collected, irrespective of amount of CSF. HD, Huntington's disease.

Supplementary Table 1. Participant cohorts

Cohort		CAG	DBS	UHDRS DCS	UHDRS TFC
Healthy controls		<36 (or no known family history)	-	-	-
Gene expansion carriers	Early premanifest	≥ 40	< 250	< 4	-
	Late premanifest	≥ 40	≥ 250	< 4	-
	Early manifest	≥ 36*	-	4	7-13
	Moderate manifest	≥ 36*	-	4	4-6
	Late manifest	≥ 36*	-	4	0-2

*The current protocol (version 3 from 19 December 2018) requires manifest gene expansion carriers to have a CAG repeat count of 40 or more, but previous versions allowed participants with ≥ 36 repeats (version 1 from 6 October 2015, and 2 from 21 June 2016). CAG, CAG repeat count; DBS, Disease Burden Score ((CAG – 35.5) × age); DCS, Diagnostic Confidence Score; TFC, Total Functional Capacity; UHDRS, Unified Huntington's Disease Rating Scale.

Supplementary Table 2. Comparison of participants characteristics at successful (i.e., when dura was pierced and CSF was collected, irrespective of amount of CSF) and unsuccessful visits (i.e., where an LP was attempted, but no CSF was collected).

	Successful visit	**Unsuccessful visit**	**p**
N	560 (97.90%)	12 (2.10%)	n/a
Age	48.35 ± 12.63	52.42 ± 9.97	0.272
Female	272 (48.57%)	7 (58.33%)	0.506
Caucasian	549 (98.04%)	12 (100.00%)	0.624
Right-handed	488 (87.14%)	10 (83.33%)	0.404
BMI (kg/m^2)	26.09 ± 5.00	29.94 ± 5.80	0.064
Study Cohort	**HC:** 129 (23.04%) **PM:** 259 (46.25%) **M**: 172 (30.71%)	**HC:** 1 (8.33%) **PM:** 5 (50.00%) **M**: 6 (41.67%)	0.487
UHDRS TMS	17.19 ± 22.30	24.67 ± 29.57	0.260
UHDRS TFC	11.33 ± 2.88	10.92 ± 3.45	0.624
UHDRS IS	90.83 ± 15.43	87.50 ± 20.17	0.465
UHDRS FA	22.55 ± 4.94	21.33 ± 6.85	0.406
SWR	81.88 ± 28.60	67.75 ± 25.36	0.095
SCN	64.32 ± 22.40	49.33 ± 15.50	0.108
SDMT	42.94 ± 17.93	32.75 ± 14.38	0.175
VFC	19.12 ± 7.36	16.25 ± 5.63	0.183

Continuous variables are reported as mean ± standard deviations. Categorical variables are reported as absolute and relative frequencies. BMI, body mass index; HC, healthy controls; PM, premanifest HD; M, manifest HD; UHDRS, Unified Huntington's Disease Rating Scale; TMS, UHDRS Total Motor Score; TFC, UHDRS Total Functional Capacity; IS, UHDRS Independence Score; FA, UHDRS Functional Assessment; SWR, Stroop Word Reading test; SCN, Stroop Color Naming test; SDMT, Symbol Digits Modality Test; VFC, Verbal Fluency Categorical; n/a, not applicable.

Supplementary Table 3. Comparison of participants characteristics at visits with and without adverse events, headaches, and post-lumbar puncture headache

	Adverse events			Headaches			Post-lumbar puncture headache		
	No	**Yes**	**p**	**No**	**Yes**	**p**	**No**	**Yes**	**p**
N	434 (75.87%)	138 (24.13%)	n/a	487 (85.14%)	85 (14.86%)	n/a	502 (87.76%)	70 (12.24%)	n/a
Age	49.84 ± 12.42	44.01 ± 12.09	>0.001	48.96 ± 12.60	45.43 ± 12.16	0.024	49.00 ± 12.53	44.42 ± 12.34	0.008
Female	200 (46.08 %)	79 (57.25%)	0.048	229 (47.02%)	50 (58.82%)	0.057	239 (47.61%)	40 (57.14%)	0.155
Caucasian	427 (98.39%)	134 (97.10%)	0.402	479 (98.36%)	82 (96.47423%)	0.313	492 (98.01%)	69 (98.57%)	0.793
Right-handed	375 (86.41%)	123 (89.13%)	0.297	423 (86.86%)	75 (88.24%)	0.428	435 (86.65%)	63 (90.00%)	0.267
BMI (kg/m^2)	26.36 ± 5.22	25.57 ± 4.41	0.113	26.28 ± 5.13	25.55 ± 4.46	0.233	26.27 ± 5.12	25.42 ± 4.36	0.213
Study Cohort	**HC:** 96 (22.12%) **PM:** 122 (28.11%) **M**: 216 (49.77%)	**HC:** 34 (24.64%) **PM:** 55 (39.86%) **M**: 49 (35.51%)	0.023	**HC:** 104 (21.36%) **PM:** 145 (29.77%) **M**: 238 (48.87%)	**HC:** 26 (30.59%) **PM:** 32 (37.65%) **M**: 27 (31.76%)	0.023	**HC:** 108 (21.51%) **PM:** 151 (30.08%) **M**: 243 (48.41%)	**HC:** 22 (31.43%) **PM:** 26 (37.14%) **M**: 22 (31.43%)	0.041
UHDRS TMS	19.68 ± 24.08	10.04 ± 14.19	>0.001	18.83 ± 23.52	8.88 ± 12.15	0.001	18.61 ± 23.31	8.34 ± 11.79	0.001
UHDRS TFC	11.08 ± 3.10	12.08 ± 1.91	0.002	11.17 ± 3.03	12.19 ± 1.60	0.006	11.20 ± 3.00	12.21 ± 1.61	0.011
UHDRS IS	89.48 ± 16.59	94.78 ± 10.65	0.002	89.89 ± 16.36	95.76 ± 7.73	0.003	90.10 ± 16.22	95.50 ± 7.72	0.012
UHDRS FA	22.10 ± 5.41	23.88 ± 2.92	0.002	22.25 ± 5.29	24.14 ± 1.85	0.004	22.30 ± 5.24	24.19 ± 1.76	0.010
SWR	79.35 ± 29.41	88.52 ± 24.71	0.004	79.99 ± 28.98	90.61 ± 24.50	0.004	80.08 ± 29.00	92.26 ± 22.97	0.003
SCN	62.39 ± 22.96	69.01 ± 19.70	0.007	62.84 ± 22.66	70.59 ± 19.55	0.006	62.88 ± 22.72	71.96 ± 17.94	0.004
SDMT	40.89 ± 18.03	48.35 ± 16.39	>0.001	41.57 ± 17.90	49.16 ± 16.66	0.001	41.68 ± 17.95	50.03 ± 16.00	0.001
VFC	18.44 ± 7.52	21.00 ± 6.39	0.002	18.75 ± 7.51	20.82 ± 6.02	0.025	18.78 ± 7.49	21.06 ± 5.84	0.025

Continuous variables are reported as mean ± standard deviations. Categorical variables are reported as absolute and relative frequencies. BMI, body mass index; HC, healthy controls; PM, premanifest HD; M, manifest HD; UHDRS, Unified Huntington's Disease Rating Scale; TMS, UHDRS Total Motor Score; TFC, UHDRS Total Functional Capacity; IS, UHDRS Independence Score; FA, UHDRS Functional Assessment; SWR, Stroop Word Reading test; SCN, Stroop Color Naming test; SDMT, Symbol Digits Modality Test; VFC, Verbal Fluency Categorical; n/a, not applicable.

Supplementary Table 4. Overall frequency of adverse events. Categorical variables are reported as absolute and relative frequencies. The unit of analysis is the adverse event.

Absolute and relative frequencies (n=189)		
Headache	90	47.62%
Back pain	54	28.57%
Vasovagal reactions	10	05.29%
Nausea & vomiting	7	03.70%
Bruising	7	03.70%
Paraesthesia	2	01.06%
Other	19	10.05%

Supplementary Material 1. Biosample collection and processing procedures

CSF collection

LUMBAR PUNCTURE

1. Identify L4/5 or L3/4 space using surface markings (i.e., the intercristal line)
2. Place subject into lateral decubitus position with pillow between knees
3. Disinfect skin using antiseptic applicator.
4. It is highly recommended to use adequate lidocaine to reduce the discomfort of this LP procedure. If, after noting allergies or sensitivities to lidocaine and discussing the risks and benefits of local anesthesia, it is decided to forgo this step, it should be noted in the case report form. Inject up to 5ml of 2% lidocaine for local anesthesia. Use the 25G 1" needle and inject lidocaine to raise a skin wheal. Then inject lidocaine more deeply using the 21G needle.
5. Obtain CSF using the supplied spinal needle. If the participant is thin, do not insert the deep infiltration needle all the way. Use only about 2/3 of its length (to prevent entering the subarachnoid space with anything other than the pencil-point spinal needle).
6. If CSF cannot be obtained, up to three needles may be used. An alternative design of spinal needle supplied by the site may be used if, after at least one attempt with the supplied needle, it is felt this will increase the chance of success.
7. If the CSF collection fails, then there is no need to collect blood samples from the participant at this visit
8. An adjacent space may be used (with further lidocaine, max. total 10 ml, if needed).
9. If necessary, the CSF space may be located by sitting participant up, but once CSF is seen, it is recommended to have participant lie back in lateral decubitus position for 30 seconds before collection begins. Document positions of participant during puncture and collection in the eCRF
10. Document the space used for lumbar puncture, the number of needle passes (i.e. the number of times a needle is inserted and removed from the skin), the number of attempts (i.e. the number of times the lumbar space, the participant position, or the investigator conducting the LP change), the volume of lidocaine used, and the time CSF collection started and ended in the eCRF
11. Omit pressure measurement for all subjects (this is because polypropylene manometers are not available)
12. CSF is collected without suction in 50ml tubes placed on wet ice in the Styrofoam cup
13. Collect the first 1 ml of CSF into the supplied tube labelled ‘CSF’. If the first 1 ml (approx. 15 drops) is not macroscopically bloody, continue sampling CSF in the same tube up to 15-20 ml, as allowed locally, keeping the tube in the wet ice cup.

    If the first 1 ml is macroscopically bloody,

    - Stop collecting CSF by reinserting the stylet partially

- Discard the tube, and collect a second 1 ml in a new pre-cooled ‘CSF’ tube, and examine it visually for blood contamination
- If it is free of blood, continue collecting CSF up to 14-19 ml (1ml less than the locally permitted maximum).
- If the second separately collected ml of CSF is also macroscopically bloody, discard the tube, and continue to collect 13-18 ml of CSF in a third pre-cooled ‘CSF’ tube.
- If the third tube is macroscopically bloody, stop collecting and abandon the procedure or attempt the LP in a different space, if there is reason to believe blood-free CSF can be obtained. You may need to open a new collection kit to provide sufficient tubes; if this creates any discrepancies in the kit ID numbers, it must be noted carefully and explained in the eCRF.
- Stop collecting CSF when sampling time exceeds 20 minutes. Document these details in the eCRF.

14. Place cap on tube and leave on wet ice until further processing.
15. Reinsert the stylet before withdrawing the needle.
16. Cover the puncture site with sterile dressing.
17. Record time of CSF collection (time when CSF was first seen).
18. At the discretion of the Site Principal Investigator, participants may be instructed to lie flat for 1 hour.

Transport CSF immediately to laboratory for processing, do not wait for the blood samples to be ready as this can cause delays

Blood collection

! Please make sure that all caps are tightly secured.

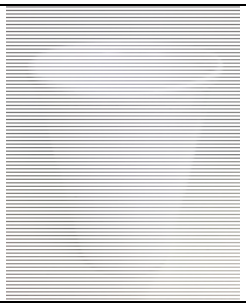
! Check the expiration date on the tube- do not use expired tubes!

! Do not collect blood samples if CSF collection was not successful!

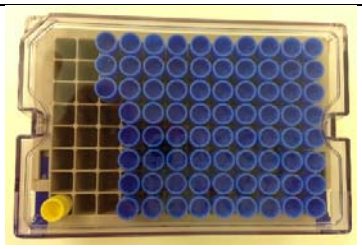
Specimens are best collected through venipuncture using a butterfly needle vacuumed directly into the required tube.	
1. Fill 4 x 10 ml blood in lithium heparin tubes	
2. Gently invert each lithium heparin tube 10 times immediately after collection, and place on wet ice	

3. Fill 1 8.5 ml serum tube	
4. Immediately after collection transfer all blood samples to the lab for processing	

CSF processing

Sample Collection	1. Lab to receive one 50ml CSF collection tube filled up to 20mls with CSF (collected from participant between 08:00 - 10:30 local time) 4 tubes are provided in case of blood contamination. All clean CSF sent to the lab should be in a single tube.	
	2. CSF sample is collected while the collection tube is in the Styrofoam cup filled with wet ice. Sample is transported to the lab in wet ice (container to be supplied by site).	
	3. Samples transported immediately to laboratory for processing.	 **Processing must start within 15 minutes of sample collection**
	4. After CSF collection, details including the Kit ID are recorded in the **CSF** eCRF, 'CSF collection' box.	
Sample Processing	5. Note the CSF processing start time	
	6. Agitate the entire CSF sample for 10 seconds using a vortex mixer to homogenize CSF	
	7. Using a sterile individually wrapped polypropylene 1 ml pipette tip, extract 200 µl of the CSF and use it to determine white blood cell count and erythrocyte count per µl in triplicate according to local GLP- approved laboratory practice	

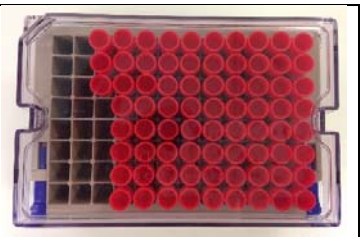
	as instructed at the Site initiation visit and in the Manual CSF Cell Count SOP Cell counts should be recorded on the 'CSF Quality' eCRF in the 'Onsite CSF Sample Quality Control' box.	  **Triplicate cell count should be done within 60 minutes of sample collection.**
	8. Balance the centrifuge and before filling the balance tube with water please clearly mark the tube so that it can easily be identified as water (not CSF). 9. Centrifuge the 50 ml tube containing residual CSF at **400 × g for 10 min at 4°C** to remove cells while preserving cell integrity for potential future use. Cell integrity in needed so that intracellular substances do not contaminate the non-cellular phase of the CSF	**Label your balance tube!**
	10. Using the polypropylene Pasteur pipette, transfer the supernatant into a single 30 ml polypropylene tube labelled "CSF supernatant" and agitate for 10 seconds to homogenize CSF **If the polypropylene Pasteur pipettes are damaged, then it is acceptable to decant the supernatant into the tube. No pipettes should be used other than those supplied.**	 
	11. Aliquot the CSF in 300 µl aliquots into the cryovials labelled "CSF", using a sterile individually wrapped polypropylene 1ml pipette tip	

	Note the tube rack ID, tube ID (this must be the same for all aliquots) and the number of aliquots for later recording on the eCRF. Please dispose of any unused aliquots CSF aliquots must have blue lids. Any samples that do not have the expected lid color will be discarded by BioRep.	
	12. Re-suspend the CSF cell pellet in 300 µl of supplied RNA*later* solution, using gentle vortex agitation, and use another sterile pipette tip to transfer to a cryovial with yellow lid labelled "Cells from CSF" **Dispose of empty vials – Do not ship or re-use them**	 
Sample Storage and Shipment	13. Immediately after processing freeze CSF aliquots and the resuspended cells in your -80°C freezer. Ensure samples are stored upright and all lids are secure Plasma, Serum and CSF do not need to be stored in the freezer at the same time – if waiting for the blood to be ready will cause a delay, then store the CSF in the freezer first, rather than waiting. If there will be any delay in getting the samples into the freezer then they can be kept in dry ice for a short period of up to 5 minutes. Please document this on the worksheet or source notes to explain how the samples were stored if not transferred immediately to the freezer.	FREEZE AT -80°C AND SHIP AFTER A MINIMUM OF 3 MONTHS, AND WHEN YOU HAVE AT LEAST 5 SAMPLES
	Details of CSF processing are recorded on the **CSF** eCRF, 'CSF processing' box. Record the following parameters; Start time of CSF processing End time of CSF processing	

	CSF tube rack ID CSF aliquot tube ID and number of cryovials Cells from CSF tube ID Date and time the samples are stored Any discrepancies in ID must be explained bearing in mind the ID is the only way to reconcile samples with participants	 

Blood processing

Sample Collection	1. Gently invert each tube 10 times immediately after collection, and place on wet ice	
	2. Samples transported immediately to laboratory for processing.	 Processing must start within 15 minutes of sample collection
	3. Lab to receive 4 x 10 ml blood in lithium heparin tubes	
Sample Processing	4. Note the following for later entry into the eCRF, or enter directly: Lithium heparin tube IDs Plasma aliquot tube ID Start time of plasma processing	 
	5. Spin lithium heparin tubes at **1300×g for 10 min at 4°C** immediately on arrival	
	6. Discard any tubes whose plasma is pink due to hemolysis. In the unlikely event that they are all pink then use all of the tubes but clearly label the sample as contaminated.	
	7. Combine the supernatant in one tube labelled "plasma" and mix by inverting 10 times. Place on wet ice.	
	8. Aliquot the plasma into 300 µl cryovials labelled 'plasma' using a sterile individually wrapped polypropylene 1 ml pipette tip	Dispose of empty vials – do not ship!

	9. Plasma aliquots must have red lids. Any samples that do not have the expected color lid will be discarded by BioRep. **Dispose of empty vials – Do not ship or re-use them**	
Sample Storage and Shipment	10. Freeze samples on dry ice and store at -80°C Ensure samples are stored upright and all lids are secure	FREEZE AT -80°C AND SHIP AFTER A MINIMUM OF 3 MONTHS, AND WHEN YOU HAVE AT LEAST 5 SAMPLES
	11. Record the following on the Blood Processing' tab in the eCRF; LiHep tube ID Processing start time Plasma aliquot tubes ID Plasma aliquot tube count Time plasma processing is completed Time of frozen storage (if serum and plasma times of freezing are different then it is the time of freezing the **plasma** which is most important to record in the EDC)	

Supplementary Material 2. HDClarity Investigators

Central Coordination
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