Participant Information Sheet

Sponsor Protocol Number: 148491
IRAS ID number: 1006207

Study Title: Hereditary Sensory Neuropathy Serine trial (SENSE trial)

University College London (the Sponsor of the study) would like to invite you to take part in a research study. Before you decide we would like you to understand why the study is being done and what it would involve for you. One of our team will go through the information sheet with you and answer any questions you have. Talk to others about the study if you wish.

Part 1 - *What is involved in the Research Study?*
Tells you the purpose of this study and what will happen to you if you take part.

Part 2 – *Supporting Information*
Gives you more detailed information about the conduct of the study.

Ask us if there is anything that is not clear. Take time to decide whether you wish to take part. We appreciate it may not answer all your questions, so please do not hesitate to contact a member of the study team on the telephone numbers given at the end of this Information Sheet if you would like to discuss any aspect of the study further.

Important things you need to know

You have been invited to take part in the SENSE trial because you have been diagnosed with genetically proven HSN1, due to SPTLC1/2 mutations.

The SENSE trial will test whether L-serine is an effective drug treatment to slow or stop disease progression in HSN1 due to mutations in the SPLTLC1 or SPTLC2 gene. The other aim is to assess if Magnetic Resonance Imaging (MRI) can accurately detect the changes which occur in the muscles of people who have HSN1.
The SENSE trial is a double blind, randomised, placebo-controlled trial. This means that if you take part in the trial, you will receive ***either*** the study drug being tested (L-serine) ***OR*** a placebo. The placebo looks identical in every way to the study drug; however, it does not contain any active substance. Placebos are used as a control to measure the effectiveness of the study drug (L-serine). Those receiving placebo do not experience the effects of the study drug and their treatment is used as a comparison to the effects of the study drug treatment. Both products will be provided by Modepharma, Medications and Services for Clinical Trials, Beckenham, England.

As this is a randomised trial, you will be allocated a treatment group (either L-serine or placebo) at random. Neither you nor the research team will be aware of which treatment you have been allocated. This is called a double blind. This information will be made available if desired, following completion of the trial. In case this is deemed medically required, emergency unblinding procedures are in place. A 24-hour emergency contact card has been provided for quick and easy access to the research team should any support be required.

This is a summary of what taking part in the trial will involve:

- The trial will look at HSN1 and measure if use of L-serine will slow down or stop disease progression in affected patients.
- You will receive either L-serine OR placebo – which treatment you get will be decided by chance and at random.

- You will need to take a dose of either L-serine or placebo, three times daily, for 1 year. This will be administered in powder form and dissolved in water.
- You will have 5 visits in total: 4 in person visits at clinic and one telephone call.
- You will complete some questionnaires during the site visits.
- At 4 of these visits, you will have blood samples taken
- At 2 of these visits, you will undergo a neurological examination, MRI of the lower legs, nerve conduction studies and skin biopsies.
- The trial will last for approximately 1 year.
- After the trial is complete you will no longer receive L-serine or placebo.

Are there people who cannot take L-serine or take part in the trial?

For safety reasons, pregnant and breast-feeding women, and people with certain underlying medical conditions will not be able to take part. You may not be eligible to participate if you have certain medical conditions (including other neuromuscular diseases, kidney stones, diabetes type 1 & 2 and any condition that precludes having an MRI scan). Your medical history will be checked to see if there is any reason why you cannot take part in the trial. Potentially eligible participants will be invited to attend a screening visit during which their suitability to take part in the study will be assessed against a list of criteria. If any of these criteria are not met, enrolment into the study will not be allowed. The outcome of this screening will be shared and fully explained to you once all screening data is collected and reviewed by a qualified member of the research team. This participant information sheet will provide further information about the trial and what is involved in more detail.

Part 1 - What is involved in the Research Study?

1. What is the purpose of the study?

Hereditary Sensory Neuropathy Type 1 (HSN1) is a rare genetic neuropathy which causes pain, sensory loss, and variable weakness in the upper and lower extremities for which there is no current treatment.

The purpose of this study is to assess whether L-serine is an effective drug treatment to slow or stop disease progression in HSN1 due to mutations in the SPLTLC1 or SPTLC2 gene.

The other aim is to assess if Magnetic Resonance Imaging (MRI) can accurately detect the changes which occur in the muscles of people who have HSN1. 'We will scan the leg muscles (feet, calf and thigh) to take a look at structural muscle changes in affected limbs of HSN1. You will have 2 scans over the course of the trial, one at Visit 1 (Baseline visit) and another after 12 months (Visit 3). The two scans will be studied and compared to detect any changes to the muscles over the 12-month period. We will also look for correlations between MRI leg findings and other findings from clinical and laboratory blood and skin biopsy test results. We hope that the results from this study will help us to confirm that MRI is an adequate measure to detect changes in the muscles of people who have HSN1, which then could be used in future studies of HSN1 and other similar inherited neuropathies to measure change over a period of time.'

2. Why have I been invited?

You have been chosen as a potential participant in the study because you have been diagnosed with HSN1 due to a mutation in either the SPTLC1 or SPTLC2 gene.

3. Do I have to take part?

It is up to you to decide to join the study. We will describe the study and go through this information sheet. If you agree to take part, we will then ask you to sign a consent form. You are free to withdraw at any time without giving a reason. This would not affect the standard of care you receive

4. What will happen to me if I decide to take part?

You will be in this study for approximately 12 months. Participation will involve four visits in total. Visits will be conducted at the Queen Square Centre for Neuromuscular Diseases, National Hospital for Neurology and Neurosurgery, London.

Some people will not be eligible to be in the study or parts of the study, for example if there is a reason you cannot safely have an MRI scan (e.g., metallic implants or fragments, or claustrophobia), you are planned to have foot surgery during the period of the study, you have diabetes or kidney disease, or you are pregnant, breastfeeding or planning a pregnancy. Female participants of childbearing age will be asked to use contraception during the study period.

This study is a 'randomised study'. We do randomised studies when we don't know which way of treating patients is best. To find out, we need to compare different treatments. We put people into groups and give each group a different treatment. The results are compared to see if one is better. To try to make sure the groups are the same to start with, each patient is put into a group by chance (randomly). The chance of you getting the study drug is 50%.

This is a double blinded study which means that neither you nor your doctor will know which treatment group you are in. However, your doctor will be able to find out which treatment group you are in if required (e.g., for a medical emergency).

One of the treatment groups in this study will get a placebo instead of L-serine. A placebo is a dummy treatment such as a pill or powder which looks like the real thing but contains no active ingredient.

The initial visit will be a screening visit to confirm you are eligible to participate in the study. This will include assessments listed in the visit schedule plan table below.

The second visit will be a baseline visit in which tests will be performed to obtain a general idea of your current level of function before commencing treatment. This will include a neurological examination, blood tests, skin biopsies, patient questionnaires, nerve conduction studies and MRI. You will also be randomised at this visit and receive either L-serine or placebo.

You will take the trial medication which will be either L-serine or the placebo, three times a day, every day for one year. You will be asked to keep a patient diary for your doctor to monitor your progress.

The third visit will take place after six months and it will include a short assessment to monitor your progress. The fourth visit will occur at 12 months where the tests will be repeated. You will no longer receive L-serine or placebo after the 12-month period is complete. The final visit will be a telephone call approximately 28 days after you have finished taking either L-serine or placebo.

Visit Schedule Plan

Timing of assessments	*What will happen (list all assessments done at the visit)*	*How much time will this take?*
Screening visit	✓ Study explanation ✓ Informed Consent ✓ Physical examination including weight ✓ Neurological Examination ✓ Blood tests ✓ Vital Signs ✓ Urine tests for pregnancy test (if you are female and of childbearing potential) ✓ Medications History	*2 hours – in clinic*
Baseline Visit (Visit 1)	✓ Urine test (this will include a pregnancy test if you are female and of childbearing potential) ✓ Medications History	*6-8 hours – in clinic*

	✓ Physical exam ✓ Neurological exam ✓ Vital signs ✓ MRI of lower limbs ✓ Nerve conduction studies ✓ Patient questionnaires ✓ Blood tests ✓ Skin biopsies	
Visit 2	✓ Blood tests ✓ Safety checks ✓ Urine test (this will include a pregnancy test if you are female and of childbearing potential)	*30 mins - 1 hour – in clinic*
Visit 3	✓ Neurological exam ✓ MRI of lower limbs ✓ Nerve conduction studies ✓ Patient questionnaires ✓ Blood tests ✓ Skin biopsies	*6-8 hours – in clinic*
Visit 4	✓ Safety checks	*20 mins- Telephone call*

5. What will I have to do?
You will take the study medication three times a day, every day for one year. This will be provided in powder form and can be dissolved with water. You will be instructed on how to dissolve the medication by the research nurse or doctor. You will be asked to keep a treatment diary so your doctor can monitor your progress. You will also be asked to keep the medication container to return to your doctor. You will be able to continue taking your regular medications but should let your doctor know if you have started any other medications or prescribed or over-the-counter drugs during the study. You will be required to attend all study visits so that your doctor can perform safety assessments and monitor your progress.

6. What are the alternatives for diagnosis or treatment?
Taking part in this study is your choice and entirely voluntary. It is up to you to decide whether you should take part. We will explain the study and go through this Participant Information Sheet with you. If you agree to take part, we will then ask you to sign an Informed Consent Form. You will be given a copy of this Participant Information Sheet and the signed Informed Consent Form to keep for your records.
If you decide to take part, you are free to withdraw at any time, without giving a reason. If you decide not to take part, or to withdraw, this will not affect the standard of care you receive.

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

Trial drug: L-serine is a supplement and has been used in other trials involving human participants and has been proven to be safe and well tolerated. Possible side effects may include nausea, vomiting, eye movement changes, startles to loud noises and brief, involuntary muscle twitching. These side effects have been noted in studies where patients have taken L-serine at higher doses than what will be used in this study, therefore it is thought to be unlikely that you will experience them. You will be given a diary during the course of the trial for you to record any symptoms or possible side effects you have experienced. When you come for your hospital visit, your doctor will also ask you about any side effects you have experienced. It is important that you tell them about any problems. Your doctor will monitor you closely for any possible side effects and they may suggest additional investigations if they consider it appropriate.

If you need to contact your doctor at any time, for example if you become unwell between hospital visits, or if you are unsure about any symptoms or possible side effects you may be experiencing in between your trial visits then you can contact your doctor via telephone or email for advice. Their contact details are provided on the last page of this information sheet, and you will also be provided with a 24hr contact card in case of emergencies. If you suddenly become unwell you should immediately contact your GP, emergency services or go to your local Accident & Emergency department.

Patient Reported Outcome Measures (Patient questionnaires): These are questionnaires designed to help us learn about your experience. Occasionally some individuals may find some questions upsetting. If you do not wish to complete them or need a break, please let the Study Doctor know.

Lower limb MRI (thigh,calf,foot): MRI is a safe and generally well tolerated procedure. You cannot have an MRI in this study if you are pregnant or planning a pregnancy or have magnetic metal in your body – we will check this with a safety questionnaire. There is no exposure to X-ray or harmful forms of radiation. A scan involves lying on your back with your legs covered with a plastic “MRI receiver coil” and being moved feet first into a tunnel. You will be able to communicate with the technician performing the scan throughout the procedure. The MRI machine is fairly noisy (ear protection is provided) and some people find the procedure slightly claustrophobic. In this study your legs and lower abdomen will be in the tunnel and your head outside.

Blood Test: Blood tests do not pose a significant risk to your health. At the site where the blood is taken you may experience brief discomfort. There is a small risk of bruising, bleeding, fainting, and a very small risk of infection if the skin is broken. Bloods will be drawn by a trained health care professional and the upmost care will be taken to avoid these risks.

Skin Biopsies: Two tiny samples of skin will be taken from the side of the thigh after an injection of local anaesthetic. The risks include feeling sick or lightheaded, bleeding, infection or scarring at the site of the procedure, discomfort or stinging from the procedure or the local anaesthetic lasting a few seconds. If you have a known allergy to lidocaine (local anaesthetic used), alternative local anaesthetics will be chosen as per UCLH trust standard operational procedures or you will be excluded from the skin biopsy. Participants who decline skin biopsy for other reasons will not be excluded from further trial participation.

Nerve Conduction Studies: This test will examine the electrical function of the nerves in your arms and/or legs using surface sticky pads. Mild discomfort may be briefly experienced during performance of nerve conduction studies. It is an unusual feeling, and some patients find them a little uncomfortable. They will be performed by a trained doctor. Testing will be discontinued at any point if you feel distressed and will only be resumed you feel comfortable with continuation.

Incidental Findings: It is possible that, during the study, another medical condition (known as an incidental finding) could be detected during the clinical assessment or MRI scan. If this happens,

you will be informed and any required referrals, investigations and/or treatments will be arranged as we would in routine clinical practice.

Other risks: There are no other immediate risks in taking part in the study. There may be risks involved in taking part in the study that are not known to the researchers at this time. If new risks are identified during the study, we will make you aware of these. You will always be free to withdraw from the study without giving a reason.

8. Pregnancy and Contraception Information

It is not known if L-serine is harmful to unborn babies. Therefore, if you are pregnant [or breast-feeding] or plan to become pregnant during the study you will not be able to take part in the study. If you could become pregnant, your doctor will ask you to have a pregnancy test before taking part to ensure that you are not pregnant.

Women who could become pregnant must use a highly effective contraceptive during this study from the time consent is signed until six days after treatment discontinuation (this is due to a lack of safety data on use of L-serine in pregnant and breastfeeding women; and to allow for medication wash out post treatment discontinuation).
Highly effective methods of contraception acceptable for this trial for female participants are listed below:

- Combine hormonal contraception associated with inhibition of ovulation
- Progesterone only hormonal contraception associated with inhibition of ovulation
- Intrauterine device
- Intrauterine hormone-releasing system
- Bilateral tubal occlusion
- Vasectomised partner
- Sexual abstinence (refraining from heterosexual intercourse during the entire period associated with the study treatments)

If you become pregnant during the study, we will need to stop the treatment and find out whether you were on L-serine or placebo.

With your consent, we will request information on the pregnancy and child's birth that is relevant to your participation on the study. If this relevant information needs to be reported to the sponsor, ethics committee or UK regulatory body for medicines, the information will be anonymised so that neither the new-born child nor you can be identified.

Your participation in the study could affect any insurance you have (e.g., travel insurance, protection insurance (life insurance, income protection, critical illness cover) and private medical insurance) and you may need to seek advice on these issues if you think you could be affected.

9. What are the possible benefits of taking part?

We do not know whether you will benefit personally from taking part in this study, but the knowledge gained from this study will inform future treatment and potentially lead to improved treatment for patients with HSN in the future. You may benefit from the contact with the healthcare professionals in the study and from taking the study medicine.

10. What happens when the clinical study stops?

When the research study finishes, the results will be analysed to determine whether L-serine stops or slows disease progression. We will also assess whether MRI scans are an adequate way to measure changes in the muscles of people who have HSN1**.**

11. What if there is a problem?
Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. The detailed information concerning this is given in Part 2 of this information sheet. If you have any concerns or complaints, you should contact the study doctor in the first instance.

12. Will my taking part in the study be kept confidential?
Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. The details are included in Part 2 – Supporting Information.

13. Expenses and payments
Up to £70.00 will be reimbursed for travel expenses to attend the study visits. Please present your original receipts to the Study Doctor who will submit an expenses claim on your behalf to the UCL Finance Department. It may take up to four weeks for your claim to be processed.

14. Contact Details

Study Doctor:

Name: Dr Caroline Kramarz Tel. Number: 08002118730
Secure Email: caroline.kramarz@nhs.net

Study Research Nurse:

Name: Ms Mariola Skorupinska Tel. Number: 02031087544
Secure Email: mariola.skorupinska@nhs.net

This completes Part 1 of the Information Sheet.

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

Part 2 - Supporting Information

1. What if relevant new information becomes available?

On receiving new information, we will tell you about it and discuss whether you should continue in the study. If you decide that you should continue in the study, we will ask you to sign an updated consent form. We might consider it to be in your best interest to be withdrawn from the study. If so, we will explain the reasons and will make arrangements for your care to continue. If the study is stopped for any other reason, we will tell you why.

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

Your participation in this study is entirely voluntary. You are free to decline to enter and can withdraw from the study at any time without having to give a reason. Significant new findings developed during the course of the research which may relate to your willingness to continue participation will

be provided to you. If you choose not to enter the study, or to withdraw once entered, this will in no way affect your future medical care. Please inform the doctor if this is the case. Participation in this study will in no way affect your legal rights.

The principal investigator may terminate your participation in this study at any time with or without your consent. You will be informed if this needs to happen.

The data collected up to the date of withdrawal may still be used. Any stored tissue samples which cannot be identified will still be used for the study and, with your consent, will be stored for future research when the study ends. If you do not want your tissue samples to be stored for future research, then they will be disposed of at the end of the trial.

3. What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions (contact details at the bottom of the sheet). If you remain unhappy and wish to complain formally, you can do this within 12 months of the events concerned, or within 12 months of becoming aware of the problem. Your complaint will be recorded as part of our formal complaints policy.

Please write with full details to the Chief Executive (details above) or to the Complaints Manager at:
Quality and Safety Department, UCLH
2nd Floor West
250 Euston Road
London
NW1 2PG
Telephone: 020 3447 7413
Email: uclh.complaints@nhs.net

Every care will be taken during this study. However, in the unlikely event that you are harmed by taking part, compensation may be available. UCL provides insurance for harm arising from the design of the research and you will also be covered by NHS indemnity schemes or professional indemnity.

If you suspect that the injury is the result of the Sponsor's (University College London) or the hospital's negligence (if the injury probably resulted from taking part in the study), then you may be able to claim compensation and will not need to prove negligence.
After discussing with your study doctor, please make the claim in writing to Professor Mary Reilly who is the Chief Investigator for the study and is based at the Centre for Neuromuscular Diseases, 8-11 Queen Square, London NW1 3BG. The Chief Investigator will then pass the claim to the Sponsor's Insurers, via the Sponsor's office. You may have to bear the costs of the legal action initially, and you should consult a lawyer about this.

Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated by members of staff or about any side effects (adverse events) you may have experienced due to your participation in the study, you should initially contact the Principal Investigator, who will do their best to answer your questions. Their contact details are at the end of this information sheet.

If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from UCLH or PALS.
Ground Floor Atrium
University College Hospital
235 Euston Road
London NW1 2BU

Telephone number: 020 3447 3042 or by email: Uclh.pals@nhs.net

You can also contact the Research Governance Sponsor of this study, University College London. Please write to:
Joint UCLH/UCL Biomedical Research Unit,
R&D Directorate,
Rosenheim Wing,
Ground, 25 Grafton Way,
London WC1E 5DB
(quoting UCLH reference
18/0244)

The normal National Health Service complaints mechanisms are available to you. Please ask the study doctor if you would like more information on this. Details can also be obtained from the Department of Health website: http://www.dh.gov.uk.

4. How will we use information about you?

UCL is the sponsor for this study based in the United Kingdom. The sponsor is the organisation responsible for ensuring that the study is carried out correctly. We will be using your personal data (such as contact details [name, telephone number(s), email address, NHS/hospital number], demographics [age, gender, marital status, ethnicity, education, occupation]) from your medical records in order to undertake this study.

UCL will act as the data controller for this study. This means that they are responsible for looking after your information and using it properly. UCL will keep this information about you for 25 years after the study has finished. The UCL Data Protection Office provides oversight of UCL activities involving the processing of personal data and can be contacted at data-protection@ucl.ac.uk. Further information on how UCL uses your information can be found on our general research privacy notice here https://www.ucl.ac.uk/legal-services/privacy.

We will need to use information from you, your medical records, your GP and/or hospital team for this research project. This information will include your initials, NHS number, name and contact details. People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. We will keep all information about you safe and secure. Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

5. What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. If you choose to stop taking part in the study, we would like to continue collecting information about your health from central NHS records/ your hospital or your GP. If you do not want this to happen, tell us and we will stop.

We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

6. Where can you find out more about how your information is used?

You can find out more about how we use your information:

- at https://www.hra.nhs.uk/information-about-patients/
- by contacting the research team via phone or email using the details below.

7. Will my GP be informed of my involvement?

8. With your permission, your GP, and other doctors who may be treating you, will be notified that you are taking part in this study. They will be updated and provided with any information deemed relevant or necessary to your ongoing care during your participation in the trial Any information on side effects you may experience from treatment may be shared with your GP if necessary. **What will happen to any samples I give?**

Your samples will be collected and labelled with your coded identifier. Your samples will not contain any personal or identifiable details. They will be sent for analysis in the UK at laboratories at the National Hospital for Neurology and Neurosurgery in London and at the Centre for Neuromuscular Diseases Biobank. You will be asked to complete a consent form for storage of blood and/or skin samples in the biobank; the Study Doctor will explain this in detail. Some blood and skin samples collected during the study will be sent to Prof. Hornemman lab, University of Zurich, Switzerland and to Prof. Bennett lab, University of Oxford, Nuffield Department of Clinical Neurosciences for specific analysis. Skin biopsies will be used to look at the nerve fibres and to generate fibroblasts.

If you consent to it, any leftover samples will be stored anonymously after the study has ended and will be used for future research which is approved by a Research Ethics Committee. If you don't want to give your consent, the surplus samples will be destroyed when the study ends. If you do not want your samples to be stored for use in future research, then the samples will be disposed of carefully at the end of the trial.

9. Will any genetic tests be done?

Genetic testing will not be performed.

10. What will happen to the results of the clinical trial?

The results of the study will be available after it finishes and will usually be published in a medical journal or be presented at a scientific conference. We will also hold a patient information meeting to inform participants of the study results. The data will be anonymous and none of the patients involved in the trial will be identified in any report or publication.

Should you wish to see the results, or the publication, please ask your study doctor.

11. Who is organising and funding the research?

The study is funded by the CMT Association (USA) and sponsored by University College London.

12. How have patients and the public been involved in this study?

Members of the public and patient representatives were involved in reviewing the trial application and making appropriate suggestions and recommendations.

13. Who has reviewed the study?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by the Research Ethics Committee, Health Research Authority (HRA) and Medicines and Health Regulatory Authority (MHRA)

14. Further information and contact details

You are encouraged to ask any questions you wish, before, during or after your treatment. If you have any questions about the study, please speak to your study nurse or doctor, who will be able to provide you with up-to-date information about the drug(s)/procedure(s) involved. If you wish to read the research on which this study is based, please ask your study nurse or doctor. If you require any further information or have any concerns while taking part in the study, please contact one of the following people:

Study Doctor: Dr Caroline Kramarz, tel: 08002118730 email: caroline.kramarz@nhs.net

Study Nurse: Ms Mariola Skorupinska: 02031087544, mariola.skorupinska@nhs.net

Alternatively, if you or your relatives have any questions about this study you may wish to contact one of the following organisations that are independent of the hospital at which you are being treated:

CMT UK
3 Groveley Road
Christchurch
BH23 3HB
Freephone: 0300 323 6316 Tel: 01202 474203
Email: enquiries@cmt.org.uk

If you decide you would like to take part, then please read, and sign the consent form. You will be given a copy of this information sheet and the consent form to keep. A copy of the consent form will be filed in your patient notes, one will be filed with the study records, and one may be sent to the Research Sponsor.

You can have more time to think this over if you are at all unsure.

Thank you for taking the time to read this information sheet and to consider this study.

15. Potential commercial benefit

Participants will not benefit financially in any way, if commercialisation of any study findings are successful.

Sponsor Protocol Number: 148491
Patient Identification Number:

CONSENT FORM

Title of Project: **Hereditary Sensory Neuropathy Serine trial (SENSE trial)**

Name of Researcher:

Please initial each box to indicate your agreement:

1. I confirm that I have read and understand the information sheet dated..... (version.....) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	☐
2. I understand that my participation 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.	☐
3. I understand that relevant sections of my medical notes and data collected during the study, may be looked at by individuals from the sponsor of the trial (University College London) and responsible persons authorised by the sponsor, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.	☐
4. I agree to my GP being informed of my participation in the study and to be contacted if and when required.	☐
5. If I or my partner becomes pregnant whilst I am on this study, I understand that my doctor will inform the treating obstetrician of my involvement in this study and that the obstetrician may be requested to provide relevant information regarding the pregnancy and or birth. I understand that this may involve requesting access to my medical records and that anonymised information relating to the pregnancy or birth may be reported to the sponsor, ethics committee or regulatory authorities. I give permission for these individuals to have access to my medical records.	☐
6. I agree to have a skin biopsy (optional)	☐

7. I understand that my samples will be stored and tested at laboratories located in the UK and internationally.	☐
8. I understand that my samples will be coded, and all personal identifiers will be removed, but the results of tests on my samples may be linked to clinical data about me collected during the course of treatment on this study. I understand that my identity will remain anonymous.	☐
9. I agree to take part in the above study.	☐

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_____	_____	_____
Name of Patient	Date	Signature
_____	_____	_____
Name of Person taking consent	Date	Signature
_____	_____	_____
Name of Witness (if applicable)	Date	Signature

When completed: 1 for participant; 1 (original) for researcher site file; 1 to be kept in medical notes.

Sponsor Protocol Number: 148491
Patient Identification Number:

OPTIONAL CONSENT – For the Future Use of Research Samples

Title of Project: Hereditary Sensory Neuropathy Serine trial (SENSE trial)

Name of Researcher:

We would like to ask for consent for any remaining blood/skin samples you provided for the Study to be retained after the end of the study.

Future use of your blood/skin samples is optional and is not required in order to participate in the study. If you do not consent to future use of blood samples, please simply leave the section below blank.

Please initial each box to indicate your agreement:

1.	I agree that any remaining blood/skin samples I provided for the Study may be retained after the end of the study for future research	☐
2.	I understand that the use of my tissue samples in future research will be restricted to ethically approved studies related to neuropathies.	☐
3.	I understand that the information collected about me may be used to support other research in the future and may be shared anonymously with other researchers.	☐

_____	_____	_____
Name of Patient	Date	Signature
_____	_____	_____
Name of Person taking consent	Date	Signature
_____	_____	_____
Name of Witness (if applicable)	Date	Signature

When completed, 1 for patient; 1 (original) for researcher site file; 1 to be kept in medical notes