[TO BE PRINTED ON SITE-HEADED PAPER]

PARTICIPANT INFORMATION SHEET & INFORMED CONSENT FORM

Regeneration in **Ce**rvical **De**generative **Myelopathy** - a multi-centre, double-blind, randomised, placebo controlled trial assessing the efficacy of Ibudilast as an adjuvant treatment to decompressive surgery for degenerative cervical myelopathy

RECEDE - Myelopathy

You have been invited to take part in a research trial. Before deciding whether to take part, you need to understand why this research is being done and what it involves. Please take time to read the following information carefully and talk to others about the trial if you wish. Please ask us if anything is not clear or if you would like more information. Please take time to decide whether or not you wish to take part.

Section 1 tells you the purpose of this trial and what will happen to you if you take part.
Section 2 gives you more detailed information about the conduct of the trial.

Section 1: Purpose of the trial and what will happen

1. What is the purpose of the trial?

Degenerative cervical myelopathy (abbreviated to DCM) is a condition where 'wear and tear' arthritis ('degenerative') affects the part of the spine in your neck ('cervical'), causing structural changes that compress and damage your spinal cord ('myelopathy'). DCM is also commonly known as "cervical spondylotic myelopathy" or "cervical stenosis". More information about the disease can be found at **www.myelopathy.org**.

At present, the only treatment available is to undergo an operation to remove the compression. The aim of this operation is to prevent any further spinal cord damage and development of new disability. In many cases, the operation provides some improvement to your existing symptoms. However, most patients with DCM will not make a complete recovery and therefore live with life-long disabilities. The reason that a full recovery is not achieved is because the spinal cord is not naturally very good at repairing itself.

Therefore, in order to optimise recovery from DCM, something is needed to stimulate spinal cord repair. We have identified a medication that may be able to do that and we wish to assess the benefits of this medication in patients undergoing surgery for DCM. This medication is an adjuvant treatment to decompressive surgery, meaning that it is in addition to surgery.

2. What is the drug being tested?

The drug we are testing in this trial is called Ibudilast. This is a licensed medication that has been used for the treatment of asthma and dizziness after stroke in Asia for more than 20 years. However ibudilast is not currently licensed for use in the UK. We plan to use ibudilast in a higher dose (up to 100mg per day) than is currently used for its licensed conditions in Asia (up to 30mg per day).

Please be aware that the drug capsule contains gelatine.

Researchers are now also looking at its potential to help in other diseases which affect the brain and spinal cord, such as Multiple Sclerosis and Motor Neuron Disease. The medication has been very well tolerated in patients across the globe. There have been no serious side effects attributed to it, even when given at the higher doses we plan to use in this study.

3. Why have I been invited?

You have been invited to participate in this trial because you suffer from DCM and you are planning to undergo surgery for it, and we believe Ibudilast may improve recovery following surgery. Your surgery is part of your normal care at your hospital and will not be affected by your involvement in this trial. Your surgeon will be able to provide you with full details of the procedure.

We plan to include 25-80 participants in the initial pilot phase with 362 participants overall with DCM from at least three hospitals across the UK.

4. Do I have to take part?

Participating in this trial is completely voluntary. If you decide to participate, you will be asked to sign an Informed Consent Form. However, you are still free to change your mind and leave the trial at any time without giving a reason. If you choose not to participate or to leave the trial, your future medical treatment and normal standard of care will not be affected in any way.

5. What will happen to me if I take part?

If you agree to participate in the trial, you will be asked to sign the Informed Consent Form at the end of this document. You will be given a copy of this form to take away and refer to later.

This trial is a randomised, double-blind, placebo controlled-trial. What does that mean?

- ***Randomised:*** As we sometimes don't know which way of treating patients is best, we need to compare a group who take Ibudilast with a group who do not. You will be allocated to one of the groups in a random way (by chance), so we can be sure that the two groups are as equal as possible. This way, any differences between groups can be attributed to the treatment they received rather than any other differences between groups. In this trial, the size of the groups will be the same, therefore you will have a 50% chance of receiving Ibudilast.

- ***Double Blind:*** This means that you, your relative/friend, and your trial doctor will not know which treatment you are receiving; however, your trial doctor can find out if necessary.

- ***Placebo:*** This is sometimes called the 'dummy capsule'. It looks the same as the treatment but does not contain any of the active ingredients and will have no effect on you.

Once you have given consent and we have confirmed you are eligible to participate in this trial, you will be assigned randomly to take either Ibudilast or the placebo. The treatment is due to start no later than 2 weeks from your first visit and within 10 weeks before your surgery and will continue for a maximum of 24 weeks after surgery. If treatment cannot be started within 2 weeks from your first visit, you might be asked to come back for further tests. Treatment will be stopped 5 days prior to surgery and restarted at the previous maximum dose as soon as possible after operation. After contacting you by phone to confirm that you are eligible to participate, the first supply of trial medication may be collected from the hospital or be delivered to you by courier. More trial medication will be sent to you by courier in the event that your surgery is delayed beyond 10 weeks. If medication has to be delivered to you by courier, the local research team will pass on your contact details and home address to the authorised personnel of a courier company. We are asking you to take the trial treatment prior to surgery because the drug could have positive effects independent from surgery and possibly prevent symptoms from worsening.

The treatment will be administered twice daily for up to 34 weeks (approximately 8 months). The trial medication comes in the form of a gelatine-based capsule. Initially, you will be asked to take six capsules per day, and if you tolerate this after two weeks, this will be slowly increased to 10 capsules per day (taken as 5 capsules twice daily, morning and evening, with or shortly after a meal). The trial team will contact you again shortly after the medication has been received to

confirm you have received it and started treatment; during this phone call you will also be asked whether you have had any adverse event(s) after the last visit.

At the end of the first visit you will be given a dosing diary to record when you take the medication and how much. The trial team will show you how to store the trial drug and how to complete this diary. Please use it to keep an accurate record of the trial medication you have taken as this is important for understanding whether or not the drug is effective.

Approximately one month after you started the treatment, a member of the local team will be in contact with you by telephone to make sure that you are taking the correct dose of the drug and to see how you are. These assessments could also be performed during the pre-operative visit if it is scheduled around that time.

Participation Duration

You will be in the trial for approximately 15 months. At multiple times during the trial, we will use detailed assessments to see how DCM affects you. Some of these assessments will be carried out by clinicians and some of them by you.

These assessments will take place: at enrolment; before and after surgery; and later at three, six, and 12 months after surgery.

The majority of these assessments are not routinely used for patients with degenerative cervical myelopathy but provide a far more detailed picture of your progress. We will now outline what these assessments are and what they involve.

Tests and Assessments

- There are five questionnaires that you will be asked to complete at multiple times during the trial. Each time, it will take you approximately half an hour to complete all five questionnaires. You may complete the questionnaires either by yourself or with the assistance of a relative/friend. We may contact you by post, email, telephone, or at a routine outpatient visit. If you require the questionnaire in another format (e.g. different language, large print), please let us know.
- Additionally your doctor will complete some assessments by asking you a number of questions about your DCM and carrying out an examination. This will include tests of your strength, walking and ability to feel. This will take approximately 1 hour.

We are also interested in understanding how your DCM affects those around you and, we would like you to identify your supporters (those you rely on) to invite them to complete a short questionnaire of their own. This is optional.

- As part of this trial, you will have two magnetic resonance imaging (MRI) scans, one before and one after surgery. This is one more than you would have under standard care. In order to enter this trial you will already have undergone a MRI scan; a MRI scanner is a large, narrow tube that uses powerful magnets to image your spinal cord, whilst you lie in side. This assessment will take up to 40 minutes and will allow us to observe structural changes in your spine.
- ECG – An electrocardiogram (ECG) is a simple test that can be used to check your heart's rhythm and electrical activity. Sensors attached to the skin are used to detect the electrical signals produced by your heart each time it beats. These signals are recorded by a machine and are looked at by a doctor to see if they're unusual. This assessment will take 5 minutes and will allow us to see if you are fit to participate in this trial.
- Blood tests: You will be asked to give a number of blood samples which will be sent to a hospital’s laboratory to analyse your liver function, full blood count, urea and electrolytes.

This is to ensure that you are suitable for this trial and to monitor the effect of the treatment. Approximately 10 ml (2 teaspoons) will be taken from your arm at the screening visit and 10 ml (2 teaspoons) of blood before surgery and later at three, six, and 12 months after surgery. You will also be asked to give extra blood to measure the amount of ibudilast in your blood. Extra blood samples (10 ml, 2 teaspoons) will be taken at screening, during surgery and later at three, six, and 12 months after surgery. The total amount of blood to be taken during the trial will be 100 mL (equivalent to 20 teaspoons).

- Spirometry – Spirometry is a simple test used to help diagnose and monitor certain lung conditions by measuring how much air you can breathe out in one forced breath. It's carried out using a device called a spirometer, which is a small machine attached by a cable to a mouthpiece. This test will take 30 minutes.
- Pregnancy test – If you are a woman, part of your screening blood sample will be used to assess if you are pregnant before participating in this trial.

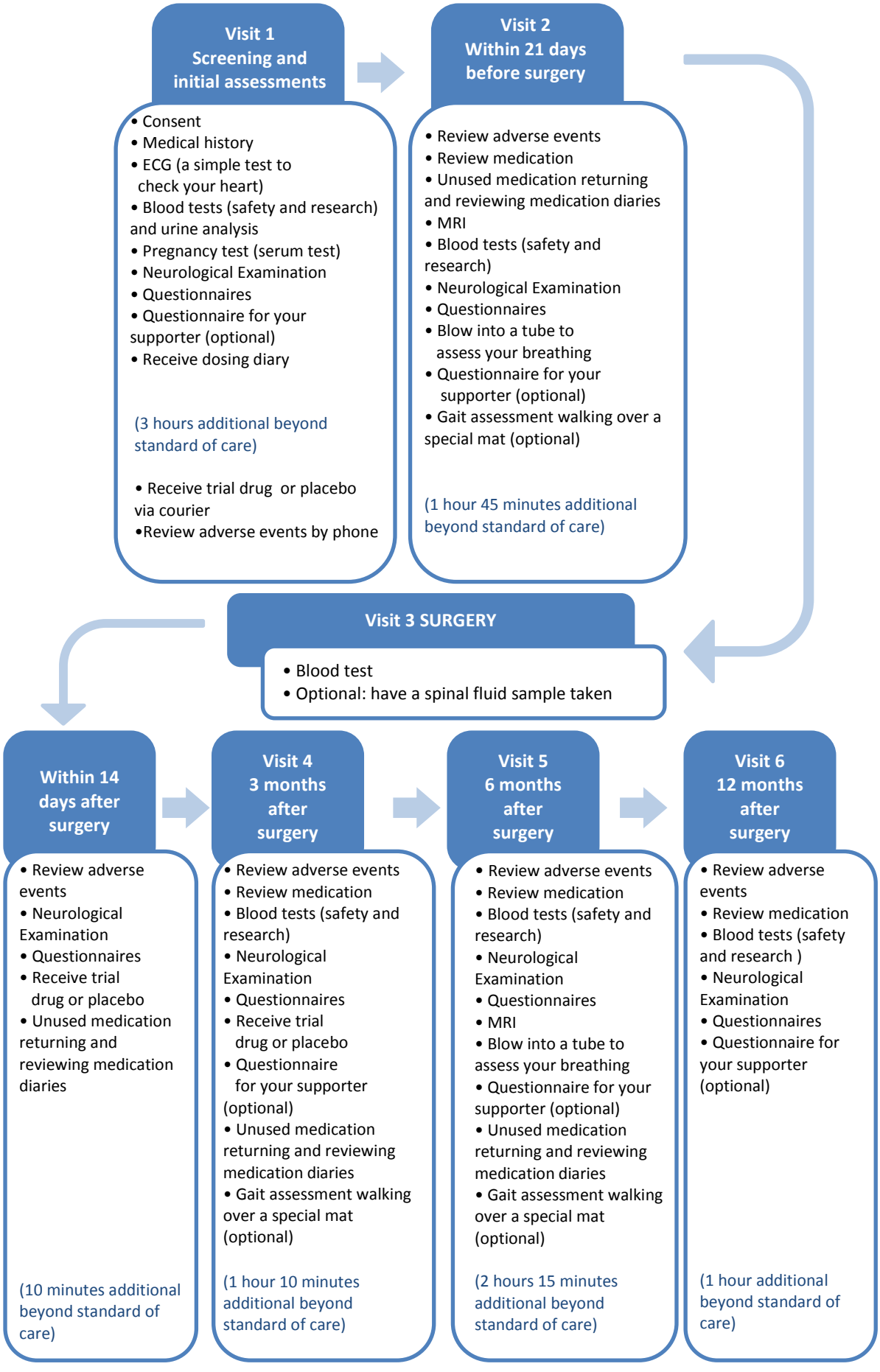
Optional Tests and Assessments

CSF sample

Independently of which trial treatment you are allocated to, you will also be asked to give a separate and **optional** cerebrospinal fluid (CSF) sample, which would be acquired by performing a lumbar puncture (LP), preferably at the time of surgery whilst you are asleep. The CSF sample will be 10 mL (equivalent to 2 teaspoons). The CSF runs around your spinal cord and by analysing this fluid we hope to better understand how your spinal cord has been affected by the drug.

A LP is performed by inserting a small, fine needle into your back, well below your spinal cord. If this is performed during surgery, you should not notice anything difference. If the LP is performed whilst you are awake, you will either be asked to lie on your side or sat upright. The skin of the lower back will be cleaned with an antiseptic and a local anaesthetic will be injected under the skin. This may sting a little initially, but then the area will go numb. Once the area is numb, you may feel a sensation of pushing and/or pressure as the LP needle is inserted and then a brief tingling/pushing sensation when the needle is pushed forward. The practitioner will collect samples to send to the laboratory for testing; the whole procedure usually takes about 20 minutes.

Trial Flow Chart



6. What will I have to do?

In addition to your normal care you will be asked to take the trial medication and keep an accurate record in your dosing diary. This will start approximately 10 weeks before you undergo surgery and continue for a maximum of 24 weeks after surgery (a maximum of 34 weeks in total). The trial drug could potentially lead to an increased bleeding risk (due to interference with blood platelets). Therefore you will have to stop trial treatment for 5 days prior to your surgery and resume it at the previous maximum dose as soon as possible two days since the operation. We ask you to keep all your study medication bottles, even if empty, and bring them to your study appointments. You will also be asked to undergo various assessments as outlined above.

Your local trial team will provide you with their contact information (also found at the end of this sheet). You should tell the trial team if you feel unwell or different in any way. If you have any concerns or are feeling unwell, please contact your trial doctor immediately using the contact numbers at the end of this information sheet.

You should discuss your participation in this trial with any insurance provider (e.g protection insurance, life insurance, income protection, critical illness cover and private medical insurance) and seek advice if necessary, as failure to notify them may affect or invalidate your cover.

The effect of the trial medicine on an unborn baby or nursing infant is unknown. Therefore, you will not be able to take part in this trial if you are pregnant or breastfeeding, or if you are planning to become pregnant or father a child during the trial. Therefore, for safety, contraception will be necessary in situations in which sexual activity could result in pregnancy:

- Women who are able to have a baby must use a reliable form of contraception for the entire duration of treatment and for 90 days after your last treatment with the trial drug. This includes any of the following:
    - Oral contraceptive (either combined or progestogen alone)
    - Contraceptive implant, injections or patches
    - Vaginal ring
    - Intrauterine device (IUD, coil or intrauterine system)
    - Condom **and** cap or diaphragm **plus** spermicide (chemical that kills sperm)

- For men, you are required to use barrier contraception for the entire duration of the trial and for 90 days after the completion of the last treatment. You must refrain from donating sperm for the duration of the trial and 90 days thereafter.

- You do not need to use contraception if:
    - You have only one partner, and the man has had an operation to cut the tubes that carry sperm (vasectomy) or
    - You (or your partner) are a woman who cannot become pregnant or
    - You practice true abstinence as part of your usual and preferred lifestyle (confirmed negative pregnancy test at screening visit and no sexual activity until 90 days after the last dose of trial medication). If you become sexually active, you must use one of the methods listed above.

If you or your partner become pregnant during the trial or within 90 days of stopping treatment, you should inform your trial doctor immediately. Your trial doctor will discuss all the options available to you. The outcome and progress of any pregnancy would be followed and you would be asked questions about the pregnancy and baby, if appropriate.

Please ensure your partner is aware of these requirements, if applicable.

7. What are the side effects of the drug being tested?

The potential side effects of Ibudilast are listed below.

Less than 5 out of every 100 patients will experience:

- Rash
- Dizziness, headache
- Anorexia, nausea, vomiting, abdominal pain, indigestion
- Changes in liver parameters

Less than 1 out of every 1000 patients will experience:

- Itching
- Tremor, insomnia, sleepiness, apathy
- Feeling of enlarged abdomen, diarrhea, gastric ulcer
- Heart palpitation, drop in blood pressure, hot flushes
- Reduction of platelets or red or white blood cell count
- Jaundice
- Feeling unwell, ringing in the ears, facial swelling, floating feeling, taste abnormality

As the trial drug potentially increases the risk of bleeding during surgery, you need to halt trial treatment 5 days before surgery and resume it after the operation. Currently, there are no known interactions with any other medications, however, your study doctor will take a record of any medications you currently take. If you develop any side effects or have any concerns, you should notify your trial doctor immediately. At each visit, they will also assess for side effects, which will include performing blood tests. In the unlikely event of any serious unforeseen reactions, or if any concerns arise, the dose will be reduced or the drug stopped immediately.

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

You will continue to receive the standard care for your condition. You may be asked to consider additional hospital visits to complete assessments, but we will endeavour to have this coincide with a routine clinical appointment and make the process as efficient as possible.

Taking a blood sample may cause some discomfort. There may be slight pain, a small amount of bleeding, discolouration or bruising at the site where the needle is inserted. There is also a risk of infection or phlebitis (inflammation of a vein caused by small blood clots) but these side effects rarely happen.

Some people (less than 5%) find the MR system claustrophobic, but the radiographer conducting the scan will be able to see you and talk with you at all times, and will stop the scan if necessary. The MR system is noisy, but you will be provided with ear protection. You will not be eligible to take part in the trial if there is any recognised contra-indication to having an MRI examination. This would include the presence of a pacemaker for the heart, or cochlear (inner ear) implant. You will be screened prior to commencement of the trial for any contra-indications. If anything unusual is found related to your health during your scan, you will be informed in line with the local hospital radiology trials policies.

Lumbar punctures are routinely performed for many different health conditions, and rarely cause a problem. The most common complaint is to experience a headache (around 1 in 50 people). This normally goes within a few hours and is helped by lying down and drinking plenty of fluids. Swelling and lower back pain where the needle was inserted is also possible. This should get better on its own within a few days. In some very rare circumstances, the procedure can cause an infection,

bleeding at the site of the LP or extremely rarely a nerve injury. If you have further questions about the procedure, it may be helpful to talk to your trial doctor.

9. What are the possible benefits of taking part?

There is no guarantee that you will benefit from taking part in this trial. You may experience an improvement in your disease. The assessment of your disease will be more detailed and occur more often than normal. These assessment results will be available to the health professionals looking after you.

The information collected as part of your participation in this trial will be useful, as it may benefit patients with a degenerative cervical myelopathy in the future.

10. What are the alternatives for treatment?

Currently the alternatives for treatment are routine standard of care at this hospital. You will still receive all routine standard of care treatment as part of this trial. If you choose not to take part in the trial, will continue to receive the standard treatment regimen offered by your hospital and proceed on the patient pathway as normal.

11. What happens when the trial stops?

Once treatment with the study medication has finished, you will continue to be treated and managed according to the routine standard of care at your hospital. There is no need to continue taking study medication after the trial ends. Ibudilast will not be available to you following the trial.

12. Expenses & Payment?

You will not receive any payment for participating in this trial. We can, however, make a contribution towards your travelling expenses incurred by your participation in this trial.

Section 2: Trial Conduct

13. What if new information becomes available?

Sometimes during the course of a trial, new information becomes available which might affect your decision to continue participating in this trial. Your trial doctor or a delegated member of the trial team will contact you to discuss the new information and whether you wish to continue participating in the trial. If you still wish to continue participating in the trial, you will be asked to sign a new Informed Consent Form.

The trial sponsor, the regulatory authority, or the trial doctor may decide to stop the trial at any time. If that happens, we will tell you why the trial has been stopped and arrange for appropriate care and treatment for you.

14. What if I decide I no longer wish to participate in the trial?

You are free to stop your participation in this trial at any time without giving a reason and without affecting your future care or medical treatment. If you decide not to participate any further, you will no longer receive the treatment for this trial. No further tests will be performed on you and no further research samples will be collected. Any data already collected or results from tests already performed on you or your samples will continue to be used in the trial analysis.

The trial doctor may also choose to withdraw you from the trial if they feel it is in your best interests or if you have been unable to comply with the requirements of the trial. Reasons for trial withdrawal could include:

- You have experienced a serious side effect
- You are unable to complete the visits, medication, or trial documentation as required
- You become pregnant or plan to become pregnant
- The trial doctor feels that it is not in your best interest to continue in the trial.

If you experience any serious side effects during the course of the trial which require you to withdraw from the trial, your trial doctor will follow up with you regarding your progress until the side effect has stabilised or resolved.

15. What if there is a problem?

Any complaint about the way your participation has been managed during the trial or any possible harm you might suffer will be addressed. If you have concerns about any aspect of this trial, you should speak to your trial doctor who will do his/her best to answer your questions.

In the event that something does go wrong and you are harmed by taking part in the research and this is due to someone's negligence, then you may have grounds for a legal action for compensation against Cambridge University Hospitals NHS Foundation Trust, the University of Cambridge, or your treating hospital. The normal National Health Service complaints mechanisms will still be available to you. The University of Cambridge has obtained insurance, which provides no-fault compensation (i.e. for non-negligent harm), and you may be entitled to make a claim for this.

If you wish to complain or have any concerns about any aspect of the way you have been approached or treated during this trial, you can do this through the NHS complaints procedure. In the first instance, it may be helpful to contact the Patient Advice and Liaison Service (PALS) or the equivalent service at your hospital. The contact details can be found in section 21 of this information sheet.

16. Will my taking part in this trial be kept confidential?

Cambridge University Hospitals NHS Foundation Trust (CUH) and The University of Cambridge are the Sponsors for this clinical trial based in the United Kingdom. They will be using information from you and your medical records in order to undertake this trial and will act as the data controller for this trial. This means that they are responsible for looking after your information and using it properly. The Sponsor organisations will keep identifiable information about you for 5 years after the trial has finished to ensure your safety and allow the trial to be reviewed by the authorities after it is finished.

Your rights to access, change or move your information are limited, as the Sponsor organisations need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the trial, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how the Sponsors use your information using the information below:

- For Cambridge University Hospitals NHS Foundation Trust, please visit: https://www.cuh.nhs.uk/corporate-information/about-us/our-responsibilities/looking-after-your-information, or email the Data Protection Officer at: gdpr.enquiries@addenbrookes.nhs.uk

- For University of Cambridge, please visit: https://www.medschl.cam.ac.uk/research/information-governance/, or email the Information Governance team at: researchgovernance@medschl.cam.ac.uk

For participants recruited at CUH (where the Sponsor is also the site):

Cambridge University Hospitals will collect your name, NHS number and contact details to contact you about this trial, and make sure that relevant information about the trial is recorded for your care, and to oversee the quality of the trial. Individuals from the Sponsors and regulatory organisations may look at your medical and research records to check the accuracy of this trial. Cambridge University Hospitals will pass these details to the Sponsors along with the information collected from you and your medical records. The only people in the Sponsor organisations who will have access to information that identifies you will be people who need to contact you in relation to

this trial and to audit the data collection process. Cambridge University Hospitals will keep identifiable information about you from this trial for 5 years after the trial has finished.

Cambridge University Hospitals local team will collect information about you for this trial from the Hospital Episode Statistics database (HES). This information will include your name, NHS number, contact details and health information about your stay in hospital, which is regarded as a special category of information. The local team will use this information to record all relevant data about your stays in hospital during you participation in this trial. MRI imaging will take place at Wolfson Brain Imaging Centre (WBIC), University of Cambridge. Your MRI scans, medical and personal identifiable information (name, NHS number and contact details) will be stored at the WBIC for a minimum of 10 years after acquisition.

For participants recruited at other participating sites
(Add site name) will keep your name, NHS number and contact details to contact you about this trial, and make sure that relevant information about the trial is recorded for your care, and to oversee the quality of the trial. Certain individuals from the Sponsors and regulatory organisations may look at your medical and research records to check the accuracy of this trial. The Sponsors will only receive information without any identifying information. *(Add site name)* will keep identifiable information about you from this study for X years after the study has finished.

(Add site name) local team will collect information about you for this trial from the Hospital Episode Statistics database (HES). This information will include your name, NHS number, contact details and health information about your stay in hospital, which is regarded as a special category of information. The local team will use this information to record all relevant data about your stays in hospital during you participation in this trial, but no personal identifiable data will be sent to the Sponsor. Your MRI images labelled with your trial ID will be sent to Addenbrooke's Hospital for analysis and storage in line with the current regulatory requirements.

In case medication has to be sent to you by courier, local team will pass your contact details and home address to the authorised personnel of a courier company.

This trial will comply with data protection act 2018 and the General Data protection Regulation 2018s. All information collected about you as a result of your participation in the trial will be kept strictly confidential. Your personal and medical information will be kept in a secured file and be treated in the strictest confidence.

Once you have agreed to participate in this trial, you will be allocated a unique subject ID number, which will be used on trial documentation along with your date of birth. This unique subject ID number will be linked to your personal information; however, you will only be identified on trial documentation by this unique number and your date of birth. Your date of birth is considered to be personal information. We collect this personal information on trial documentation to help ensure that the data we receive as part of your trial participation is correctly allocated to you. By cross checking these two unique references we can ensure the integrity of the data.

Your personal information will form part of the trial data held by the local research team and will be used for monitoring, quality checking and analysis purposes. Only anonymous trial data, without any personal information, will be published at the end of the trial. The people who analyse the information will not be able to identify you and will not be able to find out your name, NHS number or contact details.

When you agree to take part in this trial, the information about your health and care may be provided to researchers running other research studies in this organisation and in other organisations. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad. Any serious side effects that occur during the trial will also be shared to the manufacturer of ibudilast (Medicinova, USA) using your trial-specific

identifiers.. The information will only be used for the purpose of health and care research, and cannot be used to contact you or to affect your care. It will not be used to make decisions about future services available to you, such as insurance.

Your coded trial data may be sent to other country(ies) outside the European Economic Area (EEA) for analyses, where the data protection laws are not the same. However this information will not identify you and will not be combined with other information in a way that could identify you.

We will need to inform your GP of your participation in this trial so that any medical decisions made by your GP account for any treatment you receive as part of this trial.

In the event that we are unable to contact you during the follow-up stages of the trial, we may contact your GP to obtain information about your health status.

17. What will happen to my samples?

Collected serum and cerebrospinal fluid (if applicable) samples will be labelled with a participant's unique trial ID and stored at your local hospital. Only authorised staff will have access to the trial samples. It will not be possible for laboratory staff to identify you based upon samples/sample labels. Samples will be transported periodically to the central trial laboratory at Cambridge University Hospitals NHS Foundation Trust, for central analysis.

Samples collected for this trial could be of great interest for future research and that is why we will ask you for optional consent to use any remaining sample in future research. Any future research performed on these samples will only undertaken if approval has been given by an independent Ethical Committee to ensure that your rights are maintained.

18. What will happen to the results of the trial?

The results of the trial will be anonymous and you will not be able to be identified from any of the data produced. When the results of this trial are available, they may be published in peer-reviewed medical journals and used for medical presentations and conferences. The results will also be published on the EU Clinical Trials Register website, a central registry for all clinical trials conducted in the EU.

Anonymous datasets from the trial may also be made available to other researchers in line with national and international data transparency initiatives.

You will be able to view trial results on the trial website: www.recede-myelopathy.org. Additionally, the local site team will contact you to inform you about when the results of the trial are available and how to access them.

19. Who is organising (sponsoring) and funding the trial?

This trial is jointly sponsored by Cambridge University Hospitals NHS Foundation Trust and The University of Cambridge.

This project was funded by the National Institute for Health Research. The drug company MediciNova will provide the drug ibudilast and matching placebo free of charge for this trial.

20. Who has reviewed this trial?

All research within the NHS is reviewed by an independent group of people called a Research Ethics Committee, to protect your interests. This trial has been reviewed and given favourable opinion by ##. The Medicines and Healthcare Products Regulatory Agency (MHRA), which is responsible for regulating medicines in the UK, has also reviewed this trial.

21. Further information and contact details

If you would like more information or wish to discuss any aspect of this trial, please call one of the research team members at any time, **…….. or ……** on the numbers below.

If you have any concerns about the trial, you may approach your local Patient Advice and Liaison Services (or equivalent) for independent advice [details to be provided locally].

Thank you for your time in considering this research. After you have signed the consent, please keep a copy of the consent form and this information sheet for future reference.

In the event of an emergency please contact:

[Details to be added for local contacts]

[TO BE PRINTED ON HOSPITAL HEADED PAPER]

PARTICIPANT INFORMED CONSENT FORM

Trial Title: **Re**generation in **Ce**rvical **De**generative **Myelopathy** - a multi-centre, double-blind, randomised, placebo controlled trial assessing the efficacy of Ibudilast as an adjuvant treatment to decompressive surgery for degenerative cervical myelopathy

Principal Investigator: [Printed name to be inserted]

Participant Number: _____

If you agree with each sentence below, please initial the box		**INITIALS**
1	I have read and understood the Participant Information Sheet version 2.1 dated 07/08/2020 for the above trial, and I confirm that the trial procedures and information have been explained to me. I have had the opportunity to ask questions and I am satisfied with the answers and explanations provided.	
2	I understand that my participation in this trial is voluntary and that I am free to withdraw at any time, without giving a reason and without my medical care or legal rights being affected.	
3	I understand that my personal information will be collected and used in accordance with the information sheet version 2.1 dated 07/08/2020. This information will be kept in the strictest confidence and none of my personal data will be published.	
4	I agree to my personal contact details being used by the local site team for the purpose of answering the questionnaires by email, post, or telephone.	
5	I understand that sections of my medical notes or information related directly to my participation in this trial may be looked at by responsible individuals from the sponsor, R&D department, regulatory authorities and research personnel where it is relevant to my taking part in research and that they will keep my personal information confidential. I give permission for these individuals to have access to my records.	
6	I understand my GP will be informed of my participation in this trial and sent details of the trial. I understand that the local site team may contact my GP to obtain health status information if I am uncontactable for the trial follow-up.	
7	I have read and understood the compensation arrangements for this trial as specified in the Participant Information Sheet.	
8	I have read and understood the arrangements should I have any concerns about my care or management of the trial, as specified in the Participant Information Sheet.	
9	I understand that the doctors in charge of this trial may close the trial or stop my participation in it at any time without my consent.	
10	I have read and understood my responsibilities for the trial including using appropriate contraception as listed in section 6.	
11	I agree to give blood samples for research in this trial. I understand how these samples will be collected and that giving these samples is voluntary. I understand that my labelled blood samples for research will be sent to central trial laboratories for storage and analysis.	
12	I agree to the use of the blood samples, data derived therefrom, and the results of the trial overall as specified in the Participant Information sheet	
13	I understand that if I withdraw or am withdrawn from the study, the samples that I have already provided will be retained for analysis.	

14	I agree to participate in this trial.		
OPTIONAL		**YES**	**NO**
1	I agree to give a cerebrospinal fluid (CSF) sample for research in this trial. I understand that my CSF sample would be sent to central trial laboratories for storage and analysis. I understand that if I withdraw or am withdrawn from the study, the CSF sample that I have already provided would be retained for analysis.		
2	I agree that materials obtained from remaining blood and CSF samples may be stored for 1 year after the end of the trial for future research. I agree to the storage of blood and CSF samples in the central trial laboratory and its research use, along with data collected in this trial (including date of birth) after independent Ethical Committee review and approval.		

_____ _____ _____

Name of patient Signature Date

_____ _____ _____

Name of person taking consent Signature Date

Time of Consent (24hr clock) _____:_____

1 copy for the patient, 1 original for the Investigator Site File, 1 copy to be retained in the hospital notes