What is the purpose of the study?
Motor neurone disease (ALS) affects approximately 2 people in every 100,000 in the UK. One of the main symptoms of ALS is breathlessness. The muscles that people use to help them breathe (the main muscle being the diaphragm) become weak and so patients cannot breathe as well as they once could. This study will determine if adding a new treatment to the usual treatments for ALS breathing problems are of benefit to patients.

What are we studying?
As you are aware, we are studying two different treatments in the two groups of this trial:
Arm 1 – Non Invasive Ventilation (NIV); in this group patients will be given NIV alone
Arm 2 – Diaphragm Pacing (DP) plus NIV; in this group patients will be given DP alongside NIV.
The purpose of this study is to find out if having the NeuRx/A4 Device fitted as well as receiving NIV may offer added benefits, such as prolonging life and improving quality of life, to receiving NIV alone. We do not know which treatment is better and this is why we are asking for your help.

In this part of the study we are asking the carers of patients who have had the DP device fitted to take part in 2 interviews. We would like to draw directly on both of your experiences and views of having DP within the context of everyday lives. Interviews will provide an opportunity to take account of your views and experience of the device.

Why have I been chosen?
As you are aware, you and your relative are already part of the DiPALS study. When you initially gave consent, you agreed to be contacted for the interview stage of the project. We would now like to invite you to participate in these interviews. You do not need to make a decision immediately as to whether or not you want to take part.
We are conducting these interviews on 12 patients and their carer's in this group. We are contacting people in Sheffield, Manchester, Oxford, Birmingham and Newcastle to take part.

Do I have to take part?
No. 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. If you wish to withdraw, your relative may remain in the study if they wish. We will ask you if you are happy for us to use the information that you have already contributed.

What will happen to me if I take part?
Your relative will have now had the DP device fitted and have been identified as somebody we would like to interview for this part of the research. If you consent, an experienced researcher will conduct the interviews at a time and location that is convenient for you. There will be 2 interviews for both you and your relative;

the first one 1 month after your relative's operation and the second one 6 months after their operation.
The first interview at 1 month will focus on the DP device and the practicalities of having the implant fitted and adjusting to life using the device.
The 6 month interview will focus on the impact the device has had on your quality of life. This will allow enough time for you and your relative to become familiar with the device and its impact on your life.

Ideally we would like you both to be interviewed separately but joint interviews can be undertaken if this is your wish. The interviews will take about half an hour, but might be shorter if your relative feels tired.

Are there any risks or discomforts?
We do not anticipate that participating in this part of the study poses any physical risk, but we appreciate that you may find it upsetting talking about your relative's experiences. If you become upset during the interview, we will stop and let you decide what you want to do. If you wish to postpone the assessments and interviews, this can be arranged. If you feel you want to withdraw from the study altogether you can do so without your relative's care being affected in any way.

What happens if I don't want to continue with the study?
You are free to withdraw from the study at any time and without giving a reason.

Will my taking part in the study be kept confidential?
All information which is collected about you during the course of the research will be kept strictly confidential, and any information about you which leaves the hospital will have your name and address removed so that you cannot be recognised. Interviews will be tape recorded and then transcribed to assist with analysis. Anything you say in your interviews will be treated in the strictest confidence, and although we might use direct quotes in anything we write as a result of this study, these will also be anonymised. These recordings and transcripts will be kept secure within the department and accessed only by the research team. They may also be looked at by authorised people to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant and we will do our best to meet this duty.

What happens if something goes wrong?
Any complaints should be addressed to the local study doctor in the first instance (contact details are given at the end of this information sheet). If you have any concerns about the study you should ask to speak to the researchers who will do their best to answer your questions [contact number]. If you remain unhappy and wish to complain formally, you can do this via the NHS Complaints Procedure. Details can be obtained from [insert site specific details].

What will happen to the results of the study?
We will publish the results in a scientific journal and produce a report that is freely available to anyone who wishes to read it. You will not be personally identified in any report or publication we produce. Please contact us using the

details below if you would like to see a summary of the results when the trial is completed.

Who is organising and funding the research?
The research is organised by the University of Sheffield and funded by the Department of Health and the Motor Neurone Disease Association.

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 Cambridge Central Research Ethics Committee.

Further information can be obtained from:
<insert local PI name>
<insert local PI hospital name>
<insert local PI hospital address>
<insert local PI telephone number>

Or contact the Chief Investigator:
Dr Christopher McDermott
Chief Investigator
Sheffield Institute for Translational Neuroscience
University of Sheffield