POsterior **L**aminectom**Y** and **FIX**ation for **D**egenerative **C**ervical **M**yelopathy

POLYFIX-DCM Study
Participant Information Sheet and Informed Consent Form

https://polyfix-dcm.com

Carer Quality of Life sub-study

You are receiving this information sheet and consent form because your relative/friend is taking part in POLYFIX DCM, a clinical trial, and we would like to invite you to provide information for a sub-study. 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 provide information for this sub-study.

Section 1 tells you the purpose of this sub-study and what will happen to you if you agree to provide information.
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 (DCM) can leave patients with permanent disability and reliant on others for support. The impact of the disease on their carers is not well known. This is why we want to assess the effect of this disease and its treatment on your quality of life as the participant's carer or potential carer. To do so, we will use the Care Related Quality of Life (CarerQol) questionnaire to measure the perceived burden and its effect on your happiness.

2. Do I have to take part?

Providing information for this sub-study is completely voluntary. If you decide to provide information for this sub-study, you will be given the opportunity to ask questions and then be asked to sign an Informed Consent Form. However, you are still free to change your mind and leave the sub-study at any time without giving a reason. Your relative/friend participation in the main trial will not be affected by your decision.

3. What will I have to do?

If you agree to provide information for this sub-study, 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.

You will be asked to complete the CarerQoL questionnaire initially, again at the time of surgery, and then at 6, 12 and 24 months afterwards. Each questionnaire will take up to 10 minutes to complete.

You will be asked to complete the questionnaires by yourself; all answers should be your view. You will be asked to complete the questionnaires when you accompany your friend or family member to the hospital for an appointment, or by post, email, or telephone. If you would prefer to answer the questionnaire over the phone, please let us know.

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

There are no risks or disadvantages for you when taking part in this trial.

5. What are the possible benefits of providing information for this sub-study?

There is no benefit for you when providing information for this sub-study.

However, the information collected in **POLYFIX DCM** trial will be useful in understanding the impact that DCM has on the lives of those supporting individuals with DCM.

6. What happens when the sub-study stops?

Once you have completed the 24 month questionnaire, you will have finished your involvement in the sub-study.

7. Expenses & Payment?

If we ask you to complete a postal questionnaire, we will send you a pre-stamped, addressed envelope to return the reply. You will not receive any payment for providing information for this sub-study.

Section 2: Trial Conduct

8. What if I decide I no longer wish to provide information for this sub-study?

You are free to stop providing information for this sub-study at any time without giving a reason. If you decide not to provide information any further, you will no longer receive follow-up questionnaires. Any information already provided will continue to be used in the sub-study; however, no further information will be collected.

9. What if there is a problem?

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

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 12 of this information sheet.

10. Will the information provided 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 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 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. 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

Where CUH is the recruiting site
Cambridge University Hospitals NHS Foundation Trust will keep your name and contact details to contact you about the trial, make sure that relevant information about the trial is recorded, and to oversee the quality of the trial. Cambridge University Hospitals NHS Foundation Trust may pass these details to the Sponsor organisations, along with information collected from you

Cambridge University Hospitals NHS Foundation Trust will keep identifiable information about you from this trial for 5 years after the trial has finished.

For participants recruited at other participating sites:
(Add site name) will keep your name and contact details to contact you about this trial, and make sure that relevant information about the trial is recorded and to oversee the quality of the trial. Certain individuals from the Sponsors and regulatory organisations may look at your 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 XX years after the study has finished.

All information collected from you in the sub-study will be kept strictly confidential. Your personal and follow-up questionnaires will be kept in a secured file and be treated in the strictest confidence. You may ask to see your personal information at any time and correct any errors if necessary.

Once you have agreed to provide information for this sub-study, you will be identified under the trial ID of your relative/friend along with your kinship to them. This unique ID number will be linked to your personal information; however, you will normally only be identified on trial documentation by this unique number.

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. However, this personal information will not be shared with any other third parties and will not be published in any way. Only anonymous trial data, without any personal information, will be published at the end of the trial.

This trial will comply with data protection regulations. Your contact details will be documented and securely kept by your local research team, separate from the trial data. All information provided for this sub-study will be transferred to the trial coordinating centre in Cambridge where it will be stored in a secure manner.

11. 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 Yorkshire & The Humber - Sheffield Research Ethics Committee.

12. 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 wish to make a complaint or have any concerns about any aspect of the way you have been approached or treated during this sub-study, you can do this through the NHS complains procedure. In the first instance, it may be helpful to contact your local Patient Advice and Liaison Services (or equivalent) at your hospital 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.

NIHR | National Institute for Health Research

Please insert a local logo with address here

SUPPORTER INFORMED CONSENT FORM - TELEPHONE

POsterior **L**aminectom**Y** and **FIX**ation for **D**egenerative **C**ervical **M**yelopathy

Principal Investigator: [Printed name to be inserted]

Participant Number: _____

Please initial the box, with the participant's initials, to confirm they have agreed to each statement		**INITIALS**
1	I have read and understood the Supporter Information Sheet – Telephone version 1.0 from 07/07/2022 for the above sub-study, and I confirm that the sub-study procedures and information have been read and explained to me over the phone and I understand this. I have had the opportunity to ask questions and I am satisfied with the answers and explanations provided.	
2	I understand that providing information for this sub-study is voluntary and that I may withdraw my consent at any time, without giving a reason and without my relative/friend participation in the trial being affected.	
3	I verbally give my permission for the collection, use and disclosure of my personal information in accordance with this information sheet version 1.0 from 07/07/2022.	
4	I verbally agree to my personal contact details being documented for the purpose of sending the questionnaires by email, post, or telephone.	
5	I understand that information collected in this sub-study may be looked at by responsible individuals from the sponsor, R&D department, regulatory authorities and research personnel where it is relevant to my involvement in this research and that they will keep my personal information confidential. I verbally give permission for these individuals to have access to my records.	
6	I have read and understood the compensation arrangements for this sub-study as specified in the Supporter Information Sheet.	
7	I verbally agree to provide information for the above sub-study and am aware that my involvement is entirely voluntary.	

_____
Name of participant (*to be completed by staff taking verbal consent*)

_____
Date participant verbally consented (*to be completed by staff taking verbal consent)*

_____ _____ _____
Name of person taking consent Signature Date

Witness Signature
When applicable: As an impartial third party, I witnessed the entire consent discussion. I attest that the above named participant received a verbal description of the study. This

individual had sufficient time to consider this information, had an opportunity to ask questions, and voluntarily agreed to participate in this study.

_____	_____	_____
Name of witness	Signature	Date

Time of Consent (24hr clock) _____:_____

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