Exploring Patient Outcomes in Pulmonary Rehabilitation (ExPORt)

Invitation & Summary

During your Pulmonary Rehabilitation programme we collect clinical data and we would like your permission to add this to the rehabilitation database and use this clinical information to

- Gain a better understanding of our pulmonary rehabilitation programme and its effect on respiratory diseases.
- To contact you at points in the future to how well you are managing your disease.
- To provide accurate information to patients about pulmonary rehabilitation.
- To try to improve the results of the rehabilitation.
- To explore the global results and share results appropriately.
- To contact you about future research trials that you may be suitable for.

What's involved?

The data we are interested in are part of your usual clinical care and include your medical history, exercise tests and questionnaire responses. We will only use the clinical information that is important to answering our research questions and provide reports on the clinical service. If you are happy for us to use your clinical information please check yes below. You will not need to do any extra testing outside of your usual clinical management.

What are the possible benefits of taking part?

The results from this data set help us shape our clinical service. This tells us when things are/ are not working. This may benefit you and other patients in the future.

What are the possible disadvantages or risks of taking part?

As this is part of your usual clinical management there are no identified risks to taking part.

How will my information be kept confidential?

Any information which allows identification of you as an individual is kept strictly confidential and where possible a unique identifier will be used instead. We will store all your information on a password protected database on secure computers. Only certain members of staff will access this database. Procedures for handling, processing, storage and destruction of your data are compliant with GDPR 2018. The paper records are retained and filed in your medical notes.

Regulating authorities will have access to anonymous data only for the purpose of monitoring the quality of the research and Pulmonary Rehabilitation service and ensuring patient safety. Anonymous data will be retained for 5 years within University Hospitals of Leicester NHS Trust. Results from any research studies that use clinical data will be disseminated in peer and lay journals, professional publications and in presentations at conferences. Results will be reported to respect confidentiality. No identifiable information will be published. You are entitled to see any results or information about you under the Freedom of Information Act 2000.

What will happen with the results of this study?

Results will be presented at conference and published in scientific journals. This will also help us with our service design.

Who has reviewed this study?

All research that involves NHS patients and staff, information from medical records or uses NHS premises must be granted a favourable opinion from the NHS research ethics committee prior to commencement. This study has been reviewed and given favourable opinion by the Leicester South Research Ethics Committee.

Patient Identification Number:

PATIENT CONSENT FORM

Exploring Patient Outcomes in Pulmonary Rehabilitation ExPORt

Patient to initial

Principal Investigator: Professor Sally Singh

1. I confirm that I have read and understand the patient information sheet dated **31/07/2019** **version 1** for the above study and have had the opportunity to ask questions. ☐
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 and that all data collected up until withdrawal will be retained. ☐
3. I understand that relevant sections of my medical notes and/or study data may be looked at by individuals from the study and clinical team, the sponsor, NHS Trust or from regulatory authorities where it is relevant. I give permission for these individuals to access my records. ☐
4. I would like to be contacted about further research opportunities ☐
5. I agree to take part in the above study. ☐

_____	_____	_____
Name of Patient	**Date**	**Signature**