To be printed on the local trust headed paper

DEVELOP-UK
A Study of Donor Ex-vivo Lung Perfusion in United Kingdom Lung Transplantation

Participant Information Sheet Version 5.0

You are being invited to take part in our research study as you have a severe lung disease that makes you a candidate for a lung transplant. Before you decide if you want to take part, it is important for you to understand why the research is being done and what is involved in taking part.

One of our research team will go through this information sheet with you and answer any questions you have about what the study involves, how your information will be used and what the possible benefits and risks of taking part are. Please take time to read the following information carefully. Talk to others about the study if you wish. Please ask if there is anything that is not clear or if there is anything you would like more information about. Take time to decide if you wish to take part.

Part 1 tells you about the purpose of this study and what will happen if you take part.

Part 2 gives you general information about how the study will be conducted.

PART 1
Study Summary

Each year a number of patients on the transplant waiting list do not survive long enough for suitable matching donor lung(s) to become available.

The shortage of organ donors in the United Kingdom has made it even more difficult for those waiting for lung transplant, as donor lungs are very delicate and often deteriorate due to events that happen before the lungs are removed from the donor. The effect of this is that currently only 1 in 5 or 20% of the potential donor lungs available in the UK are currently acceptable for use in lung transplant surgery. Despite a lot of effort to promote organ donation recently, there remains a major shortage of usable donor lungs for UK patients waiting for lung transplantation.

In this study, a new technique called **Ex-Vivo Lung Perfusion** or **EVLP** will be tested to find out how effective it is at increasing numbers of lung transplants performed, by turning previously unusable donor lungs into lungs which can be safely used for transplant. EVLP involves attaching the donor lungs, after they are removed from the donor, to a modified heart-lung bypass machine for several hours. The modified bypass machine pumps a specialised nutrient liquid through them, while at the same time provides the lungs with oxygen via a breathing machine. The EVLP technique has been used successfully in an increasing number of lung transplant centres around the world to improve the condition of

otherwise unusable donor lungs so that they can be given successfully to patients awaiting lung transplant.

Although, there are promising early results, the EVLP technique has not been tested in a controlled clinical trial that assesses whether EVLP is an effective way to increase the number of donor lungs available for lung transplantation. The **DEVELOP-UK** study will aim to answer this question.

The UK is in a very good position to conduct this study as most of the UK lung transplant centres have already developed some experience with the EVLP technique with 17 patients on UK lung transplant waiting lists receiving EVLP assessed and improved donor lungs. By August 2011, this meant 25% of lung transplants performed worldwide using EVLP have been done in the UK. Our experience to date suggests that approximately half of the donor lungs treated with EVLP can be improved successfully for transplant. This means many of the 80% of donor lungs currently found to be unusable may have the potential to be improved sufficiently to be used for lung transplantation.

What is the purpose of the study?
It has been shown that the current method used to assess whether potential donor lungs are usable for lung transplantation is not optimal. This suggests that many donor lungs deemed unusable could in fact be suitable for lung transplantation. EVLP may therefore allow many previously unusable donor lungs to be carefully assessed and improved for safe use in lung transplantation. This would help to significantly increase the chances of a suitable donor organ being found for patients on the lung transplant waiting list.

The **DEVELOP-UK** study has been designed to carefully assess the results of lung transplants performed with donor lungs which have been assessed and improved with EVLP compared to those done with standard donor lungs.

Donor lungs offered but considered not suitable for standard transplant, will be transferred to the transplant centre where they will be placed on the EVLP system. The donor lungs will then be monitored for up to 4 hours to measure how well their function improves and to make sure there is no irreversible damage present. If their function improves to a level where they can pass a rigorous assessment, the donor lungs are then offered to a patient on the lung transplant waiting list who has given their prior agreement to take part in the study.
The study will be deemed a success if it shows that survival in the first 12 months after lung transplant is as good in patients who have received EVLP improved donor lungs as in patients who received standard donor lungs.

The DEVELOP-UK research team will also look to see if there are any more early complications, such as a longer stay on intensive care, more frequent infections or more episodes of transplant rejection, in patients who have received EVLP improved donor lungs compared to standard donor lungs.

A Quality of Life Questionnaire will be used to assess whether changes in quality of life in the first post-transplant year in patients who received EVLP assessed and improved donor lungs are similar to those in patients who received standard donor lungs.

Finally, the cost to the NHS of using the EVLP technology will be calculated. All the information generated in the study will be used by the NHS commissioners, who pay for UK

transplant services, to decide if this technique can be adopted as part of normal practice in the future.
In addition, by carrying out **detailed interviews** with some of the patients agreeing to take part in the DEVELOP-UK study, the research team will try to understand the experiences and any concerns expressed by patients about undergoing transplantation with EVLP donor lungs. This will enable clinicians to address effectively any patient concerns in the future.

Why have I been invited?
You have been invited to participate in this study because you are 18 years old or over and you have either already been accepted onto an active lung transplant waiting list in the UK or are under serious consideration for potential lung transplantation in one of the adult lung transplant centers.

Do I have to take part?
It is up to you to decide whether to take part in the study. You do not have to participate if you do not wish to. However, if you do decide to participate, the research team will describe carefully to you what the study involves and give you this information sheet to keep. The team will explain how decisions are made about donor lungs' usability for lung transplantation and why the majority are felt unusable for standard lung transplantation.

They will also explain which unusable donor lungs are suitable for EVLP and how their function after EVLP is assessed to decide if they have become usable for lung transplant. The donor lungs assessed and improved by EVLP have to reach the same level of function as standard lungs before they will be considered usable for lung transplantation. The research team will provide firm reassurance that if donor lungs do not improve sufficiently after EVLP they will not be used for transplantation.

All the questions you have about the study will be answered by the team. You will be given time to think this over and talk to your family and friends about it. If you agree to take part, you will be asked to sign either an expression of interest form and then a consent form or the consent form itself depending on whether the discussion with you has happened in person or over the telephone.

As the time between going on the waiting list and getting a lung transplantation varies widely and can in some cases exceed 12 months, you will be asked to reconfirm your consent when you are called in and offered transplantation with an EVLP assessed and improved donor lung(s). However, if you sign the consent form on the day of transplant you do not need to reconfirm your consent. The clinical transplant team will inform you whether you are to receive an EVLP assessed and improved donor lung or a standard donor lung. You will not be asked to reconfirm your consent if you have signed the consent form prior to being called in for transplantation and are offered transplantation with standard donor lung(s).

If you decide to take part you are still free to withdraw from the study at any time and you do not have to give a reason. This will not affect the standard of care you receive either now or in the future. If you decide not to participate, you will have equal access to donor lungs for standard transplant but would not be considered for donor lungs that have undergone EVLP assessment and improvement.

What will happen to me if I take part?

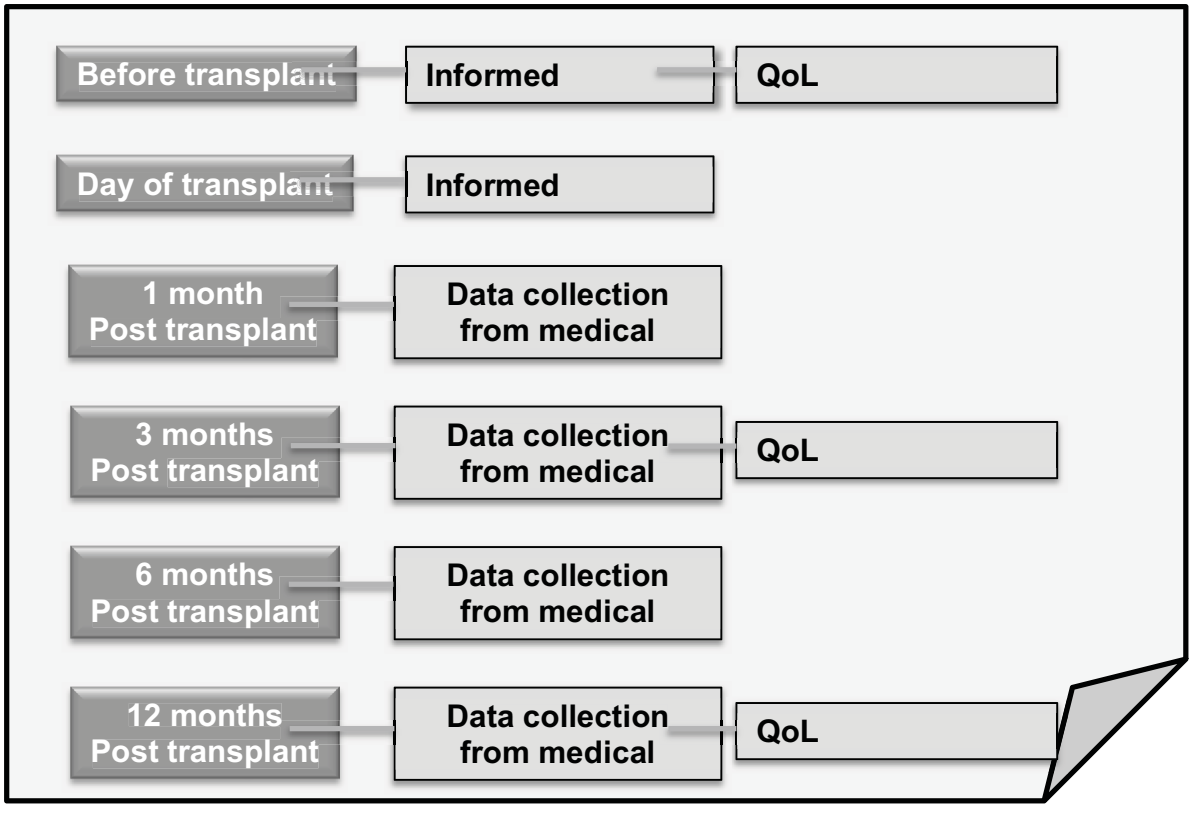
This is an observational study. It means that no extra tests or procedures will need to be done on you. The EVLP process to assess whether the donor lungs have improved enough for use in a lung transplant is performed before any transplant surgery is started.

You will not need any extra clinical visits to hospital or your GP as a result of being in the study. All your hospital visits will be arranged by the transplant team as a part of routine care after lung transplant. Collection of your information for the purposes of the study will be coordinated with your routine post-lung transplantation clinic visits.

The research team will ask if you are willing for them to collect data that can be extracted from your medical records. If you were to *lose capacity* (become unable to decide whether to carry on with the study) over the follow-up period, the research team will aim to continue data collection from your medical notes. This will not impact on the standard of medical care you receive. Once you have signed an expression of interest form or informed consent form for the DEVELOP-UK we will ask you to complete a Quality of Life Questionnaire. It will take you approximately 15 to 20 minutes.

When you are called in for possible transplantation, the transplant team will explain to you whether you are to receive EVLP-assessed and improved donor lung(s) or standard donor lung(s). If you have signed consent form before the day of transplant you will be asked whether you wish to reconfirm your consent and continue to participate in the study if you are offered EVLP assessed and improved donor lung(s) but not for standard donor lung(s). If you sign consent form on the day of transplant you do not need to reconfirm your consent. If you decide not to continue in the study then any possible transplant with EVLP assessed and improved lungs will not go ahead.

Following lung transplantation you will be asked to complete the same Quality of Life Questionnaire 3 months and 12 months after your lung transplant (see the diagram below).



Expenses and payments
This is an observational study. As all the information needed for the study will be collected when you are already attending the transplant centre for routine clinic visits, there are no payments made to you to participate in the DEVELOP-UK study.
What will I have to do?
Please consider carefully the clinical and research aspects of the study.

The study visits will be coordinated to coincide with your routine clinic visits at 1 month, 3 months, 6 months and 12 months after your lung transplantation. The data we collect for this study will be part of your routine follow up care and recorded from your medical notes and from computerised results in the hospital.

If you decide to participate in the DEVELOP-UK you will need to complete a Quality of Life Questionnaire before lung transplantation, and then at 3 and 12 months after receiving your lung transplant.

If you have been taking part in another clinical or drug study in the past 12 months please discuss this with the study doctors. It may not prevent you from participating in the DEVELOP-UK study. After undergoing lung transplantation you should not participate in any clinical study that might affect your standard post-transplant care for 12 months. After this 12 months post-transplant period you can participate in any clinical or drug studies as you wish. Please contact the study doctor if you have any questions. If you wish to participate in any observational studies before or after lung transplant please discuss it with the study doctor.

What are the alternatives for diagnosis or treatment?

For selected patients suffering from long lasting severe lung disease, lung transplantation is the only realistic therapeutic option.

What are the possible disadvantages and risks of taking part?
The main risk of taking part in the study is that you might receive an EVLP assessed and improved donor lung that does not function well after transplant. This could mean requiring a longer stay in the intensive care unit to give artificial support to the transplanted lung or even death. However, similar risks also exist for standard donor lungs as a significant proportion of standard donor lungs do not function well after lung transplant. The DEVELOP-UK study is designed to address the question as to how effective the EVLP technique is at safely increasing availability of donor lungs. By May 2013, worldwide experience in more than 150 patients suggests that transplanted EVLP assessed and improved lungs are likely to work as effectively as standard donor lungs. Any possible risks of taking part in the study should be balanced against the risk of not receiving a lung transplant at all because a standard donor lung has not been available in adequate time.

Transplanted lungs, whether standard or EVLP assessed and improved, always remain vulnerable to the possibility of rejection and one of the main risk factors is low immunosuppression levels. Therefore prior to being accepted onto the transplant list you were counselled about the absolute necessity to comply with your treatment and to attend all arranged post-transplant follow-up appointments.

Topics in the Quality of Life Questionnaire that you will be asked to complete will include your views about how much your condition affects your health, your regular daily activities and your emotional state. It is possible that you may find some of these questions upsetting due to their nature. It also includes such topics as bodily pain, depression and your social life. Please be assured that all of your responses are entirely confidential.

What are the possible benefits of taking part?
By agreeing to take part in the DEVELOP-UK study you may have access to a larger number of potential matching donor lungs for your transplant. This is because EVLP allows otherwise unusable donor lungs to be meticulously assessed and potentially improved for successful lung transplantation. This technology therefore may have the capacity to reduce the time an individual spends on the waiting list for lung transplant.

What happens when the research study stops?
This is an observational study. Therefore there will be no change to your standard medical care throughout and after the study.

What if there is a problem?
Any complaint about the way you are dealt with during the study or any possible harm you might suffer will be addressed. The detailed information on this is given in Part 2.

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

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
General information

What if relevant new information becomes available?
If new information about the EVLP technique, that might affect the way the study is conducted, becomes available, your study doctor will tell you and discuss whether you should continue in the study. If you decide not to carry on, your standard medical care will not be affected and you will have equal access to standard donor lungs for transplant.

What will happen if I don't want to carry on with the study?
You can withdraw from the study at any time, and without giving a reason. However, we might ask you if you are happy for us to record why you have decided to withdraw.

If you initially agreed to participate in DEVELOP-UK but then decided to withdraw on the day of transplantation, then any possible transplant with EVLP assessed and improved lungs will not go ahead. If you are to receive standard donor lungs but decided to withdraw from the study then no follow up data will be collected from your medical notes. If you have signed initial consent, then (if necessary) reconfirmed your consent on the day of transplant to receive EVLP assessed and improved donor lung(s) and then received the transplant but decided to withdraw later, data collected up to the point of withdrawal will be retained.

What if there is a problem?
If you have a concern about any aspect of this study, you should speak to the study doctor who will do their best to answer your questions (add local contact details). If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details of how to complain can be obtained by contacting (add local contact details (Trust PALS))

In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for legal action for compensation; however you may need to meet your own legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate). NHS Indemnity does not offer no-fault compensation (i.e. for harm that is not anyone's fault). Neither the sponsor (The Newcastle upon Tyne Hospitals NHS Foundation Trust) who has undertaken to manage the study, nor the management of the hospital/research centre you are attending for your routine treatment, is able to agree in advance to pay compensation for non-negligent harm.

Will my taking part in this 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/surgery will have your name and address removed so that you cannot be identified.

The data that is collected from your clinical notes will be entered onto a secure computer database. Access to this database will be password protected and available to your doctors and the research staff for the purpose of the study. All data stored on the computer will be coded and your name will not appear. You will be given a unique study number under which all data and test results will be entered. These data will be analysed to find out how well

EVLP assessed and improved donor lungs function in comparison with standard donor lungs after transplantation. The analysis of the data we obtain from Quality of Life Questionnaire will be used to measure the health related costs of the EVLP technique.

If you join the study, some parts of your medical records and the data collected for the study will be looked at by authorised persons from the sponsor of this study (The Newcastle upon Tyne NHS Foundation Trust) or their representatives. They may also be looked at by authorised people from regulatory authorities and the Newcastle Clinical Trials Unit to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant and will do their best to meet this duty. All the information about your participation in this study will be kept confidential. All data will be stored for at least 15 years and then disposed of securely. Your data will not leave the UK nor will it be passed onto anyone outside of this study.

Involvement of the General Practitioner/Family doctor (GP)
We will ask you specifically if you want your GP to be informed about your participation in DEVELOP-UK. You can refuse for your GP to be informed without giving any reasons.

What will happen to any samples I give?
No samples will be collected from you that are not part of your standard medical care. However at the start and at the end of the EVLP process the research team will take a small sample of lung tissue from the donor lung. These samples will be studied by the research team themselves to help understand how EVLP is working. Some of this work might be done in partnership with other academic organisations or companies both inside and outside the UK. No identifiable personal information will accompany any samples.

What will happen to the results of the research study?
The results from this study will be published in widely read medical journals which review the quality of the results and will be presented at national and international medical meetings. The results will also be reported to the Sponsor (The Newcastle upon Tyne NHS Foundation Trust) and Funders (National Institute for Health Research Health Technology Assessment Programme in the Department of Health and Cystic Fibrosis Trust), and will be available on the study website www.develop-uk.net. As a participant in the trial you will not be identified from any publication, study report or presentation. You will be informed about your contribution to the study at the end of the study, including a summary of the results.

Who is organising and funding the research?
The research is being organised and delivered by a team of researchers from across the UK including representatives from all 5 adult lung transplant centres. Professor Andrew Fisher from The Institute of Transplantation at Freeman Hospital, Newcastle and Newcastle University is the Chief Investigator and the Newcastle University Clinical Trials Unit is managing the study. The work is supported by a Project Grant awarded from the Department of Health via the National Institute for Health Research Health Technology Assessment Programme and by funding from The Cystic Fibrosis Trust UK.

Who has reviewed the study?
All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given a favorable opinion by NRES Committee North East - Sunderland. The Chief Executive of the Newcastle upon Tyne Hospitals NHS Foundation Trust has agreed to provide indemnity for

the study in terms of its management. The conduct of the study at [please add Trust/centre name], for your treatment has indemnity cover through the normal NHS schemes.

The NHS is trying to improve the quality of clinical and research standards. This is being achieved through 'clinical governance'. As part of this process, this study may be reviewed by a clinical governance team. Such a team would need to look at any information that you provide us with, to make sure that the research was carried out in accordance with proper procedures.

Further information and contact details
For further information about the study you can speak to one of the Study Team:

Dr: PI's name + contact details
Research Nurse: Name + contact details

Alternatively you can speak to the Independent contact: please add local independent contact.

Emergency out of hours contact details: Name and contact details

Thank you for taking the time to read this information sheet

Participant Information Sheet Interview Study v 1.0, 1 November 2011

To be printed on the local trust headed paper

DEVELOP-UK
A Study of Donor Ex-vivo Lung Perfusion
in United Kingdom Lung Transplantation

Interview Study

Participant Information Sheet Version 1.0

You are being contacted because you expressed an interest in receiving more information about the interview component of the DEVELOP-UK study. We are sending you this participant information sheet to help you to decide whether you would be willing to take part in an interview about your views and experiences. This is entirely **optional** and you are under no obligation to take part. If you decide you do not want to be interviewed this will have no effect on your involvement in the rest of the DEVELOP-UK study. **If you do not want to take part, you do not need to do anything further.** We will not contact you again about this matter. However, if you are still willing to take part in an interview we would like to give you more information to help you to decide.

To help you to decide if you want to take part in the interview study, it is important that you understand why the research is being carried out and what it will involve for you. Please take time to read the following information carefully, and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. If, having read this information, you are interested in taking part in the interview study please either call the research team directly on 0191 222 3805 or return the form (attached at the end of the information sheet) in the enclosed Stamped Addressed Envelope and they will call you to arrange the interview.

Part 1 tells you the purpose of this interview study and what will happen to you if you take part.
Part 2 gives you general information about the conduct of the study.
Please ask us if there is anything that is not clear.

PART 1
Study Summary

Ex-vivo lung perfusion or EVLP is a new technique that allows assessment and improvement of poorly functioning donor lungs so that they can be safely used in lung transplantation. To date research related to people's experiences of receiving a donor organ is very limited. We know that waiting for a transplantation impacts on patients and their families and we would like to speak with patients about their experiences. We also do not know what patients think about EVLP. Therefore we would like to conduct interviews with patients either before or after lung transplantation, and with some patients both before and after. The interviews will help the research team to understand your experiences of waiting for lung transplantation, your hopes and expectations of EVLP and, if you receive EVLP assessed and improved lung, your views of living with an EVLP transplant.

What is the purpose of the study?
The aim of this interview is to understand more about your views of EVLP before and after lung transplantation.

Why have I been invited?
You have been invited to participate in this sub-study because you have expressed an interest in taking part in the DEVELOP-UK Study.

Do I have to take part?
It is up to you to decide whether to join this interview sub-study. If you do decide to participate, we will describe carefully what is involved with the study and give this information sheet to keep. You will be given time to think this over and talk to your family and friends about it.

This interview study is purely optional – you do not have to take part. It would not affect your participation in the DEVELOP-UK study. If you agree to take part, you can withdraw at any time without giving a reason and you will not be asked to participate in this interview study again.

What will happen to me if I take part?
Once you have indicated that you are willing to be interviewed then one of the DEVELOP-UK research team from the Institute of Health and Society, Newcastle University will contact you by telephone and discuss the interview study with you and will answer any questions you have.

We will ask you whether you prefer to be interviewed face to face either at your home or in a suitable hospital room, or you may choose to be interviewed by telephone. If you choose to be interviewed in the hospital we will arrange for the interviews to take place during your usual appointments at the transplant centre.

We will ask you to sign a consent form which shows that you agree to take part. If you decide to be interviewed face to face, the consent form will be signed before the interview occurs. You can invite your relative or another person who cares for you to participate in an interview with you. A separate consent form will be provided for her/him. If you decide to have the interview by telephone we will go through the consent form with you and record you verbal consent.

We are approaching you as we would like to speak to people at different times; we would like to speak to people who are waiting for a transplant or who have already had a lung transplantation operation. Interviews will last approximately 45-60 minutes although may be slightly longer or shorter.

If you are waiting for a lung transplant we would like to talk about the following topics during the interview:

- Your view of your health and experience of living with your condition
- Your experience of waiting for lung transplantation
- Your understandings of EVLP and its acceptability in comparison with other donor lungs
- Your hopes and expectations for EVLP

If you have already had a lung transplant we would like to talk about the following topics during the interview:

- Recollection of your health and experiences before the operation
- Your accounts of waiting for a transplant
- Your views and experiences of receiving and living with an EVLP transplant (if you received EVLP assessed and improved donor lung)

All interviews will be recorded. This is to help the researcher listen to the discussion and accurately record what is being said. These tapes will be transcribed and the study team will securely store both the tape and transcription. All data will be confidential and all data will be anonymised.

Expenses and payments

The interviews performed in this study will be conducted either during a routine visit to the transplant clinic, in your own home or over the telephone. We will therefore not be able to pay for you to participate in the Interview study for DEVELOP-UK. If a telephone interview is chosen then the researcher will telephone you at our expense.

What will I have to do?

Please consider carefully all aspects of the Interview Study. This study is purely optional and will not affect your participation in DEVELOP-UK. You can withdraw at any time without giving any reason.

If you like, a relative or another person who cares for you can also be interviewed with you. If you decide to take part you and your relative or person who cares for you will also need to sign a consent form. Once we receive your signed form indicating you are interested in taking part in the Interview Study, one of our research team members will contact you to arrange the time of the interview either at a place of your choice or over the telephone. Each interview will last approximately 45-60 minutes.

What are the possible disadvantages and risks of taking part?

You may find some of the topics and issues discussed during interviews upsetting. We would like to know how much your health, regular daily activities and personal relationships were affected before and after lung transplantation, and we will discuss specifically your views and experiences of EVLP.

Please be reassured that all of your responses are entirely confidential. If you do become upset at any time you can choose to stop the interview immediately. We will only continue with the interview if you are happy for us to do so.

What are the possible benefits of taking part?

There are no direct benefits from taking part in this interview study but it will help us to understand what you think and expect from EVLP. Understanding what patients think plays a very important part in the possible successful introduction of this new EVLP technique to lung transplantation in the UK.

What if there is a problem?

Any complaint about the way you have been dealt with during the Interview study will be addressed. Detailed information on this is given in Part 2.

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.

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
General information

What will happen if I don't want to carry on with the Interview Study?
You can choose to stop the interview at any time for any reason, and without giving a reason. If you do so you can choose whether to have the earlier part of the interview destroyed, or whether you are willing for the research team to use the data they have collected.

If you are approached whilst you are waiting for transplantation, there is a chance we will contact you again after your transplant operation to find out more about your experience.

You can withdraw from the Interview study at any time for any reason, and without giving a reason. If you decided to withdraw, data collected up to the point of withdrawal will be retained.

What if there is a problem?
If you have a concern about any aspect of this study, you should speak to the study researcher who will do their best to answer your questions (Dr Catherine Exley, Institute of Health and Society, Newcastle University [redacted]).

If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details of how to complain can be obtained by contacting (Dr Catherine Exley, Institute of Health and Society, Newcastle University [redacted]).

In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for legal action for compensation; however, you may need to meet your own legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate). NHS Indemnity does not offer no-fault compensation (ie. for harm that is not anyone's fault). Neither the sponsor (The Newcastle upon Tyne Hospitals NHS Foundation Trust) who has undertaken to manage the study, nor the management of the hospital/research centre you are attending for your routine treatment, is able to agree in advance to pay compensation for non-negligent harm.

Will my taking part in this 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/surgery will have your name and address removed so that you cannot be recognised.
The data we collect from your interviews will be entered onto a secure database. Access to this database will be password protected. All data stored on the computer will be coded and your name will not appear. The analysis of your interviews will help us to improve future practice development.

If you join the interview study, some parts of your interviews may be looked at by authorised persons from the sponsor of this study (Newcastle upon Tyne NHS Foundation Trust) or their representatives. However, none of your personal information will be linked with extracts of your interview. They may also be looked at by authorised people from regulatory authorities and the Newcastle Clinical Trials Unit to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant and will do their best to meet this duty. All the information about your participation in this study will be

kept confidential. All data will be stored for at least 15 years and then disposed of securely. All the information collected will be managed by the study team only and will be destroyed after a period of fifteen years.

What will happen to the results of the research study?
The results from this interview study will be published in professional journals where the quality of the results will be assessed. In addition results will be presented at national and international meetings. The results will also be reported to the Sponsor (the Newcastle upon Tyne NHS Foundation Trust) and Funder (National Institute for Health Research Technology Assessment Programme in the Department of Health and the Cystic Fibrosis Trust), and will be available on the study website www.develop-uk.net. As a participant in interview study you will not be identified from any publication, study report or presentation.

A summary of the findings of the interview study will be made available to you at the end of the whole study.

Who is organising and funding the research?
The Interview study is being led by Dr Catherine Exley who is based at Newcastle University's Institute of Health & Society. The people who are doing the interviews either work directly with Dr Exley at the University or are nurses at one of the transplant centres. The work is supported by a Project Grant awarded from the National Institute for Health Research Health Technology Assessment Programme and the Cystic Fibrosis Trust.

Who has reviewed the study?
All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given a favourable opinion by NRES Committee North East - Sunderland. The Chief Executive of the Newcastle upon Tyne Hospitals NHS Foundation Trust has agreed to provide indemnity for the study in terms of its management. The conduct of the study at (please add Trust/centre name), for your treatment has indemnity cover through the normal NHS schemes.

The NHS is trying to improve the quality of clinical and research standards. This is being achieved through 'clinical governance'. As part of this process, this study may be reviewed by a clinical governance team. Such a team would need to look at any information that you provide us with to make sure that the research was carried out in accordance with proper procedures.

Further information and contact details
For further information about the study you can speak to one of the Study Team:
Dr Catherine Exley
Institute of Health and Society
Newcastle University
[redacted]
Research Nurse: Name + contact details.
Alternatively you can speak to the Independent contact: please add local independent contact.
Emergency out of hours contact details: Name and contact details

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

Please return this page to us in the enclosed stamped addressed envelope if you are willing to be interviewed

I am interested in taking part in the Interview study.

I am happy for a member of the research team at the Institute of Health and Society, Newcastle University to contact me to arrange a convenient time for me to take part.

Please contact me:

Name: ----------

Address: ----------

Telephone: ----------