

*To be printed on the local trust headed paper*

Date:

Patient's name and Address:

Dear.....

RE:

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

I am contacting you because you are on the active waiting list for a lung transplantation and would like to invite you to consider taking part in the **DEVELOP-UK** study. This letter will be followed by a telephone call within one week by one of the research team to answer any questions you may have after reading the detailed patient information sheet and to ask about your willingness to take part.

The **DEVELOP-UK** study is funded by the Department of Health and the UK Cystic Fibrosis Trust and is being performed in all 5 adult lung transplant centres in the UK. The study aims to examine how effective a new technique called Ex-Vivo Lung Perfusion (known as EVLP) is at assessing and improving the function of donor lungs before transplant.

The shortage of donor lungs is made worse because many possible donor lungs are found to be unusable for transplant because their function is not good enough. EVLP is a new technique in which unusable donor lungs which have poor function or in which the function is uncertain, can be carefully assessed and often improved to allow their safe use in lung transplantation.

However EVLP is not yet part of standard practice and the **DEVELOP-UK** study will test whether this new technology is effective at safely increasing the number of lung transplants performed in the UK and help decide if it should become standard practice. The study will observe how the condition of patients who have received EVLP assessed and improved donor lung(s) compares in the first 12 months after their transplant to patients that have received standard donor lung(s).

Agreeing to take part in the study means you may be offered the chance of receiving EVLP assessed and improved donor lung(s) if they are found to be a good match for you. This will certainly increase the number of possible donor lungs available to you but may not necessarily mean you will get your transplant performed more quickly. You will not need any extra visits to the hospital for the study as all results will be collected at the time you attend for your usual hospital visits after transplant.

The study also involves completing a short **Quality of Life Questionnaire** before your transplant surgery, and at 3 and 6 months after receiving a lung transplant.

Some but not all patients taking part in the study will be invited to take part in a **detailed interview** with a researcher to identify, describe, and understand views of

EVLP before and after lung transplantation. Taking part in the interview is optional and does not affect your opportunity to participate in the **DEVELOP-UK** study.

In order to provide you with more information about the study, I have enclosed a detailed patient information leaflet. Please read the leaflet and feel free to discuss the study with your family and/or friends.

After you have had a telephone call from the research team we will ask you to complete the **Expression of Interest Form** that accompanies this letter. It will ask you to declare whether or not you are interested in taking part in the **DEVELOP-UK** study.

When your completed **Expression of Interest Form** is received your response will be recorded on the transplant waiting list. If you declared an interest in participating in **DEVELOP-UK** you will be able to sign the Informed Consent Form when you attend a hospital appointment at the transplant centre or when called into the transplant centre for a potential lung transplant. When you are called for a potential lung transplant you will be told whether you are to receive a standard donor lung(s) or an EVLP assessed and improved donor lung(s). If you have been told that you are to receive an EVLP assessed and improved donor lung (s), then you will be asked whether you wish to continue with the study and confirm your consent.

Thank you for taking the time to read the information sheet regarding this research study. Please tick the appropriate boxes on the form, and return it in the enclosed reply-paid envelope. If you do not wish to take part you don't have to return the form, but it would be helpful for us if you could.

If you have any questions please do not hesitate to contact me:

(Name and signature of local PI and contact phone number)

## DEVELOP-UK Expression of Interest Form

<b>Name (capitals)</b>	
<b>Date</b>	
<b>Signature</b>	
<b>Telephone number and/or email address</b>	
<b>Best time to contact me</b>	

*Please initial all boxes that apply*

**Yes, I am interested in taking part in the DEVELOP-UK study.**

**Initial in box**

I understand that I can withdraw my interest at any time and that my current and future care will continue exactly as before.

**No, I am not interested in taking part in this research study.**

**Initial in box**

I understand that my current and future care will continue exactly as

Before but I understand I can change my mind in the future and contact the transplant team to express my interest.

**If you answered YES to an interest in taking part in the DEVELOP-UK study, please complete the question below about the Interview study:**

**Yes, I am willing to be contacted about a detailed interview with a researcher.** I understand that I can withdraw my interest in this interview at any time and that my participation in DEVELOP-UK study will not be affected.

**Initial in box**

**No, I do not wish to be contacted about a detailed interview with a researcher.** I understand that my participation in the DEVELOP-UK study will not be affected.

**Initial in box**

Please return the completed Expression of Interest Form in the enclosed prepaid envelope to:

Address of the relevant transplant centre