

Letter to GP v 1.0, 1 November 2011

To be printed on the local trust headed paper

Date:

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

Dear Dr

Patient's Name: _____

Address: _____

DOB: _____

Your patient has agreed to participate in the DEVELOP-UK study.

This observational study aims to examine survival during the first 12 months after lung transplantation in recipients of ex-vivo lung perfusion (EVLP) assessed and reconditioned donor lungs (treatment group) compared to that of recipients of standard donor lungs (control group), in order to assess whether survival in the EVLP treatment group over that period is non-inferior to that in the standard control group.

DEVELOP-UK will also evaluate early clinical outcomes and changes in Quality of Life in the treatment and control group in their first post-transplant year; assess (by statistical modeling) the survival benefit for waiting list patients and determine if EVLP is a cost-effective intervention for the NHS to support as standard care within UK lung transplant centers in the future.

An optional qualitative sub-study will be based on interviews with patients awaiting lung transplantation (and their carers) and with patients receiving EVLP reconditioned lungs to explore their attitudes towards and experiences of EVLP.

Please find enclosed a copy of the information sheet given to your patient.

Please do not hesitate to contact me for any queries relating to the study, or to report any untoward symptoms experienced by patient. I can be contacted on the following telephone number:

(Name of local PI and contact phone number)

Yours sincerely



**Update on DEVELOP-UK Study
Donor Ex-vivo Lung Perfusion in United Kingdom Lung Transplantation**

Date

Dear XXXX

I am writing to update you with some new information about the **DEVELOP-UK** study.

You will recall that this study is running in all the United Kingdom lung transplant centres and is designed to investigate a technique called ex-vivo lung perfusion (or EVLP). The study is assessing how effective EVLP is at improving donor lungs that are currently not suitable for transplant, to allow them to be safely transplanted.

Previously, you were contacted by our research team with information about the DEVELOP-UK study and have already signed an expression of interest form or a consent form, confirming your interest in taking part in the study.

As the study has progressed, the investigators leading the study in each of the 5 UK centres have met regularly to review progress and to learn from other experiences with EVLP around the world. This information is then shared with the independent Trial Oversight Committees.

Experience with the EVLP technique has been growing steadily around the world since the study began in April 2012. This includes experience using the specific EVLP machine that is being used in the DEVELOP-UK study. In particular, we were aware that an alternative way of using the machine, differing from our approach in only a few details, appeared to result in more donor lungs being available for transplant. In response to this, and with agreement from the Trial Oversight Committees, the investigators have made some changes to the way the EVLP technique is performed in the DEVELOP-UK study.

These changes mean that we are now using the machine in a way that in some other centres, results in a higher proportion of lungs being available for transplant as well as with good early results after transplant.

I have included with this letter an updated participant information sheet for your records. I encourage you to read this and if you have any questions please do not hesitate to contact us. In the first instance you can contact XXXX the DEVELOP-UK study research nurse at the hospital.

Your participation in the study remains entirely voluntary and I would remind you that before any transplant with EVLP improved lungs happens, you would be given the opportunity to reconfirm your willingness to receive them.

I would be very grateful if you could sign the attached acknowledgement form which confirms that you have received this updated information and return it to me in the prepaid envelope.

Yours sincerely

Signed

Principal Investigator