[On local hospital headed paper]

Centre No.

TracMan Study

PATIENT INFORMATION SHEET: RETROSPECTIVE CONSENT FROM PATIENT

Version 9 – 6 March 2006
MainREC number: 04/MRE00/43

Title of project: A study to investigate whether the use of "early" or "late" tracheostomy is of benefit to patients in intensive care.

Principal Local Investigator: [name and telephone number here]

During your stay in the intensive care unit you took part in a research study that is currently taking place in many intensive care units throughout the UK. It is important for you to understand why the research is being done and what it involves. Please read the following information carefully and, if you wish, discuss it with your relatives or friends. Ask if there is anything that is unclear or if you would like any more information. Thank you for reading this.

What is the purpose of this study?
Patients who need help with their breathing (artificial ventilation) have a tube placed through their mouths into their lungs. This tube is connected to the machine that assists their breathing.

If patients require assistance with their breathing for long periods of time, the tube that goes into the lungs via the mouth is often changed to one that goes through an incision in the front of the windpipe (trachea) in the neck. This is called a tracheostomy. Tracheostomy is an established procedure rather than a new technique. Tracheostomies are used in virtually all intensive care units.

At present we do not know if it is better to perform a tracheostomy in the early stages (first 4 days) of a patient's illness, or wait until 10 days or more. By doing the tracheostomy earlier, patients may recover faster, but by doing it later some patients may avoid the need for a tracheostomy altogether. Doctors really do not know which is best.

The Intensive Care Society, a professional body representing most of the doctors working in intensive care units, is trying to find the answer. It is conducting a national study involving over 1200 intensive care patients in many hospitals around the UK. This will compare the progress of the patients who receive "early" or "late" tracheostomy.

This study has been reviewed and approved by a Main Research Ethics Committee.

Why was I chosen and what happened to me?
At the time you entered the study your doctors believed that it was going to take 7 or more days before you were going to be able to breathe on your own without any help from a ventilator (breathing machine). As we do not know whether it is better to perform a tracheostomy early or later in a patient's illness, we

need to make comparisons. Patients are put into groups and then compared. The groups are selected by a computer that decides on a chance basis (as if it were tossing a coin) whether the patient should receive an "early" tracheostomy (within 4 days of admission to the intensive care unit), or a "late" tracheostomy after 10 days or more. In your case the decision on when to perform the tracheostomy was made this way. The local investigator [local consultants name here] will be able to tell you if you received an early tracheostomy, a late tracheostomy, or no tracheostomy at all.

We then collected some information about your treatment whilst you were on the Intensive Care Unit, and collected some personal identifying details to enable us to follow up your health status once you have left the unit.

What if something had gone wrong?
This study is investigating an established procedure rather than a new technique. Tracheostomies are used in virtually all intensive care units. If you have been harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action but you may have to pay for it. Regardless of this, if you wish to complain about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms will be available to you.

What happens now?
Your remaining stay in hospital will continue as normal. There is no need for you to undergo any special tests or investigations or for you to be inconvenienced in any way.

Why are you explaining this to me?
As we enrolled you in a study whilst you were too ill to receive an explanation, it is important that we explain what the study involved now you are recovered.

What information has been/will be collected about me?
As part of the study routine information on your treatment was collected. If you do not wish for the data collected about your treatment to be used, this will be destroyed. Information in your hospital records remains unaffected. In addition, appropriate personal identifying details were collected to enable us to be kept informed about your health once you have left the Intensive Care Unit. It is possible that we will contact your GP to see how you are doing, or we may follow your health through a government agency called the Office of National Statistics which is told about all the births and deaths in the United Kingdom. If you decide not to allow us to follow up your health status, then we will abide by your wishes and not collected follow up data on you. You do not have to give a reason, and the standard of care you receive will not be affected.

Will my taking part be kept confidential?
All the information that has been collected about you during the course of the research study will be kept strictly confidential. Your identifying details will be held in a secure environment and only accessed by the research team for the purposes of follow up.

What will happen to the results of the research study?
The study is estimated to take just over three years and it is hoped that the results will be available on the Intensive Care Society's web page (www.ics.ac.uk) in 2008. If you would like a copy of the published results, please contact the Principal Local Investigator [local consultant and telephone number here] who is the consultant leading the study at the intensive care unit.