PATIENT RETROSPECTIVE INFORMATION SHEET FOR 3CPO STUDY
(Is non-invasive ventilation effective in patients with acute heart failure?)

You were recently admitted to hospital with acute heart failure, which had left fluid on your lungs. We are currently undertaking a research project, looking at the use of a new ventilator machine in this condition. As you were very unwell at the time, it was impossible to inform you fully about the research study and to expect you to understand this information. Your doctor therefore carried out your treatment in your best interests and your initial enrolment in the research study may also have been discussed with an important relative. Now that you are feeling better it is very important that you are made aware of what the research study is all about and that we ensure you are happy to continue to take part in it. You are being asked to read the following information carefully, to discuss it with others and to ask us if you would like further information about the study. You will be given this information sheet to keep and asked to sign a consent form if you wish to continue to take part in the research. Thank you for taking the time to read this.

Why was I chosen as a potential study patient*?*

You were chosen as a potential study patient because you had heart failure, which had left fluid on your lungs. We aim to study 1200 such patients in a nationwide research study.

What is the purpose of the study?

To find out if a machine designed to deliver oxygen under pressure into a facemask, improves the condition of patients with fluid on the lungs caused by heart failure. These machines are known to help patients with other breathing problems (such as emphysema).

What treatment did I receive?

In this study, we are comparing three different ways of delivering oxygen because we do not know which one is best. **ALL** patients in this study receive the usual drug treatment for acute heart failure and oxygen.
However, the oxygen may be delivered in one of THREE different ways:

1) **by a simple face mask**
2) **by a tight fitting face mask connected to a breathing machine (ventilator) which is delivering oxygen at one continuous pressure (CPAP)**
3) **by a tight fitting face mask connected to a breathing machine (ventilator) which is delivering oxygen at a higher pressure when you breathe in than when you breathe out (NIPPV).**

These treatments are being selected entirely at random by a computer, (i.e. by chance). There was a one in three chance of receiving either of the treatments. Patients in the three groups will then have received oxygen in three different ways and these will be compared.

The treatment that you received was_____

Were there any side effects to treatment in my case?

There ***may*** be some **side effects** to treatment and these include:

1) minor skin damage to the face due to the tight fitting mask

2) vomiting

3) a drop in blood pressure

4) claustrophobia

You suffered the following side effects _____

How long will the research study last?

You were involved in the research for around two hours in the emergency department (A&E) whilst the early treatment of your condition was going on. No additional tests or clinic visits will be required. We will send you a questionnaire by post at 1, 3 and 6 months after the date of your hospital admission to help us assess how well you are. We may telephone you at home to remind you to fill in these questionnaires.

What happens if I am unhappy to continue to take part in the study?

You are free to provide informed consent to continue to take part in the research or to withdraw from the project, if you so wish. This will not affect the standard of care you receive or your legal rights.

If you decide to withdraw from the study, after initially being enrolled, then only the information already collected about you will be used in any subsequent data analysis for the purposes of the research. It will, however, remain in your medical records to assist in the treatment of your medical condition.

How will my confidentiality be maintained?

Your medical records and other routine NHS data sources may be inspected for the purpose of analysing the results. All information that is collected about you during the course of this study will be kept strictly confidential. Any information about you that leaves the hospital will have your name and address separated from it so that you cannot be identified. We hope to publish the results of this study in medical journals, but your name will not be entered in any publication.

Other information

Sometimes, during the course of a research project, new information becomes available about the treatment being studied. If this happens, your research nurse will tell you about it and discuss whether you want to continue in the study. If you or decide to withdraw, the research nurse will make arrangements for your care to continue. An updated consent form will be provided.

If you were harmed during the course of this research project, there are no special compensation arrangements. If you were harmed due to someone's negligence you may have grounds for legal action but may have to pay for it. If you or your relative wish to complain about any aspect of the way they have been approached or treated during the course of this study, the normal NHS complaints mechanisms should be available to you.

We hope that all the treatments have helped you. The information we get from this study may help us to improve the treatment of future patients.

The study has been approved by a Multicentre Research Ethics Committee and reviewed by the Local Research Ethics Committee.

Further information can be obtained from:

THANK YOU VERY MUCH IN ADVANCE FOR YOUR HELP WITH THIS STUDY