**Consultee and Nominated Consultee Information Sheet**

**The PROBESE Study**

**Protective Ventilation with Higher versus Lower PEEP during General Anesthesia for Surgery in Obese Patients**

**A randomized controlled trial.**

**1. Introduction.**

Your relative or friend (or the person for whom you are being asked to act as a nominated consultee) has previously agreed to take part in this research project. We are now in the follow up period of the study and no more interventions are planned.

The reason we are contacting you is because they are at present unable to confirm they wish to continue with the study, because they havelost capacity to take decisions. The reason for this will vary, but typically it means that they are no longer in a position to confirm their wishes for a variety of medical or other reasons, such as they are now sedated on intensive care or are otherwise indisposed. The law is such that we need to confirm that you feel they would wish to allow us to carry on following up their progress as we would have done if they had not become incapacitated.

They were originally invited to join the study because they had a body mass index of 35 or more and were due to have an operation. Body Mass Index is a measure of your weight related to your height.

The research project is testing what is the best way to help your breathing whilst you are asleep during an operation. The operation is now over and we are following up to see what has happened to each treatment group

This Information Sheet tells you about the research project. It explains the treatment that has taken place and the follow up involved. Knowing what is involved will help you decide if you want you relative or friend (or the person you are acting as a nominated consultee for) to continue in the research, so we can collect the follow up data.

Please read this information carefully. Ask questions about anything that you don’t understand or want to know more about. Before deciding whether or not to continue your relative or friend‘s participation, (or the person you are acting as a nominated consultee for), you might want to talk about it with another relative, friend or the doctor responsible for your care.

Continued participation in this research is voluntary. If you don’t wish your relative or friend (or the person for whom you are being asked to act as a nominated consultee) to take part, they don’t have to. They will receive the best possible care whether or not they continue to be followed up.

If you decide your relative or friend would want to take continue taking part in the research project, you will be asked to sign a declaration form. By signing it you are telling us that you:

• Understand what you have read

• Agree to your relative or friend continuing to take part in the research project

• Agree to the follow up data being gathered and thie information being used as described

**2. What is the purpose of this research?**

The research is aimed at reducing the number of breathing related problems patients suffer after a surgical operation.

This is because, when patients are anaesthetized the lower parts of the air passages in the lungs tend to close up and this is made worse if the surgery is on the abdomen. This adds to the stresses the lungs are exposed to during surgery and problems with breathing are the most common complications in the days after surgery. Overweight patients already have an increased risk for impaired lung function, not only during surgery, but this is especially the case in the period after a big operation.

Therefore, we are looking at the best ways to reduce this potential problem. One way may be to keep some pressure in the airway as the patient breaths out whilst anaesthetized.

While under anaesthesia, it is normal practice during some types of operation, for the breathing to be helped by a machine called a ventilator. This is a machine that takes over the work of breathing for the patient and blows air into the lungs, resulting in a breath. Between breaths the pressure is reduced as you breathe out. Ventilators are designed so that a small pressure can be kept on whilst breathing out. This may help to improve airflow through all parts of the lung, by holding the airways open.

This may not only improve lung function during general anesthesia, but also in the period after surgery and reduce the possibility of pulmonary complications such as pneumonia or low blood oxygen (called 'hypoxia'). This could improve well-being after surgery as well as even shortening the hospital stay.

At the moment the positive pressure during expiration is not in routine clinical use, because it is not known how high the pressure actually needs to be. Current practice is to use a relatively low pressure, which unfortunately allows parts of the lung to collapse. On the other hand, a higher pressure may improve the distribution of air in the lung, but may also cause blood pressure to drop. So at the moment we don’t know what is the best compromise airway pressure that produces the most benefits and the fewest problems. This is what we want to find out.

**3. What does participation in this research involve?**

The main objective of this trial is to find out, what of level positive pressure during breathing out can reduce lung complications and whether extra pressure can reinflate collapsed areas of lung during surgery and anaesthesia.

What has happened so far: First, an anaesthetist or research nurse used set criteria, particularly concerning a patient’s weight to determine if they were a suitable candidate for the trial. Overweight people tend to be more vulnerable to breathing problems during and after an operation.

Your relative or friend (or the person for whom you are being asked to act as a nominated consultee) agreed to take part and so the researchers recorded information about their health and started to follow them through the surgery and into the postoperative period to see how they got on. This information is stored in such a way that they cannot be identified from it. They do not need any extra blood tests or Xrays, instead we have recorded the results of some of those tests that were routinely taken before and after surgery as part of their normal treatment, so we could assess how quickly they were recovering. This process is ongoing

During their operation and anaesthetic they received mechanical ventilation (which is routine) and as part of the study and had their airways held open between breaths by one of two levels of pressure, rather than the pressure falling to zero, with the aim of reducing how much the small airways closed up during the operation. This phase is now complete and now we are following each patient to see whether either of these techniques helped reduce complications after surgery, especially problems related to the lungs and breathing and whether administering a few large breaths helped as well.

After agreeing the patients were randomly assigned to either the slightly higher or lower pressure during breathing out strategy. During surgery we recorded how their breathing and blood pressure performed and we continue to do this while the patients is recovering. A research doctor or nurse then visits the patient every day for the first five days and on the day before your hospital discharge. The physician will also call the patient by telephone after at least three month after surgery. The trial does not affect any other aspects of their treatment or hospital stay and does not include any additional tests after they go home.

**4. Does** your relative or friend (or the person for whom you are being asked to act as a nominated consultee) **have to continue taking part in this research project?**

Participation in any research project is voluntary. If you do not wish their participation to continue, you do not have to agree to it. If you decide they should continue to take part and later change your mind, you are free to withdraw them from the project at any stage without giving a reason why.You should try to judge what your relative or friend (or the person for whom you are being asked to act as a nominated consultee) would want. Would they wish to carry on with data collection.

Your decision whether or not to take part, or to withdraw, will not affect the clinical care you receive.

**5. What are the possible benefits of taking part?**

We have reason to believe that having some extra pressure during breathing out whilst anaesthetised for an operation may reduce breathing complications. However at present we do not know what the best pressure should be. Therefore knowledge gained from this research may assist us in making anaesthesia safer in the future.

**6. What are the possible risks of taking part?**

We believe that mechanical ventilation with a higher continuous pressure can reduce the risk of lung-associated complications, but we don’t yet know what the best pressure is. Mechanical ventilation is an important part of normal practice for your type of operation, regardless of whether you are involved in our study. Mechanical ventilation can sometimes cause temporary reductions in blood pressure and increased airway pressure may make this more common. Therefore the pressure will always be adjusted if lung function worsens or blood pressure falls significantly. It is getting this balance right that we are studying in this trial because we do not know what is the optimum ventilator pressure. Breathing problems are so common after major operations that we hope by doing this we can make them less common.

 The recovery visits by the trial doctor or nurse do not include any invasive or painful tests.

**7 Can the patient have other treatments during this research project?**

There is no restriction on the other treatments that they may receive whilst you are participating in this research project.

**8 What if I withdraw from this research project?**

If you decide to withdraw your relative or friend (or the person for whom you are being asked to act as a nominated consultee) from the project, please notify a member of the study team before they withdraw. There are no health risks linked to withdrawing. If you do withdraw the consent during the research project, the study team will not collect additional personal information from your relative or friend (or the person for whom you are being asked to act as a nominated consultee), although personal information already collected will be retained to ensure that the results of the research project can be measured properly. You should be aware that data collected by the investigators up to the time you withdraw will form part of the research project results

**9 What happens when the research project ends?**

A plain language summary of the results will be available to participants after the study ends. You can ask to receive a copy of this via a member of the study team.

 **10 What will happen to information about the patient?**

By signing the consent form you consent to the study doctor and relevant research staff collecting and using personal information about your relative or friend (or the person for whom you are being asked to act as a nominated consultee) for the research project. Any information obtained in connection with this research project that can identify your relative or friend (or the person for whom you are being asked to act as a nominated consultee) will remain confidential. The information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law.

Information about your relative or friend (or the person for whom you are being asked to act as a nominated consultee) will be obtained from your health records held at this hospital and may be obtained from other health services for the purpose of this research.

To help keep the information safe, all participants will be allocated a study code number. All information about your relative or friend (or the person for whom you are being asked to act as a nominated consultee) that is collected for the study will be labelled with this number, not your name or hospital number. The key to the code will be stored separately to your information.

Records are collected and stored either in folders (for paper records) or put onto a secure computer, which can only be accessed by the researchers. All written data will be stored in a locked filing cabinet in a locked room. Only the researchers will have access to stored written or electronic data. Information collected from participants will be kept for 15 years after which it will be destroyed. Anonymous data will be transferred electronically to the Study Project Office at Dresden, Germany during your participation in the study, b ecause they are coordinating the analysis of results from many countries.

We would like to keep the information gathered to use in future research related to this project about outcomes from anaesthesia. Consenting to this is optional. You will be asked to indicate if you agree to this when signing the consent form.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your permission.

Information about your participation in this research project will be recorded in your health records.

your relative or friend (or the person for whom you are being asked to act as a nominated consultee) has the right to request access to your information collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please contact the study team member named at the end of this document if you would like to access your information.

**11 Who is organising and funding the research?**

The study has been organised by the Department of Anaesthesia in Dresden, Germany in collaboration with the European Society of Anaesthesiology. The study has been designed by researchers from all over Europe, including the UK. Sheffield Teaching Hospitals NHS Foundation Trust is acting as the UK lead site and has coordinated the relevant approvals in the UK. Funding to run the study has been provided by the European Society of Anaesthesiology.

**12 Who has reviewed the research project?**

All research in the UK , including this study is looked at by independent group of people, called a Research Ethics Committee, to protect patients‘ interests. This study has been reviewed and given favourable opinion by the xxxxxx Research Ethics Committee.

**13 What if there is a problem?**

If you have a concern about any aspect of this study, you should ask to speak with the local researchers who will do their best to answer your questions. You can contact [Insert Name] on [Insert Telephone Number] in the first instance. If you are not satisfied with their response and wish to complain formally, you can do this through the NHS Complaints Procedure.

If you wish to talk to someone who is independent of the study, you can contact the hospital’s Patient Advice and Liaison Service [Insert Telephone Number]

In the unlikely event that something does go wrong and your relative or friend (or the person for whom you are being asked to act as a nominated consultee) are harmed during the research and this is due to someone’s negligence then you may have grounds for a legal action for compensation against [insert Trust name] but you may have to pay your legal costs.

**14 Further Information**

Further information about this study can be obtained from the following contacts:

Local Principal Investigator: [Insert Name] on [Insert Telephone Number].

Local Research Nurse: [Insert Name] on [Insert Telephone Number].

**Thank you for reading this information sheet and considering the continuation of this study.**

*If you decide that your relative or friend* (or the person for whom you are being asked to act as a nominated consultee) *would want to carry on taking part you will be given a copy of this information sheet and the signed consent form to take home with you and keep.*