All information pertinent to the clinical investigation, including at least the following, shall be provided in writing and in native, non-technical language that is understood by the subject, or their legally authorised representative.

Patient Information Sheet

1. Study Title
Perioperative Outcome Study in the Elderly (POSE): European, Large Scale, Multi-Centre, Prospective Observational Cohort Study

2. Invitation Paragraph
You are being invited to take part in a research clinical investigation. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

3. What is the purpose of the study?
In Europe, it is estimated that the elderly population (≥80 years) will increase from 5.3% of the total population in 2015 to 9% in 2040. Of note, the 65-79 year and the ≥80 year old population will both continue to grow until 2040. Compared with younger surgical patients, the elderly are at greater risk of mortality and morbidity after elective and especially emergency surgery. Data are lacking in the overall elderly surgical population for: in-hospital mortality, the need for planned and unplanned admission to the intensive care unit, the use of non-standard monitoring tools, rate of non-extubation at the end of surgery and re-intubation rate, the surgical outcome, as well as length of hospital stay and the discharge destination. All these factors are of the utmost importance in planning both in and out of hospital health-care systems in Europe. The results of this study may support health care systems to adapt to the patients´ needs (i.e. the need for critical care units for the elderly, more advanced monitoring devices, geriatricians in the surgical departments, or geriatric anaesthesia fellowship programs). Furthermore, the results may support future health facilities and budget planning.

4. Why have I been chosen?
You have been chosen to participate because your age is equal to or greater than 80 years and you are undergoing surgical and non-surgical interventions (e.g. radiological, neuroradiological), either elective or emergency, with anaesthesia care.

Seventy-five (75) patients will be recruited to this study in Cork University Hospital and the South Infirmary and Victoria University Hospital.

5. Do I have to take part?
Your participation in this clinical investigation is entirely voluntary. It is up to you to decide whether to take part or not. If you do decide to take part, you are free to leave the clinical investigation at any time without giving a reason. This will not affect your future medical care in any way.

Your doctor may withdraw you from the clinical investigation if he/she feels this is in your best interest or in case of stopping the clinical investigation early.

6. What will happen to me if I take part?
Upon consenting to be part of this study, a team member will attend to you before your surgery. This team member will complete a questionaire with the aid of your medical notes. They will also perform a frailty assessment which involves the completion of a cognitive test

and a timed ‘up and go’ test. The cognitive test will involve remembering a sequence of words and assess your ability to draw a clockface. The timed ‘up and go’ test involves standing up from a seated position, walking forward for three meters, turning around, walking back to the seat and returning to a seated position.

A member of the team will visit you on the day of your procedure to collect details on the type of procedure that you had performed and the details of the anaesthetic involvement in your care.

The third encounter with the investigative team will occur 30 days after your procedure. If you are in the hospital this will take the form of a face-to-face visit. If you have been discharged from the hospital this encounter will take the form of a phonecall. This encounter is to determine the details of your stay in the hospital after your original procedure.

Your medical care will not be impacted by your involvement in this study in any way.

7. What do I have to do?
You will be asked to complete an interview and perform two tasks, a cognitive test and a timed up and go test, before your procedure, if you are able. You will also be asked to take part in an interview thirty days are your procedure, either face-to-face or by means of a telephone call.

8. What are the possible benefits of taking part?
Due to the lack of information regarding the outcomes of elderly patients undergoing surgical and non-surgical interventions, you will be contributing to the collection of information that may support health care systems to adapt to the patients´ needs, leading to the development of future health facilities and contribute to budget planning.

9. What are the alternatives for treatment?
You may decline to participate in this study. Your care will not be impacted by your decision to participate, or not to participate, in this study.

10. What are the risks and inconvenience for subject, and when applicable for an embryo, foetus, or nursing infant:
The risks of the study are the same as that for you usual care, as the study will not impact this. The inconvenience is the three encounters that you will have with the investigating team, including a potential phonecall thirty days after your procedure.

11. What happens if new information becomes available?
If any new information becomes available during the course of the clinical investigation that may affect your willingness to participate, you will be informed of this. If you decide to withdraw, your research doctor will make arrangements for your care to continue. If you decide to continue in the clinical investigation you will be asked to sign and date a revised consent form. Your doctor may decide based on the new information, it may not be in your best interest to continue in the study. He/she will explain the reasons and arrange for your care to continue.

12. What happens when the research study stops?
Your anaesthetic care will continue with no change from standard practice.

13. Will my taking part in this study be kept confidential?
Your study doctor and staff will collect information about you. A code will replace your name on all the data collected about you. All the data collected will be kept confidential.

The data collected will be used for the evaluation of the study, and may be used in the future in related or other studies. The data may be submitted to health authorities for registration purposes. Members of health authorities, of Research Ethics Committees or other persons required by law may review the data provided. This data may also be used in publications about the new device. However, your identity will not be revealed in any compilations, study reports or publications.

In order to verify the accuracy of collected data, it is necessary for the investigators or national and international authorities to directly compare them with your medical records. Such checks will only be done by qualified and authorised personnel. All such persons are required to and will keep the data confidential.

14. Who is organising and funding the research?
This study is run locally by doctors at Cork University Hospital and is being internationally co-ordinated by doctors from the University of Aachen in Germany.

15. Who has reviewed the study?
The study has been reviewed and given a positive opinion by an independent Research Ethics Committee.

16. Contact for further information:
Dr.Peter Lee,

Dept. Anaesthesia and Intensive Care,

Cork University Hospital,

Wilton,

Cork.

Telephone: 021 4922135

You will receive a copy of the information leaflet and consent form to keep.