DNB Thesis Informed Consent Form – Format

INFORMED CONSENT FORM

The PIS must include information on the following and a copy of this must be given to the subject:

1. What is the background to and purpose of the study?
"You undergo certain investigations and treatment procedure as required by your health condition. I wish to use the reports of those investigations purely for the purpose of my research. Your identity will not be revealed. Your data will be used for academic purposes only. I request your consent to use your medical data for my research, which will not give you any additional benefit, but helps in adding to medical knowledge".

2. Do I have to take part?

3. What will happen to me if I take part?

4. What do I have to do?

5. What are the possible side effects, risks and discomforts of taking part?

6. What are the possible benefits of taking part?

7. What if new information becomes available?

8. What are the costs of taking part?

9. How will my personal data be used?

10. Will there be provision for free treatment for research related injury?

11. Will compensation be paid to the subjects if disability or death results from such injury?

12. Whom should I contact if I need more information or help?

The subjects informed consent should be taken on the form that he or his legally acceptable representative can read and understand. The format of the ICF must be as follows: 9 © NBE: NBE Guidelines for Preparation & Submission of Thesis Protocol 2013

Subject identification number for this trial _____
Title of the Project: _____
_____
Name of the Principal Investigator _____ Tel. No._____

I have received the information sheet on the above study and have read and / or understood the written information.

I have been given the chance to discuss the study and ask questions.

I consent to take part in the study and I am aware that my participation is voluntary.

I understand that I may withdraw at any time without this affecting my future care. I understand that the information collected about me from my participation in this research and sections of any of my medical notes may be looked at by responsible persons (ethics committee members / regulatory authorities). I give access to these individuals to have access to my records.

I understand I will receive a copy of the patient information sheet and the informed consent form.

_____ _____
Signature / Thumb Impression of subject Date of signature

_____
Printed name of the subject in capitals

_____ _____
Signature / Thumb Impression of legally Date of signature accepted representative

The legally acceptable representative signature should be added if the subject is a minor or is unable to sign for themselves. The relationship between the subject and the legally acceptable representative should be stated. The impartial witness 10 © NBE: NBE Guidelines for Preparation & Submission of Thesis Protocol signature should be added if the subject / legally acceptable representative is unable to read or write and consent should be obtained in his presence.

_____

Printed name of legally acceptable representative in capitals

_____

Relationship of legally accepted representative to subject in capitals

_____ _____

Signature of the person conducting the Date of Signature informed consent discussion

_____

Printed name of the person conducting the Informed consent discussion in capitals

_____ _____

Signature of impartial witness Date of signature

_____

Printed name of the impartial witness in capitals 11 © NBE: NBE Guidelines for Preparation & Submission of Thesis Protocol 2013

Advances in the care of patients with chronic obstructive pulmonary disease (COPD), asthma, pneumonia, acute respiratory distress syndrome (ARDS) Managing patients on various forms of mechanical ventilation