Amendment to the previously approved protocol entitled 'Stress ulcer prophylaxis with proton pump inhibitor (pantoprazole) in adult critically ill patients in the intensive care unit: A randomised, blinded, placebo-controlled trial', version 3.0, October 20th 2015

This amendment replaces Appendix 7 in the above mentioned protocol.

Appendix 7.1 Informed consent, Denmark

In Denmark temporarily incompetent patients will be enrolled after informed consent from one physician, who is independent of the trial (trial guardians). As soon as possible after enrolment, consent will be obtained from the patient's next of kin. Patients, who regain consciousness, will be asked for informed consent as soon as possible. The process leading to the achievement of informed consent will be in compliance with all applicable regulations. The consenting party will be provided with written and oral information about the trial so he/she is able to make an informed decision about participation in the trial. The information will be given in a separate room, and the consenting party has the right to bring a companion.
Written information and the consent form will be subjected to review and approval by the relevant ethic committees.

Lack of informed consent from the patient's next of kin

If information about the patient's next of kin is not available after inclusion the investigator will seek information from e.g. the patient's general practitioner, the police, nursing homes etc. In these situations it may take 1-2 weeks to conclude that no next of kin can be identified. If no one is identified and the patient remains incompetent the trial intervention will be discontinued. All initiatives to identify the patient's next of kin will be documented in patient files, logs or similar.

Lack of informed consent from the patient's next of kin and the patient deceases

If the patient deceases before informed consent has been obtained (due to rapid progression of critical illness or because the patient's next of kin is not yet identified) and the patients has been correctly included in the trial, collected data will be kept for analysis.

Deviation from the standard informed consent

According to the standard informed consent form from the National Ethics Committee regarding competent patients, the patient can choose not to receive information about the data collected during the trial. However, the purpose of this trial is not to generate new knowledge about the

specific patient, so we find that this question is redundant, and have omitted the question from the consent form to spare the patient from making unnecessary decisions.