calgary health region

UNIVERSITY OF CALGARY

Management of Occult Pneumothoraces in Mechanically Ventilated Patients

INDEPENDENT PHYSICIAN AUTHORIZATION

I, _____, a registered Medical Practitioner not involved in the **Management of Occult Pneumothoraces in Mechanically Ventilated Patients** study have examined subject _____ at Foothills Hospital on ____/_____/_____(date) and hereby declare that he/she has suffered penetrating / blunt injuries resulting in an occult pneumothorax and could potentially benefit from avoiding the placement of a chest tube for such an occult pneumothorax. I confirm further that the medical status of the subject is as such that he/she is unable to personally provide Informed Consent to the study participation by reason of:

There is a serious threat to the prospective subject that requires an immediate decision regarding intervention or observation.

___ The prospective subject lacks the capacity to give informed consent; and

Third party authorization cannot be secured in sufficient time despite diligent and documented efforts due to:

____ The patient has no known next of kin/proxy to provide consent.

____ Attempts to contact next of kin have been unsuccessful.

___ A proxy _____(name and relationship) has been contacted by phone, and the purpose, methods ands risks of participation have been explained by _____ (name) to the proxy.
The telephone consent from proxy was obtained at _____.

____ No relevant prior directive by the subject is known to exist.

_____ _____
(Signature of authorized independent physician) (Date and Time)

INVESTIGATOR STATEMENT

I, the undersigned have noted the foregoing assessment of

_____ conducted by _____
(Name of subject) (Name of authorized independent medical practitioner)

In addition to the subject not being able to personally provide informed consent, one of the following circumstances apply:

- The patient has no known next-of-kin / legal representative to give consent on his/her behalf …….. ☐
- Attempts to contact next-of-kin / legal representative have been unsuccessful …….. ☐
- _____relative/legal representative of _____(Name of subject) has been informed telephonically of the nature and purpose of the study and has verbally consented to the subject receiving _____ or Placebo…….. ☐

I confirm that the following requirements as stipulated in ICG GCP section 4.8.15 and EEC Directive 2001/20/EC, regarding consent in emergency situations have been adhered to:

- The above research study relates directly to the life threatening condition from which the incapacitated subject suffers.
- The clinical trial has been designed to minimize pain, discomfort, fear and any other foreseeable risk in relation to the disease.
- Both the risk threshold and the degree of distress shall be specifically defined and constantly monitored.
- The interest of the patient will always prevail over those of science and society.
- Avoiding the insertion of a chest tube will likely produce a benefit to the patient outweighing the risk or produce no greater risk than that of placing a chest tube.
- An Ethics Committee endorsed the protocol.
- The subject or the subject's legally acceptable representative will be informed about the trial as soon as possible and consent to continue will be signed as soon as possible.

_____ _____ _____
Signature of Investigator Investigator Name printed Date

_____ _____ _____
Signature of Impartial witness Name of witness printed Date

REGAINED CAPACITY CONSENT

Because your illness or injury made it impossible for you to participate fully in the informed consent process, the consent of your surrogate (legal guardian) was obtained on your behalf. Your surrogate believed you would have wished to participate in this research if you had been able to express your own opinion at the beginning of the research project.

As noted earlier, the process of informed consent must go on throughout a research project. This means that patients have the right to change their minds and, therefore, must be given opportunities to voice any changes they might wish. In your situation, you are now being given the opportunity to agree or disagree with the decision made by your surrogate for you to participate.

Please check the appropriate boxes to indicate your decision:

- ❑ I wish to remain in the study.
- ❑ I wish to withdraw from the study.

_____	_____
Patient's printed name / Signature	Date and Time
_____	_____
Witness's printed name / Signature	Date of Signature
_____	_____
Investigator or Delegate Signature	Date and Time