

Nominated Consultee Declaration Form

Study title: Ventilator Aspiration with PneuX

Full study title: A single centre, open-label, feasibility randomised controlled trial to evaluate gastric microaspiration in critically ill patients intubated using the Venner PneuX system compared to standard care using pepsin biomarker (VAP-X)

Please initial boxes

I _____ have been consulted about _____'s participation in this research project. I have had the opportunity to ask questions about the study and understand what is involved.

I confirm that I have read and understood the Consultee Information Sheet Version ___ dated _____ for the above study and have had the opportunity to ask questions which have been answered fully.

I understand that I can withdraw them from the study at any time, without giving any reason and without their care or legal rights being affected.

If I decide to withdraw my patient, or they are withdrawn, from the study, I agree that the information collected about them up to the point of their withdrawal will be used in the data analysis for this study.

I understand that relevant sections of their medical records and data collected during the study may be looked at by responsible individuals from Cardiff and Vale UHB and other regulatory authorities where it is relevant to taking part in this research.

I understand that samples of fluid from the lungs will be taken and anonymised samples will be sent to the company, RD Biomed, and Cardiff University for analysis, and that these samples cannot be used to identify my patient.

I agree to allow my patient for whom I am the responsible person to continue to participate in this research study.

I am acting in the capacity of a Nominated/Professional Consultee for the patient and NOT a Personal Consultee

Name of person giving consent

Date

Signature

Name of person taking consent

Date

Signature

When completed: Original copy to be entered into medical records, 1 copy for consultee; 1 copy to be entered into researcher site file.