

Participant Consent 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 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 Participant 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 from the study at any time, without giving any reason and without my care or legal rights being affected.

If I decide to withdraw, or I am withdrawn, from the study, I agree that the information collected about me up to the point of my withdrawal will be used in the data analysis for this study.

I understand that relevant sections of my 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 me.

I agree continue to participate in this research study.

Name of participant

Date

Signature

Name of person taking consent

Date

Signature

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