Data and Safety Monitoring Plan

Study Overview

The Data and Safety Monitoring Plan (DSMP) outlined will adhere to the protocol approved by the University of California Davis (UCD) institutional review board (IRB) (protocol number 647002).

Confidentiality

Protection of Subject Privacy:

Mechanical ventilator waveform data representing pressure, flow, and time will be collected using the standard data export functionality of the mechanical ventilators. Exported data will be encrypted at the time of export and sent wirelessly to a central server using a commercially available, USB-based, wireless data storage device and a state of the art wireless data transfer encryption protocol. Wireless data transmission will occur over a dedicated, secure research wireless network to ensure that there is no interference with the health system's standard wireless network. Waveform data files will be coded at the time of collection using a unique subject identifier. Our data export and research wireless network protocols have been developed in conjunction with the UC Davis Research Information Technology (IT) division (contact Kent Anderson, Director of UC Davis Research IT, for additional questions) and with Dr. Sean Peisert, PhD, an expert in data privacy and security. The safety and security of our data export and research wireless network protocols have been vetted through the standard UCD Medical Center (UCDMC) IT Evaluation of New Technologies protocol. Research IT has approved our protocol.

In addition to ventilator waveform data, limited protected health information (PHI) will be collected such as date of birth, dates of admission/discharge/death in order to perform statistical tests to minimize the effects of confounding given the observational nature of the study. Medical record numbers (MRNs) will be collected to allow the use of unique patient identifiers and de-identified (coded) collection of PHI and non-PHI predictor variables. The code key linking unique identifiers to MRNs will be kept in an encrypted, password-protected file on the primary investigator's University computer that is protected behind the University's extensive, standard electronic security measures. PHI will not be inappropriately reused or disclosed to any other person or entity. All PHI will be deleted from the study database when all statistical analyses are completed. No materials will be used to recruit patients. Patients will not be contacted at any time before, during, or after data collection. Based on the above, signed informed consent will not be necessary. HIPAA authorization for the secondary use of routinely collected clinical data for research purposes will not be necessary in the setting of a waiver of informed consent (see Section 5 above).

All ventilator data files will be maintained initially on a local secure server, with weekly backups onto Iron-key secure USB drives. Files will then be moved to a research analysis database in REDCap maintained by the CTSC. The local server will only be accessible to the study research staff named in this application. Re-linkage of ventilator waveform data to subject data will only occur in the secure REDCap environment through the use of coded unique identifiers at the time of subject data retrieval from the electronic health record (HER).

Database Protection:

The REDCap application will be used as the database platform. In this case, the Biomedical Informatics Program of the UC Davis Clinical and Translational Science Center will be used as a central location for data management. REDCap (Research Electronic Data Capture) data collection projects rely on a thorough study-specific data dictionary defined in an iterative self-documenting process by all members of the research team with planning assistance from the Biomedical Informatics Program. The REDCap system provides secure, web-based applications that are flexible enough to be used for a variety of types of research, provides an intuitive interface for users to enter data and has real time validation rules (with automated data type and range checks) at the time of entry. REDCap offers easy data manipulation with audit trails for reporting, monitoring and querying patient records, and an automated export mechanism to common statistical packages (SPSS, SAS, Stata, R/S-Plus). REDCap servers are housed in a local data center at UC Davis Health System and all web-based information transmission is encrypted. REDCap was developed specifically around HIPAA-Security

guidelines. REDCap has been disseminated for use locally at other institutions and currently supports 240+ academic/non-profit consortium partners on six continents and over 26,000 research end-users (www.project-redcap.org).

The database will be secured with password protection. Access to the database will be controlled by the principal investigator and limited to those research personnel listed in this IRB application. Access to the database by investigators of other studies will not be permitted without separate, specific IRB approval to access this database for related research.

Adverse Event Monitoring

In this trial we can only retrieve ventilator waveform data (VWD) and EHR data. In accordance with our IRB, we cannot modify existing standards of care if a patient is enrolled in our study. Our system of data collection has also been thoroughly examined by UCD clinical engineering, and IT networking and security teams. Working with these safety assurance teams, it was determined our data collection mechanism cannot adversely affect the Puritan Bennet Model 840 ventilator. Given the minimal risk nature of the study, no specific data monitoring provisions are necessary. The study involves scientific research only and will not evaluate the safety or effectiveness of the software algorithms we develop. Data from subjects will be used for research purposes only and will not be submitted to, or held for inspection by the FDA.

Trial Monitoring: This is a single center, non-phase III trial designed to non-invasively gather VWD data from patients using a single type of ventilator at UCDMC. We do not make any direct intervention on subject care and we do not require use of a data safety monitoring board (DSMP) or any other outside expertise or resources for trial monitoring. Our PI, Jason Adams, and co-investigator Brook Kuhn perform a quarterly check that ensure enrollment data is accounted for, and to validate patient data is appropriately represented in our REDCap database.