Submission to the IRB is not required for quality improvement/assurance activities; however, submission of this form may be used when a formal determination by the IRB is desired.

If a formal determination by the IRB is desired, please email the completed form to qiirb@upenn.edu. The IRB will contact you with the results of their review and may request additional information to assist with their determination. **Please allow 5 business days for initial review.**

Activities that meet the definition of human research will require submission to the IRB via HS-ERA (https://medley.isc-seo.upenn.edu/hsProtocol/jsp/fast.do).

QA/QI activities that do not meet the definition of human research will be reviewed and acknowledgement from the IRB will be given. If there is interest in disseminating or publishing the results of the QA/QI activity, this correspondence can be submitted to a peer-reviewed journal or other publication as evidence of IRB review.

Prior to completing this form, please review the IRB's guidance document on QA/QI projects for additional information that may be helpful while completing this form: https://irb.upenn.edu/mission-institutional-review-board-irb/guidance/qiqa-project-guidance.

Project Title:	COVID Airway Provider PPE Use and Outcomes Registry
Funding Source:	N/A
Project Leader	
Name:	Mark D. Neuman
Department:	Anesthesiology

Who should the IRB contact with questions?
Name: **Lakisha Gaskins**
Penn Email: **Lakisha.gaskins@pennmedicine.upenn.edu**

Key Personnel	
Name	**Department (Affiliation if other than Penn)**
Meghan Lane-Fall, MD, MSc	**Anesthesiology**

Section A: Project Description

1. Provide a brief background that supports the need for this project to improve the quality of the program, process, etc. under study.

   Clinicians providing airway management procedures such as endotracheal intubation for patients with COVID-19 illness are at high risk for disease transmission due to aerosol and droplet exposure during procedures. At present, the risk to these healthcare providers for COVID-19 disease transmission is unknown, and additional data is needed for the purposes of improving clinical processes to protect providers.

2. Identify the project question this activity is designed to evaluate.

   The principal purpose of this project is to prevent workplace-transmitted disease among health care providers and to provide information to improve necessary public health services during the COVID-19 pandemic. Specifically, this activity will (1) evaluate current procedural approaches to airway management techniques for patients with COVID-19 disease, including use of PPE; and (2) collect providers' self-reported outcomes of new-onset symptoms or lab-confirmed COVID-19 diagnoses following airway management procedures for patients with COVID-19 disease.

3. Describe the project design, methods, and procedures.

   Web-based provider registry; using bit.ly/intubatecovid, a web-based database developed by Guy's and St Thomas' NHS Foundation Trust in the United Kingdom (Lead: Kariem El-Boghdadly) and maintained on secure cloud-based servers maintained by Knack.com (Philadelphia, PA), providers will be invited to register on as users and permitted to enter data on COVID-19 intubations in which they served as a primary or secondary laryngoscopist.

   The study registration page will state that completion of the registration form indicates consent to participation and: understanding of the project purpose; understanding of the risks and benefits of participation; confirmation that participants freel choose to participate; understanding that there will be no reimbursement for participation; understanding that participation is voluntary, and that subjects are free to withdraw any time; agreement forprovided data to be used for analysis, interpretation and reporting in posters, presentations and publications; understanding that collected study data will be publicly available, but that no personally identifiable information will be shared; and understanding regarding general standards of data security to be employed and that no personal information with be shared with any third party. Contact information for study lead(s) will also be provided.

   Information will be collected on procedure date, airway techniques used, use of techniques thought to be associated with high risk of COVID transmission, PPE used, and PPE breaches or failures. All case data will be organized by provider and made available as an ongoing case log. Providers may also voluntarily report data at any time on personal symptoms that may indicate new COVID-19 infection (fever, shortness of breath, etc...) and new diagnoses of COVID-19 disease, along with dates of symptom onset or disease diagnoses. Providers will be reminded to voluntarily report any new symptoms or illness outcomes via the website via weekly e-mail.

   Data security features of the knack.com platform include: Strong encryption of all stored and in-transit data, using both SHA-256 and AES-256 encryption, the strongest encryption available; active backps and data archives that employ both strong encryption and redudancy-based security measures; hosting on SOC 3 and ISO 27001 Certified Amazon Web Services (AWS) servers that are continuously audited, with certifications from accreditation bodies across geographies and verticals and include numerous advanced security features such as distributed denial-of-services attack mitigation. AWS servers are maintained in geographically distributed data centers and use firewalls to protect all virtual servers, databases, and load balancers. Knack data use is governed by a range of security and privacy procedures ensure data privacy, and data access and control features for Knack employees. Additional security features include password protection and password encryption of all accounts, role and permission assignment capabilities, version tracking and IP access blocking.

   The University of Pennsylvania will serve as the US coordinating site for the intubatecovid web registry, and will coordinate registration of other interested hospitals into the system. Prior to initiating data entry into the system, participants will be required to attest to having secured appropriate human subjects approval at their own institutions.

   a. Are any of the above methods or procedures untested or experimental?

   ☒ No ☐ Yes, please explain:

4. Describe any interaction or intervention with humans.

   Participants will be invited to enter data into the web platform as above. Outreach will occur to encourage participation via professional departmental channels and through professional anesthesia societies in the US and elsewhere.

5. Will identifiable data from individuals be used or collected?

☐ No ☒ Yes

a. If yes, please identify the source of the data and describe how the data will be accessed and stored securely.

Providers will be asked to provide names and email addresses at the time of site registration to permit follow-up and site access. Identifying data will be stored in a separate file from all other study data and will be accessible only to the global project lead (El-Bohghdadly) and the project chief data scientist (Danny Wong, Guy's and St Thomas' NHS Foundation Trust, London, UK).

6. Please describe how the collected data will be used- (example, prepare a report for operational leaders, publish the findings, etc.).

Collected data will be used to evaluate current practices with regard to airway management and PPE use for patients with COVID-19 infection and to track airway clinician provider health outcomes following COVID-19 airway cases. Publications of findings in peer-reviewed journals or other venues will be undertaken at intervals to communicate findings to the community and provide updates on potential best practices for personnel risk mitigation.

Section B: Project Approval

1. If the primary purpose of your project is for quality assurance or improvement/operations, have you obtained approval from the operational leader within your department or health system [Please refer to FAQ item 1 of the QI Project Guidance Document]?

☐ No [Contact the appropriate operational leader for approval]
☒ Yes – Please specify whom: Scott Falk, MD

[Examples of operational leaders include a medical director of a unit or clinical area, division/department chief, nurse manager, Dean, other health system or institutional leader that can approve the implementation of a quality assurance/improvement project].

Please Note: By submitting your proposed project for a QA/QI determination you are certifying that if the project is established to qualify as QA/QI, you and your Department would be comfortable with the following statement in any publications regarding this project: "This project was reviewed and determined to qualify as quality improvement by the University of Pennsylvania's Institutional Review Board."