

## -Grant Application

1	Project Title	An Innovative Approach to Using Lung Clearance Index (LCI) Device to Monitor New Borns Diagnosed with Bronchopulmonary Dysplasia (PBD).
2	Clinical or Operational Area	Clinical
3	Healthcare System	
4	Hospital or Entity Name	Valley Children's Hospital
5	Applicant Name	Samuel Reyes, PhD
6	Applicant Title	Clinical Research Coordinator
7	E-mail Address	sreyes5@valleychildrens.org
8	Telephone	559-353-7776
9	Mailing Address, City, State, Zip Code	9300 Valley Children's Place, Madera, CA 93636
10	Please list the names and titles/roles of the additional members of the project team:	
	<b>Name:</b>	<b>Title/Role:</b>
	Sudhakar Reddivalam, MD	Principal Investigator
	Lauro Roberto, MD	Sub-Investigator
11	Name of Senior Risk Management or Corporate Insurance Representative	Nathan Powell, Chief Risk Officer
12	Mailing Address, City, State, Zip Code	9300 Valley Children's Place, Madera, CA 93636

**13. The issue being addressed involves the following clinical areas: (Check all that apply)**

- Ambulatory Care
- Emergency Services
- Hospital/System-wide Focus
- Obstetrics/Perinatal
- Radiology/Imaging Services
- Surgical/Peri-Operative
- Other (Please specify)

Surgical/Pre-operative

**14. Briefly describe the project and its importance to the organization: (two paragraphs maximum, please attach any supporting documentation)**

Early detection of changes in health is critical in preventative medicine. By identifying changes as they occur rather than as a cumulative event enables the medical team to adjust treatment accordingly and possibly circumvent the need for expensive or invasive procedures. We propose an innovative and novel approach to use the Lung Clearance Index (LCI)

device on newborn infants with Bronchopulmonary Dysplasia (BPD) as an early detection procedure that will allow us to monitor disease progression as well as assess treatment efficacy. Currently, the use of LCI in asthma and cystic fibrosis (CF) patients is well documented, however, LCI usage is not routinely used to assess BPD in newborns. By using LCI methodology, our goal is to improve long term patient outcomes by affecting change in treatment plans early on that have the potential to minimize permanent irreversible pulmonary damage.

Diagnosis and management of pediatric chronic pulmonary diseases (CPDs) is not only expensive but often a lifetime commitment. Diagnosis of CPDs requires numerous tests such as chest x-rays, CAT scans, blood tests, and echocardiograms- all of which are either expensive or invasive procedures that carry their own inherent risks. For example, both chest X-rays and CAT scans increase the child's exposure to radiation and in some cases the child must be sedated to obtain a clear image. To compound the problem, these tests are performed repeatedly (yearly or every 3- 6 months) to monitor treatment efficacy. Another diagnostic methodology to evaluate treatment efficacy is to measure how well the lungs can move air- pulmonary function tests (PFTs). Pulmonary function can be measured using a variety of devices. Spirometry, considered the gold standard for pulmonary assessment, is commonly used to monitor lung air capacity in patients age 6 years and above. This procedure measures the forced expiratory volume in 1 second (FEV1). However, a major disadvantage of using spirometry is that significant lung disease can be present despite having a "normal" FEV1 value, thus, spirometry may be insensitive to detect early discrete changes in CPD. An alternative to spirometry is LCI, a device that measures lung physiology as determined from Multiple Breath Washout (MBW) tests. These tests involve monitoring the washout of an inert tracer gas from the lungs during relaxed tidal breathing. The tracer gas can be a gas that is normally present in the lungs, e.g. nitrogen, which is washed out when the subject is switched to breathing 100% oxygen. The LCI device has been shown to be sensitive to **early** discrete changes in lung function that are not detected by traditional methods. LCI does not involve forced inhalation/exhalation which can be problematic in children with CPD, and can be used on newborns, infants, children and adults. LCI is an ideal procedure to analyze newborn infants diagnosed with CPDs such as BPD. BPD is a form of chronic lung disease primarily seen in premature newborn infants and is a result of damage in the bronchi and lungs resulting in tissue destruction (dysplasia) of the alveoli.

**15. Describe how this project will improve patient safety or reduce the potential for liability. (one paragraph maximum)**

The goal of this project is to improve patient safety while concomitantly decreasing the potential for liability by monitoring changes in pulmonary function that result in pulmonary damage. The degree of pulmonary damage must reach a "minimal threshold" to be detected. Unfortunately, this minimal threshold represents a level of significant damage that is progressive, permanent, and irreversible. Diagnosis and treatment of BPD requires frequent imaging procedures such as chest x-rays, CAT scans, and echocardiograms, many of which require sedation. Although necessary, these procedures present additional dangers to the patient such as an increased exposure to radiation and possible complications during sedation. By utilizing the LCI device as an initial assessment procedure, doctors can identify early discrete changes in pulmonary function before they can result in significant damage. Data collected from LCI would be instrumental to doctors in the development of effective treatment plans to mitigate damage early on. This intervention has the potential to minimize pulmonary damage and could reduce the need for frequent imaging procedures (radiation exposure and sedation). This has the potential to increase patient safety while reducing the potential for liability.

**16. What metric(s) will be used to measure progress and determine the success of this project?? (one paragraph maximum)**

Key BPD symptoms, including hyperinflation of the lungs, airway reactivity, and changes in lung capacity will be assessed. LCI is sensitive enough to detect changes in these parameters. For example, in BPD a decrease in hyperinflation and airway reactivity along with an increase in lung capacity would be indicative of a positive and effective treatment plan. Conversely, if LCI detected a negative or no effect on BPD symptoms then the provider can make the necessary changes to the treatment plan. A second metric that can be used to measure success would be a decrease in the need to perform expensive and invasive imaging procedures. A third metric would be to determine the frequency of pulmonary exacerbations as determined by the number of urgent care and emergency room visits as well as hospitalizations.

**17. Please describe the tangible results of the project that can be quantified and shared as best practices with other AEIX members? (one paragraph maximum)**

Tangible results that can be quantified and shared as best practices to other AEIX members are:

- Doctors can use LCI device as an initial pulmonary assessment in newborns with BPD to develop a working protocol.
- Longitudinal data collected from individual patients diagnosed with BPD can be used to generate a pulmonary function profile to monitor disease progression.
- Pulmonary profiles can be used to generate and monitor therapies to improve long term outcomes.
- Expanded usage of LCI device on patients who are not able to successfully perform spirometry tests.

18. Please provide a financial estimate of the project \$12,000.00

19. What is the expected timeframe for completion of this project? 12-24 months

20. Is this project based on successful practices evaluated from literature or other healthcare providers?  Yes  No

21. Is this project based on an original concept created by the project team?  Yes  No

22. Do you have plans to publish the project results in a professional publication or networking forum?  Yes  No

23. Is there anything else you'd like to share about this project?

To date, LCI is commonly used as an endpoint analysis in clinical trials and not as a routine diagnostic tool. There is great potential of using LCI in a daily clinical setting to improve patient outcomes. As mentioned, LCI can be used on children 5 years and younger- a subpopulation that spirometry does not address. LCI can also be used on patients that cannot successfully perform spirometry tests. In the Pulmonology Department, we currently have patients who are older than 6 years but cannot successfully complete spirometry tests due to physical or cognitive delays. In a hospital wide setting, LCI can be used on patients from other departments. For example, during the pandemic the Infectious Disease Department oversaw patients with severe acute respiratory syndrome (SARS), Covid-19, whereas the Cardiology Department is currently monitoring patients diagnosed with long-term covid. Most recently, the Genetics Department admitted a patient diagnosed with thymidine kinase 2 deficiency (TK2D), a progressive degenerative neuromuscular disorder that results in respiratory failure and death. The patient was too weak to successfully perform spirometry assessment, an important metric to determine the efficacy of their treatment. We propose that LCI would have been an ideal, innovative, and valuable alternative in determining pulmonary function in all these patients.

**Signatures required to submit this application**

**Primary Clinical Sponsor** (The individual responsible for monitoring progress of the project, submitting receipts and other documentation supporting the use of grant funds, and will provide a summary report of the project outcome)

**VP Quality & Patient Safety & Clinical Value and Research**

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Signature	Title	Date
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**Alternate Clinical Sponsor** (The individual responsible for supporting the responsibilities of the Primary Clinical Sponsor, and assuming those responsibilities if the Primary Clinical Sponsor is unable to fulfill the requirements of the project)

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Signature	Title	Date
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**Senior Risk Management Leader**

**Executive Director & Chief Risk Officer**

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Signature	Title	Date
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CEO or CFO of Applicant's Healthcare Facility

Senior Vice President and Chief Financial  
Office

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Signature

Title

Date

Thank you for completing the application. Please follow these next steps.

- Save this document in Word format and gather your supporting documentation.
- Forward the application and documentation to your senior risk management leader or corporate insurance representative. *They will need to complete and sign the Evaluation of Awards Application Form on the final page of the application before submitting it to American Excess Insurance by **Friday August 16, 2024.***

## Evaluation of Grant Application

The evaluation must be completed and signed by the senior risk manager or corporate insurance representative. Please evaluate the Award Application by indicating the best answer to the question.

**1. How will this project improve safety and/or reduce liability?**

- Little effect on safety and liability (1)
- Some improvement but metrics are not defined and/or it is not clear that measurable effect can be sustained (2)
- Strong effect with clearly defined metrics (3)

**2. What is the potential to share this project or practice with other AEIX members?**

- Little potential – i.e. *implementation requires major budgetary commitment, topic is highly specialized, and/or metrics are not clearly defined* (1)
- Some potential but process may be hard for another organization to implement, and/or its application may be limited  
- i.e. *major budgetary commitment, topic is highly specialized, and/or metrics are not clearly defined* (2)
- Strong potential for producing best practices (3)

**3. What level of impact will this project or practice have on the severity of risk exposure?**

- Little chance of impacting severity of risk but could address other issues (1)
- Some potential to impact risk exposure (2)
- Strong ability to impact severe malpractice exposure caused by significant risk events (3)

**4. What level of innovation best describes this project?**

- Project/practice is new to this organization and is based primarily on firmly established best practices (1)
- Project/practice was created primarily by applicants with some assistance from an outside vendor and contains well-established best practices with additional innovative features (2)
- Project/practice was created solely by applicants and could be included in established literature or industry best practices (3)

**5. Share your comments or recommendations.**

Click or tap here to enter text.

Executive Director &  
Chief Risk Officer

8/\_\_\_/2024

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**E-Signature**

**Title**

**Date**

Click or tap here to enter text.

Npowell1@valleychildrens.org

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**Phone**

**Email**

Send the completed application in Word format, supporting documentation, and signed evaluation to [ana\\_taylor@premierinc.com](mailto:ana_taylor@premierinc.com) by *Friday August 16, 2024*.

**Thank you for your submission. In continued pursuit of our mission and vision to partner with forward-thinking healthcare leaders, inspire innovation, and provide the leading pathway for managing risk, we may share your project with other members of American Excess. However, this project will not be shared outside of the American Excess Insurance membership without your prior consent.**