

FY2020 New Joint ATS/ERS

Assembly/Committee Project Application

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SECTION I - GENERAL PROJECT INFORMATION

- * 1. ATS PROJECT / ERS TASKFORCE TITLE: Updated Technical Standards for the Measurement of Lung Volumes
- * 2. PROJECT PRIMARY ASSEMBLY: Respiratory Structure & Function
- * 3. ATS SECTION:

☑ Not Applicable

- * 4. ATS COMMITTEE SUBMITTING PROJECT APPLICATION:
 - Proficiency Standards Committee
- * 5. ERS ASSEMBLIES
 - Clinical physiology and sleep
 - Paediatrics
 - Allied Respiratory Professionals
- * 6. ERS MAIN DISEASE DOMAIN(s)

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* 7. What official ATS/ERS document will be developed as part of this project?

SECTION II - PROJECT DESCRIPTION

PROJECT DESCRIPTION

* A. Describe the problem and define the goals and objectives of the project.

In addition to the summary of the project, ERS requires a background and an extended description of the project (up to 10 pages). The 2005 ATS/ERS Guidelines for standardization of lung volumes have remained relevant for the past 14 years. However, because of the length of time since they were developed, there is a need to review the standards in detail, affirm those aspects of the standards that continue to apply, and make revisions where necessary. Laboratories and manufucturers around the world rely on consensus standards from the ATS and ERS to evaluate their equipment, software and systems. The task force will conduct a thorough literature review on new studies on the measurement of lung volumes. A non-systematic scan of new data since 2005 led to a number of specific areas identified to update which are summarized below.

Basic Science Overview to be added to updated Introduction of new document: We will add a brief paragraph on the new science since 2005 that raises the importance of measureing lung volumes. This work includes the importance of lung volumes in understanding the effect of obesity on airflow obstruction and response to bronchodilator (3), the value of lung volumes in identifying people at risk for COPD but without obstruction on spirometry by the usual metrics (4), and the effect of hyperinflation on FEV1 and what pathology it represents in asthma (5-7).

Computation: The 2005 document provided two methods to compute total lung capacity and residual volume after the determination of FRC: a first or preferred method, and a second or alternate one. There were no data available to rationally recommend one approach over another. Since then, at least one study has compared these methods in both obstructive and restrictive disorders (8).

Body plethysmography: Manufacturers make it easy to link the measurement of lung volumes with airway resistance even though the optimal technical requirements for each differ. There is a need to stress proper tidal breathing to establish a baseline FRC, and determine through the literature and patient survey whether having different panting rates for FRC vs airway resistance measurement is practical for patients and technologists. Technical recommendations may also be made on the use of the plethysmograph to measure gas compression during exhalation (9, 10).

Multibreath methods: Multibreath methods are growing in use and there are numerous interval

publications into its technical aspects. There is a new technical statement on inert gas washout techniques that should be integrated into the new standard (11). Data on the effects of leaks (12) and tissue nitrogen excretion (13) will inform new evidence-based recommendations. Comparisons of N2 washout devices (14, 15) and inert gases (16, 17) may also influence the standards.

Imaging modalities: New methods for analysis of imaging data for the measurement of lung volumes, as well as comparisons of the results to traditional methods, have been reported: imaging modalities include CT (segmentation methods: (18-21), comparisons: (22-27)) as well as ultrasound and MRI in fetuses and neonates (28, 29). Lung volumes assessed by CT scan were found to aid in selection of patients who will benefit from surgery for chest wall injuries (30). Two studies found that lobe volumes and relative normal lung volume assessed by CT scan provided unique prognostic information beyond FVC in idiopathic pulmonary fibrosis (31, 32).

Repeatability and agreement within and between methods: There are new data on expected limits of agreement between plethysmography and gas dilution in health and disease (33-38). Limits of agreement between methods can help laboratories and manufacturers validate equipment. Better guidance on repeatability standards within methods and within disease categories (i.e. obstructive vs restrictive vs normal) is needed if data are available. This is especially important given an increasing interest in the response of lung volumes to bronchodilator administration (39, 40).

Equipment: There are new reports on lung models to facilitate comparison of equipment between laboratories (41-43). If these models are valid they have the potential to help manufacturers provide better equipment and to increase the accuracy and precision of measurements in multi-center clinical studies. A thorough review of the availability and use of methods that were not addressed in the 2005 statement is necessary to determine if any information about them needs to be included (e.g. (41, 44).

Pediatrics: The previous technicals standard had very few recommendations on the measurement of lung volumes in children. An update can provide more guidance on the performance of body plethysmography in children including the impact of filter size on assumptions about isothermal conditions during panting, and instruction on the method and ordering of panting vs tidal breathing (45, 46). New guidelines on multiple-breath washout testing in preschool children need to be integrated into the new lung volumes technical standard (11). The committee has two pediatric pulmonologists and one pediatric pulmonary physiology scientist. The committee will review prior statements on lung function testing in children as well as the literature for guidance on what should be included in this update.

Reference values and reporting:

The new pulmonary function reporting standards and upcoming GLI reference values for lung volumes will be integrated into the update (47).

Summary of potential effects on clinical practice:

1) Computation: new knowledge on the equivalence between choices of TLC computation will give more flexibility to technologists to obtain lung volumes in *challenging populations such as those with airflow obstruction or obesity*

2) Pediatrics: better guidance on proper technique in children will lead to improved results 3) Interpretation: guidance on bounds of technical repeatability will help interpret the bronchodilator response in lung volumes for which there is growing clinical interest in asthma and COPD.

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Project File: -- empty --

* B. FOR CLINICAL PRACTICE GUIDELINES ONLY (all others leave blank), please list your specific

questions to be addressed.

Applicants should list all questions relevant to daily clinical practice that are to be covered by the guideline. Questions should be as specific as possible about the patients/populations to be included or excluded, types of diagnostic or therapeutic interventions to be considered or left out. Questions should be structured in PICO format, specifying the target patient population (P), the intervention or exposure (I), comparators (C), and outcomes of interest (O). While it is expected that the initial set of questions will undergo revision and refinement, applicants are encouraged to be as specific as possible about each one of the PICO elements. Generally speaking, fewer then eight questions are considered a manageable scope.

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* C. Are you aware of any non-ATS or non-ERS activities in this area?

No

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* D. Describe why this project should be a priority for the ATS and ERS?

Lung volumes are routinely measured as part of the evaluation of patients with respiratory symptoms. Numerous publications since 2005 have further established the importance of lung volumes in the assessment of a variety of functional defects including both restrictive and obstructive ventilatory defects. Unlike spirometry, multiple methods are used to measure lung volumes. Some of these methods, such as multiple-breath nitrogen washout and CT imaging have had technical advances in equipment, knowledge in sources of variability, and data processing. There are new data comparing the performance of different methods. Over 14 years have passed since the previous standards were developed, and although they have generally remained as the accepted standards, it is essential that the ATS and ERS, as the world's leading pulmonary societies, ensure that the technical standards for measurement of lung volumes reflect all available current knowledge and practice in this area. **Per ATS policy, we will consider adding other international respiratory societies (e.g. APSF, APSR, ALAT, and TSANZ) if our initial review suggests this will be helpful and if such a collaboration is approved by the ATS and ERS.**

* E. Describe the methodology that will be used to carry out the project objectives: For clinical practice guidelines (CPGs) include the following: Search Strategy, Review of Evidence, Rating the quality of evidence, Formulation of Recommendations and other key activities leading towards completion of this project. See table 1 on page 7 of the Guidelines for ATS Documents (GATS) on the ATS website at: https://www.thoracic.org/statements/document-development/index.php. For ERS documents please see page 4 of the ERS Guideline at

https://ers.box.com/shared/static/qj9d0ykhj87dxxn8vplnmsiv8rl083m8.doc

Please add at the end of the paragraphe: For any question on methodology, do not hesitate to contact

the ERS methodologists (at guidelines_statements@ersnet.org) prior submission of your application. We propose to produce a technical standards document according to the guidelines issued by the ATS and ERS. Specifically, this document will address how to perform lung volume measurement, and will be based on evidence gathered by literature review whenever available, supplemented by expert panel consensus when there is either no evidence or the evidence is not clear. There will be three phases of development:

Review of 2005 document in detail to identify any areas of uncertainty or missing information. The
proposed task force is comprised of researchers and clinicians with extensive experience in
measuring lung volumes and lung volumes instrumentation. The task force members provide a
combination of medical, biomedical and laboratory managment expertise. Task force members were
selected by the ATS Proficiency Standards for Pulmonary Function Laboratories Committee and the
ERS leadership. The task force will begin with a comprehensive review of all aspects of lung volume
equipment and test procedures within the current 2005 document. The assessment of needs for
standards will include instrumentation, calibration, software algorithms and the lung volume testing
technique for each method. Task Force members will meet via teleconference to review and discuss
the 2005 document and identify areas that require updating, clarification or modification.
Discussions will be held monthly via teleconference, and during face-to-face meetings (ATS 2020,
ERS 2020).

2. Review of literature to identify new information related to technical performance of lung volume measurement. A preliminary literature review relevant to lung volume measurement has identified several aspects to be addressed, as noted in the Background section. Led by the co-chairs, the task force will conduct a more thorough literature review and will also reconsider many of the studies that were used in the development of the 2005 standards as well as any newer studies. The primary data base will be NIH PubMed which comprises citations for biomedical literature from MEDLINE, life science journals, and online books. All citations related to lung volumes methodology will be collected and divided among task force members to review for pertinent evidence applicable to the development of standards for instrumentation, techniques and quality control for lung volume measurements. Acceptability criteria will be developed for inclusion of studies, particularly in regard to having adequate detail in the description of methods and equipment. Since as a Technical Statement we will not be conducting a formal systematic review or utilizing the GRADE process, we will ask for the assistance of a librarian to advise the taskforce on the organization and process of conducting the literature review. The librarian will build the search strategy by organizing searches by topic, using standardized keywords and cross-referencing, and will also pull the full-text of papers which is important given that not all members have access to all journals at their local institutions. However, the committee members will execute the search and review the titles/abstracts because their clinical and scientific expertise is necessary to decide what is

relevant from the output. Working groups will be created for method-independent topics (e.g. computations, predicted values including GLI, repeatability, pediatrics), body plethysmography, multiple-breath techniques, imaging modalities. All working group members will be responsible for reviewing the literature. **Each working group may be assigned more than one topic.**

3. Integration of literature review and expert opinion to develop revised document. The implications of measurement errors for every component of the data collection and analysis process will be reviewed in a stepwise approach to determine the accuracy and precision required to achieve acceptable lung volumes measurements. A review of current pulmonary function equipment manuals and specification sheets with comparisons to similar instrumentation used in other fields will be made to determine what level of precision is achievable in commercial pulmonary function instrumentation. We will also solicit this information directly from manufacturers, as was done for the updated Spirometry standards. The methods used for calibration will be reviewed and new calibration procedures may be recommended which will address the needs identified. New quality control standards will be developed so that the analysis software can be verified as well as the individual components. Standards will also be developed for the output of data and test results that will permit both verification of algorithms and compatibility with standard electronic reporting formats. Recommendations to use the new standardized reporting format will be included. If both ATS and ERS have endorsed GLI reference values for lung volumes, inclusion of these reference values will be integrated in the standards. Each standard will have a rationale regarding the need for the standard and the level of accuracy and precision prescribed. Standards will be developed by consensus. Where disagreements cannot be resolved through discussion and debate of the available evidence, or in cases where there is no clear consensus, the task force will present the issue with the alternative strategies, similar to the approach taken in other 2005 ATS/ERS pulmonary function standards. Finally, we will solicit input on the performance of lung volume measurements from patients via an electronic survey, similar to the process used for the updated Spirometry standards. In particular, we will seek information on patient understanding of lung volume measurement, comfort with the procedure, and any recommendations for improvement of testing from the patient's point of view. This information will be integrated into the new standards, whenever possible.

We will break up into smaller groups that will each contribute to writing, with chairs guiding the overall direction and writing.

* F. FOR CLINICAL PRACTICE GUIDELINES ONLY (all others leave blank), please identify WHO will perform the systematic reviews.

We encourage project teams to identify and make use of recently published, high quality systematic reviews performed by others. However, it is required that one or more members of the team have first-hand experience performing (and publishing) systematic reviews. Applicants are encouraged to recruit qualified individuals with adequate time to help perform systematic reviews. These may include junior members.

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* G. All applicants must review a document development video (<u>https://www.thoracic.org/members/assemblies/about/assembly-project-application-resource-</u> <u>center.php</u>) and set of document-development vignettes prior to submitting this application. Yes, I have review the document development video

H. FOR CME EDUCATIONAL PROJECTS/PRODUCTS ONLY: FOR MORE INFORMATION PLEASE SEE INSTRUCTIONS. PLEASE DESCRIBE THE FOLLOWING:

I. Joint Task Forces - Public and Patient Input Budget:

If patient involvement is required, task force chairs must consider how patients/patient organisations could be involved. We recommend contacting ELF <u>info@europeanlung.org</u> to discuss before submitting your application. Costs related to patient involvement in task force meetings should be included in the application. For further information on the ways that patients can be involved and facilitated please view the ELF process diagram <u>https://www.europeanlung.org/assets/files/en/elf-patient-input-process.pdf</u>

* I would like patient representatives to attend the task force meeting(s) in an advisory function (ELF recommends 1-2 patient representatives attend meetings):

No

* I would like to consider additional/alternative ways of involving patients (if yes, please explain in the table below). These costs will be covered and managed by ELF once an approach has been agreed. Yes

* Patient input factors (200 words max):

The Task Force will leverage its existing partnership with the European Lung Foundation (ELF) to incorporate patient experiences into the updated technical standards document. Through the ERS and ELF, we will conduct a survey of patient's who have had lung volume testing to understand their experiences, their perception of unmet needs, and their preferences around lung volume measuremesnt. As we did for the spirometry document, the survey will be designed by the committee after a number of recursive reviews, implemented by sending it out by email through the European Lung Foundation, with data analyzed by a statistician from the ELF and the results used by the committee to create a section in the document on patient feedback about their experience with the test. Examples of topics for the survey will be knowledge of the rationale for testing, problems with the duration of time for testing, size of boxes and configuration of chairs and pneumotachs in boxes, claustrophobia, and whether having different rates of panting is practical for patients. In addition to the patient survey on lung volumes, feedback collected from

patients to inform ELF's patient factsheets and information materials on lung function testing will also be used. This information will help to inform the recommendations included in the technical standards document. In addition, ELF will produce information for patients on the updated measurement recommendations, providing accessible information for patients on what the tests entail.

Given the need to also get input from the patient community served by the ATS, we have engaged with the ATS Patient and Family Education Committee to facilitate input from that group.

SECTION III - PROPOSED PARTICIPANTS

If your project intends to develop a Clinical Practice Guideline

ATS and ERS requests proposals from multidisciplinary teams that include those with relevant clinical expertise and those with expertise in methods of critical appraisal of the literature, systematic literature review and guideline development. ATS encourages involvement of diverse stakeholders, each bringing a unique and important perspective to the process. A typical team should generally include clinical experts (including physicians, nurses and respiratory therapists), clinical investigators, one or more experts in systematic review and guideline development, and one or more external stakeholders, including a patient or patient representative. For some guidelines, it may also be useful to have a health economist, a medical librarian, an expert in group facilitation and/or project management, and/or one or more members to represent the perspective of governmental and non-governmental payer and health plans.

Evidence synthesis requires appropriate methodology. ATS and ERS requires a systematic literature review for Clinical Practice Guidelines and use of GRADE to assess the quality of evidence and to rate the strength of treatment recommendations for Clinical Practice Guidelines. Starting in 2012, the ATS requires NEW project applications that intend to develop a Clinical Practice Guidelines to include 1 or more individuals with documented experience in these methodologies (i.e., have designed a systematic review; have applied GRADE for treatment recommendations); such individuals will be expected to provide methodologic support for document development in collaboration with the ERS or ATS methodologist. Alternatively, NEW project applications may include 1 or more junior members (e.g., Fellows or Assistant Professors) with an interest in learning how to perform an evidence synthesis using methods required by the ATS and ERS; such individuals ("ATS Evidence Synthesis Scholar") will be expected to work in collaboration with the ATS or ERS methodologist to design the systematic literature review and, where applicable, apply GRADE for treatment recommendations. Finally, upon request, the ATS will provide a guideline methodology trainee who will work with the supervision of the ATS methodologist to perform the methodological work for your committee.

If your project intends to develop a Clinical Practice Guideline, please indicate below which of the project participants meet the criteria described above. Also, please indicate if they have documented expertise in applying the ATS and ERS requirements for evidence synthesis OR will serve as an Evidence Synthesis Scholar. For more information, please discuss with the Document Development and Implementation Committee (contact Judy Corn, DDIC Staff) or ERS Office (Valerie Vaccaro at guidelines_statements@ersnet.org) at least 1 week before submitting the application.

To facilitate development of guideline derivatives, you will be required to submit a) 3-5 key points to be used to formulate a Clinician Summary and b) 3-5 key points to be used to formulate a Patient Summary, at the time you upload your final draft manuscript to ScholarOne.

The ERS recommendation concerning the panel for CPGs, statements and technical standards of expert are the following:

- Panels should not exceed 15 members
- Supplementary experts can participate as external consultants if needed.
- Panels should be multidisciplinary and encompass all the required areas of expertise for the completion of the document, thereby being representative of the various disciplines, professions and stakeholders involved in the considered topic

- Panels should be gender and age-balanced, the inclusion of at least one early-career member is encouraged
- The inclusion of 1 or 2 patient representatives with an advisory role is encouraged whenever appropriate
- For CPGs, the ERS strongly encourages to include in the panels experts experienced in systematic reviews and the GRADE approach

A. PROPOSED PARTICIPANTS - The proposed participants must have their conflict of interest disclosures vetted and may require approval by the co-sponsoring society before being formally added to the project committee.

Name : Niray R Bhakta
Institution : University of California, San Francisco
"Role" on Project committee : ChairATS
Area of Experties · Pulmonary function physiology asthma
Specialty : Pulmonary
Email: niray.bhakta@ucsf.edu
Airfare :
Participant will require Per Diem : Yes
Country : United States
Name : Aisling McGown,
Institution : Connolly Hospital, Dublin, Ireland
"Role" on Project committee : ChairERS
Area of Experties : Respiratory physiology and medical physics
Specialty : Pulmonary
Email : aisnmcg@yahoo.ie
Airfare :
Participant will require Per Diem : Yes
Country : Ireland
Name : David Kaminsky
Institution : University of Vermont
"Role" on Project committee : member
Area of Experties : Pulmonology
Specialty : Pulmonary
Email : david.kaminsky@med.uvm.edu
Airfare :
Participant will require Per Diem : Yes
Country : United States
1

Name : Erik R. Swenson
Institution : University of Washington, Seattle
"Role" on Project committee : member
Area of Experties : Pulmonary physiology
Specialty : Pulmonary
Email: erik.swenson@va.gov
Airfare :
Participant will require Per Diem : Yes
Country : United States
Name : Allan Coates
Institution : Research Institute of the Hospital for Sick Children, Toronto Canada
"Role" on Project committee : member
Area of Experties : Pediatric pulmonary physiology and lung function testing
Specialty : Pulmonary
Email : allan.coates@sickkids.ca
Airfare :
Participant will require Per Diem : Yes
Country : Canada
Name : Charlie Irvin
Institution : University of Vermont
"Role" on Project committee : member
Area of Experties : Lung function testing
Specialty : Pulmonary
Email: charles.irvin@med.uvm.edu
Airfare :
Participant will require Per Diem : Yes
Country : United States

Name : Kevin McCarthy
Institution : Expert PFT
"Role" on Project committee : member
Area of Experties : Pulmonary function testing
Specialty : Pulmonary function technologist
Email: expertpft@gmail.com
Airfare :
Participant will require Per Diem : Yes
Country : United States
Name : Carl Mottram
Institution : Clinical and Laboratory Standard Institute
"Role" on Project committee : member
Area of Experties : Pulmonary function testing
Specialty : Respiratory therapist
Email : carlmottram@outlook.com
Airfare :
Participant will require Per Diem : Yes
Country : United States
Name : Meredith McCormack
Institution : Johns Hopkins
"Role" on Project committee : member
Area of Experties : Pulmonary physiology and lung function testing
Specialty : Pulmonary
Email : mmccor16@jhmi.edu
Airfare :
Participant will require Per Diem : Yes
Country : United States

Name : Gwen Skloot
Institution : Mount Sinai
"Role" on Project committee : member
Area of Experties : Pulmonary function testing and physiology
Specialty : Pulmonary
Email: gwen.skloot@mountsinai.org
Airfare :
Participant will require Per Diem : Yes
Country : United States
Name : Brendan Cooper
Institution : University Hospital Birmingham
"Role" on Project committee : member
Area of Experties : Pulmonary function testing
Specialty : Pulmonary physiology
Email : brendan.cooper@uhb.nhs.uk
Airfare :
Participant will require Per Diem : Yes
Country : United Kingdom
Name : Jane Kirkby
Institution : Sheffield Children's Hospital
"Role" on Project committee : member
Area of Experties : Lung function testing
Specialty : Respiratory physiology
Email : jane.kirkby@nhs.net
Airfare :
Participant will require Per Diem : Yes
Country : United Kingdom
·

Name : Felip Burgos
Institution : Institut d'Investigacions Biomèdiques August Pi i Sunyer (IDIBAPS)
"Role" on Project committee : member
Area of Experties : Respiratory diagnostics
Specialty : Pulmonary physiology
Email : FBURGOS@clinic.cat
Airfare :
Participant will require Per Diem : Yes
Country : Spain
Name : Graham Hall
Institution : Telethon Kids Institute
"Role" on Project committee : member
Area of Experties : Respiratory physiology
Specialty : Pediatric pulmonary
Email : Graham.Hall@telethonkids.org.au
Airfare :
Participant will require Per Diem : Yes
Country : Australia
Name : Jana Kivastik
Institution : University of Tartu, Estonia
"Role" on Project committee : member
Area of Experties : Recording and interpretation of lung function data
Specialty : Physiology
Email : jana.kivastik@ut.ee
Airfare :
Participant will require Per Diem : Yes
Country : Estonia

Name : Francisco García-Río
Institution : Autonoma University of Madrid
"Role" on Project committee : member
Area of Experties : Lung function
Specialty : Pulmonary
Email : fgrio@salud.madrid.org
Airfare :
Participant will require Per Diem : Yes
Country : Spain
Name : Kathryn Ramsey
Institution : University Children's Hospital Bern, Switzerland
"Role" on Project committee : member
Area of Experties : Respiratory medicine
Specialty : Pediatric pulmonary
Email : kathryn.ramsey@extern.insel.ch
Airfare :
Participant will require Per Diem : Yes

B. Proposed member(s) who will perform the methodological tasks, including systematic reviews and grading of evidence (for Clinical Practice Guidelines only):

* C. Brief description of methodological experience/relevant publications for each person listed above (CV or list of publication can be added to your application as additional documents in **SECTION VIII**):

ATS co-chair Nirav R. Bhakta, MD, PhD Associate Professor of Medicine, Pulmonary and Critical Care Medicine, University of California, San Francisco, USA. Served as the Director of Education of the Pulmonary Function Lab at University of California San Francisco Medical Center since 2016. Member of the ATS Proficiency Standards for Pulmonary Function Laboratories Committee since 2019. Co-author on publications describing new spirometric indices. Co-author on upcoming book chapters on pulmonary function testing in a major respiratory medicine textbook. Research interests involve advancing interpretation of spirometry, lung volumes in asthma, phenotyping airway inflammation in asthma through genomics, and improved training in pulmonary physiology and testing for pulmonary fellows.

The Peak Index: Spirometry Metric for Airflow Obstruction Severity and Heterogeneity. Bhatt SP, Bodduluri S, Raghav V, **Bhakta NR**, Wilson CG, Kim YI, Eberlein M, Sciurba FC, Han MK, Dransfield MT, Nakhmani A; COPDGene Investigators. Ann Am Thorac Soc. 2019 Mar 13. New Spirometry Indices for Detecting Mild Airflow Obstruction.Bhatt SP, **Bhakta NR**, Wilson CG, Cooper CB, Barjaktarevic I, Bodduluri S, Kim YI, Eberlein M, Woodruff PG, Sciurba FC, Castaldi PJ, Han MK, Dransfield MT, Nakhmani A. Sci Rep. 2018 Nov 30;8(1):17484.

Insights from Recognition of a Contradiction in the Equations that Define the Diffusing Capacity of the Lung for Carbon Monoxide. **Bhakta NR.** Ann Am Thorac Soc. 2017 Mar;14(3):473-474.

ERS co-chair Aisling McGown, MSc Scientist experienced in Respiratory Physiology and Medical physics. Manager of Lung function and Sleep diagnostics at Connolly Hospital, Dublin, Ireland. Involved in research for 30 years and an academic Lecturer at Technological University Dublin (TUDublin) and RCSI Dublin. Passionate about delivery of high quality service to our users. ERS Spirometry education committee member for 5 years, currently chair of ERS Group 9.1. ERS spirometry interpretation skills workshop faculty member. Developed and co-ordinated recent ERS skills workshops at Congress (Body plethysmpography (2018) and Diffusing capacity (2019)). Committee member of The Irish Institute of Clinical Measurement Science and Irish Sleep society. Current research collaboration as a PhD candidate is with Heart and lung Institute /Imperial college London on lung physiology and airway microbiome.

European Respiratory Society International Congress 2018: Allied Respiratory Professionals' report of highlighted sessions M Rutter, CA Camillo, P Coss, A Sajnic, **A McGowan**, D Langer, ... ERJ open research 5 (1), 00182-2018 2019

Detailed physiological profiling of patients for a study investigating the airway microbiome **A Mcgowan**, O O'Carroll, A O'Brien, S Cox, P Goodman, C Burke European Respiratory Journal 52 (suppl 62), PA3404 2018

Impact of Global Lung Initiative (GLI) Reference Values on Spirometry Data acquired in a sample from an Irish Hospital population. **A McGowan**, C Doughty, K McEvoy, S Cox, K Fennell, A O'Brien, J Doran, ... IRISH JOURNAL OF MEDICAL SCIENCE 187, S274-S274 2018

Phrenic Nerve Palsy Secondary to Parsonage–Turner Syndrome: A Diagnosis Commonly Overlooked T McEnery, R Walsh, C Burke, **A McGowan**, J Faul, L Cormican Lung 195 (2), 173-177 3 2017

David Kaminsky, MD Professor of Medicine, Pulmonary and Critical Care Medicine, University of Vermont, Burlington, USA. Served as the Medical Director of the Pulmonary Function Lab at University

of Vermont Medical Center since 1995. Member of the ATS Proficiency Standards for Pulmonary Function Laboratories Committee since 2009, currently serving as Chair. Co-author on 2013 ATS clinical practice guideline on exercise-induced bronchospasm, 2014 ERS/ATS statements on field walking tests, 2017 ERS technical standard on bronchial challenge testing, 2017 ATS technical statement on recommendations for a standardized pulmonary function report, 2018 ERS technical standard on indirect bronchial challenge testing, and the recently approved Standardization of Spirometry - 2019 Update: An Official ATS/ERS Technical Statement. Current writing committee member on the ERS Technical Standards for Oscillometry and 2019 Update of the ATS/ERS Standards on Lung Function Interpretation, both under development. Member of the NBRC Pulmonary Function Testing exam writing committee since 2010. Research interests involve multiple aspects of pulmonary physiology, and in particular lung mechanics in asthma and COPD.

ERS technical standard on bronchial challenge testing: pathophysiology and methodology of indirect airway challenge testing.

Hallstrand TS, Leuppi JD, Joos G, Hall GL, Carlsen KH, **Kaminsky DA**, Coates AL, Cockcroft DW, Culver BH, Diamant Z, Gauvreau GM, Horvath I, de Jongh FHC, Laube BL, Sterk PJ, Wanger J; American Thoracic Society (ATS)/European Respiratory Society (ERS) Bronchoprovocation Testing Task Force. Eur Respir J. 2018 Nov 15;52(5).

Recommendations for a Standardized Pulmonary Function Report. An Official American Thoracic Society Technical Statement.

Culver BH, Graham BL, Coates AL, Wanger J, Berry CE, Clarke PK, Hallstrand TS, Hankinson JL, **Kaminsky DA**, MacIntyre NR, McCormack MC, Rosenfeld M, Stanojevic S, Weiner DJ; ATS Committee on Proficiency Standards for Pulmonary Function Laboratories. Am J Respir Crit Care Med. 2017 Dec 1;196(11):1463-1472.

Erik R. Swenson, MD Professor of Medicine and of Physiology and Biophysics, Pulmonary, Critical Care and Sleep Medicine, University of Washington, Seattle, WA, USA. He has served as the Medical Director of the Pulmonary Function Lab at VA Puget Sound Health Care System since 2001. Research interests involve multiple aspects of pulmonary physiology, and in particular gas exchange, lung mechanics and pulmonary vascular regulation at high altitude, during exercise and in other stressful environments. He is editor-in-chief of High Altitude Medicine and Biology, section editor of the "Clinical Physiologist' of the Annals of the American Thoracic Society, as well as editorial board member of the American Journal of Respiratory and Critical Care Medicine and Journal of Applied Physiology, all roles that involve considerable reviewing and judging work in pulmonary function testing and physiology in general. Robertson HT, **Swenson ER**. What do dead-space measurements tell us about the lung with acute respiratory distress syndrome? Respir Care. 2004 Sep;49(9):1006-7.

Steinacker JM, Tobias P, Menold E, Reissnecker S, Hohenhaus E, Liu Y, Lehmann M, Bärtsch P, **Swenson ER**. Lung diffusing capacity and exercise in subjects with previous high altitude pulmonary oedema. Eur Respir J. 1998 Mar;11(3):643-50.

Dehnert C, Luks AM, Schendler G, Menold E, Berger MM, Mairbäurl H, Faoro V, Bailey DM, Castell C, Hahn G, Vock P, **Swenson ER**, Bärtsch P. No evidence for interstitial lung oedema by extensive pulmonary function testing at 4,559 m.Eur Respir J. 2010 Apr;35(4):812-20.

Swenson ER, Robertson HT, Polissar NL, Middaugh ME, Hlastala MP.Conducting airway gas exchange: diffusion-related differences in inert gas elimination. J Appl Physiol (1985). 1992 Apr;72(4):1581-8.

Allan Coates, MD Professor Emeritus in Pediatrics at the University of Toronto and Senior Scientist Emeritus at the Research Institute of the Hospital for Sick Children, Toronto Canada. He has had a long standing interest in the physiology of pulmonary function testing in the evaluation of pediatric lung disease. This has included measurements in children (neonates and infants) too young to cooperate with testing and those who can do "conventional" lung function testing but where pediatric considerations are necessary. He has had a long standing interest in the promotion of joint ATS/ERS missions, having chaired the ATS International Relations Committee from 1990 to 1996. During this time the first joint working group was struck which came out with recommendation for standards for infant lung function testing. He has been a member of the ATS Proficiency Standards for Pulmonary Function Laboratories Committee from 1997 until 2016. He was an ATS representative to the joint ATS/ERS Task Force: Standardization of Lung Function Testing that resulted in the series of document published in the ERJ in 2005. Most recently he co chaired the ERS/ATS Task Force on bronchial provocation which has resulted in the revision of the previous standards.

ERS technical standard on bronchial challenge testing: pathophysiology and methodology of indirect airway challenge testing.

Hallstrand TS, Leuppi JD, Joos G, Hall GL, Carlsen KH, Kaminsky DA, **Coates AL**, Cockcroft DW, Culver BH, Diamant Z, Gauvreau GM, Horvath I, de Jongh FHC, Laube BL, Sterk PJ, Wanger J; American Thoracic Society (ATS)/European Respiratory Society (ERS) Bronchoprovocation Testing Task Force. Eur Respir J. 2018 Nov 15;52(5).

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Kaminsky DA, MacIntyre NR, McCormack MC, Rosenfeld M, Stanojevic S, Weiner DJ; ATS Committee on Proficiency Standards for Pulmonary Function Laboratories.Am J Respir Crit Care Med. 2017 Dec 1;196(11):1463-1472.

ERS technical standard on bronchial challenge testing: general considerations and performance of methacholine challenge tests.

Coates AL, Wanger J, Cockcroft DW, Culver BH; Bronchoprovocation Testing Task Force: Kai-Håkon Carlsen, Diamant Z, Gauvreau G, Hall GL, Hallstrand TS, Horvath I, de Jongh FHC, Joos G, Kaminsky DA, Laube BL, Leuppi JD, Sterk PJ. Eur Respir J. 2017 May 1;49(5). pii: 1601526.

Charlie Irvin, PhD Professor of Medicine, University of Vermont, Burlington, USA. Dr. Irvin has greater than 40 years' experience in lung function testing. From 1980-1998 he was the Medical Director of a full service, busy clinical PFT laboratory. Served on the ATS Proficiency Committee from 1993-1998 and has since served on several ATS/ERS lung function standardization committees co-authoring documents on bronchial challenge, spirometry, DLco, FENO and more recently is a writing committee member on the ERS Technical Standards for Oscillometry. He has authored numerous peer-reviewed publications and book chapters on lung function testing many of which cover the topic of lung volumes. He has served on the editorial boards of Respiratory Care, American Journal of Respiratory Cell and Molecular Biology, American Journal Respiratory and Critical Care Medicine, Journal of Allergy and Clinical Immunology: In Practice and currently COPD Journal. His research activities delve into the respiratory epithelium, lung mechanics and clinical aspects of Asthma and COPD.

An epilogue to lung function and lung disease: state-of-the-art 2015. **Irvin CG**, Hall GL. Respirology. 2015 Oct;20(7):1008-9.

Using lung function measurements to greater advantage in patients with lung disease: which test and when?

Hall GL, Irvin CG. Respirology. 2014 Aug;19(6):780-1.

Kevin McCarthy, RPFT Former manager of the Pulmonary Function Laboratories at the Cleveland Clinic Health System from 1983-2016, U.SA. Now employed as a consultant with primary responsibilities including advising on and managing quality control of pulmonary function measurements in clinical trials. Expertise in all aspects of pulmonary function testing and quality control. Member, ATS Proficiency Standards for Pulmonary Function Laboratories Committee since 2017 and ATS/ERS Task Force for updating the Spirometry Standards, 2019. Participated in dozens of peer review articles and publications on pulmonary function testing.

A survey of practices of pulmonary function interpretation in laboratories in Northeast Ohio. Mohanka

MR, **McCarthy K**, Xu M, Stoller JK.Chest. 2012 Apr;141(4):1040-1046.

Carl Mottram, RRT, RPFT Mr. Mottram is the former Director of the Mayo Clinic Pulmonary Function Laboratory and Associate Professor of Medicine, U.S.A. He currently serves as President of the Clinical and Laboratory Standard Institute (CLSI). He also serves on the National Board for Respiratory Care (NBRC) where amongst his many assignments is the Chair of the PFT Examination committee. He is a member of the ATS Working Group on PFL Accreditation. Professor Mottram is a recognized expert in the field of pulmonary diagnostics, has published numerous articles and lectured worldwide. He is the author and editor of Ruppel's Manual of Pulmonary Function Testing which is consider by many the definitive textbook in the field of pulmonary diagnostics.

Mottram C. Ed. Ruppel's Manual of Pulmonary Function Testing, 11th ed. St. Louis, MO: Elsevier, 2018.

Meredith McCormack, MD MHS Associate Professor of Medicine, Pulmonary and Critical Care Medicine, Johns Hopkins University, U.S.A. has served as the Medical Director of the Pulmonary Function Lab since 2011. She has been a member of the ATS Proficiency Standards for Pulmonary Function Laboratories Committee since 2009, currently serving as Vice Chair, and a member of the Global Lung Initiative. She has served on committees for ATS/ERS statements including the 6 minute walk test and the standardization of spirometry. She has recently co-chaired a workshop on interoperability of pulmonary function testing, held at the 2019 ATS meeting. Her research interests include pulmonary physiology, particularly in the context of air pollution health effects in asthma and COPD.

Recommendations for a Standardized Pulmonary Function Report. An Official American Thoracic Society Technical Statement.

Culver BH, Graham BL, Coates AL, Wanger J, Berry CE, Clarke PK, Hallstrand TS, Hankinson JL, Kaminsky DA, MacIntyre NR, **McCormack MC**, Rosenfeld M, Stanojevic S, Weiner DJ; ATS Committee on Proficiency Standards for Pulmonary Function Laboratories. Am J Respir Crit Care Med. 2017 Dec 1;196(11):1463-1472.

Gwen Skloot, MD is Professor of Medicine in the Division of Pulmonary and Critical Care Medicine at Mt. Sinai Medical Center in New York, NY. She is the Director of the Pulmonary Function Laboratory and the director of the pulmonary physiology program at the Icahn School of Medicine at Mount Sinai/ Mount Sinai Hospital. Dr. Skloot is an expert in pulmonary physiology and pulmonary function testing, and oversees the performance of all pulmonary function tests and interpretation on the order of 10,000 tests per year. She has been an active member in the American Thoracic Society, having most recently served as the Chair of the Respiratory Structure and Function Assembly from 2018-2019. Her research has been focused on multiple aspects of pulmonary physiology and has been funded by NIH, American Lung Association, and industry. She has over 30 original publications, as well as books and book chapters.

Peters U, Subramanian M, Chapman D, Kaminsky D, Irvin C, Wise R, **Skloot G**, Bates J, Dixon A. BMI but not central obesity predisposes to airway closure during bronchoconstriction. Respirology. 2019 Jun;24(6):543-550.

Skloot GS. The Effects of Aging on Lung Structure and Function. Clin Geriatr Med. 2017 Nov;33(4):447-457.

Skloot GS, Busse PJ, Braman SS, Kovacs EJ, Dixon AE, Vaz Fragoso CA, Scichilone N, Prakash YS, Pabelick CM, Mathur SK, Hanania NA, Moore WC, Gibson PG, Zieman S, Ragless BB; ATS ad hoc Committee on Asthma in the Elderly. An Official American Thoracic Society Workshop Report: Evaluation and Management of Asthma in the Elderly. Ann Am Thorac Soc. 2016 Nov;13(11):2064-2077.

Skloot G, Desai A, Schechter C, Togias A. Impaired Response to Deep Inspiration in Obesity. J Appl Physiol 2011 Sep;111(3):726-34. Epub 2011 Jun 23.

Brendan Cooper, PhD Consultant Clinical Scientist at University Hospital Birmingham, United Kingdom. Advisor, shaper and influential scientific leader who has raised the profile of high quality standards in clinical physiology services. This work has extended beyond the UK to his work with the European Respiratory Society (ERS) where he held high office on the Executive Committee as the Head of Assembly 9 (Allied Respiratory Professionals) and represented the views and standpoint of scientists, physiotherapists and nurses in the ERS. He has chaired the Association for Respiratory Technology and Physiology; served as a national advisor in respiratory physiology to the Department of Health, MHRA and COPD National Framework; participated in two international task forces looking at setting standards for lung function testing reference values and technical standards of gas transfer (TLCO) measurement; and published significant scientific papers on metabolism, respiratory and sleep physiology.

Is it necessary to use a noseclip in the performance of spirometry using a wedge bellows device? C Newall, T M McCauley, J Shakespeare, **B G Cooper** Chronic Respir Dis [2006]; 3: 1-5

Review: An Update on contraindications for lung function testing. **B G Cooper**. Thorax [2011] 66:714-723

Improved criterion for assessing lung function reversibility. H Ward, **BG Cooper**, MR Miller Chest

2015;148(4):877-86.

2017 ERS/ATS standards for single-breath carbon monoxide uptake in the lung. BL Graham, V Brusasco, F Burgos, **BG Cooper**, R Jensen, A Kendrick, N MacIntyre, BR Thompson, J Wanger. European Respiratory Journal 49 (1), 1600016, 2017

Spirometry **B.G Cooper** ERS Buyer's Guide -ERS Publications 2001.

Spirometry: - training, technique and equipment -Quality Control in Lung Function **B G Cooper** & K Butterfield ERS Buyer's Guide, ERJ, (2008)

Replacing your lung function equipment: what you need to know? J K Lloyd & **B G Cooper** ERS Buyer's Guide, ERJ, 63-72, (2013).

Jane Kirkby, PhD Scientist, Highly Specialist Clinical (Respiratory) Physiologist, UCL Institute of child health, London, United Kingdom. She began her training at Kings College Hospital NHS Trust, where she was responsible for performing a wide range of lung function tests on both adult and paediatric patients. In 2005 she commenced work at the UCL Institute of Child Health, to focus her interest in paediatric respiratory research. Alongside her clinical work performing lung function tests in infants and children, she was involved in a number of international research studies, collaborative initiatives including the Global Lung Function Initiative (GLI) and the specific airways resistance task force. She completed her PhD thesis entitled "Application and Interpretation of Paediatric Lung Function Tests in Health and Disease" in 2012. Much of her research has involved investigating standardisation of lung function assessments, the long term impact of lung disease in childhood and the early origins of adult lung disease. She moved to Sheffield Children's Hospital in 2016 and now manages the Action Laboratory and establishing new research links. She regularly lectures on lung function and interpretation courses, and runs several teaching sessions within her Trust.

Kirkby J, Bountziouka V, Lum S, Wade A, Stocks J. Natural variability of lung function in young healthy school children. Eur Respir J. 2016;48(2):411-9.

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Kirkby J, Aurora P, Spencer H, Rees S, Sonnappa S, Stocks J. Stitching and switching: the impact of discontinuous lung function reference equations. Eur Respir J. 2012;39(5):1256-7.

Kirkby J, Stanojevic S, Stocks J. Appropriate interpretation of lung function and exercise capacity in a

longitudinal follow-up of preterm children. Am J Respir Crit Care Med. 2007;175(1):96-7; author reply 7.

Felip Burgos, MSc in Respiratory medicine, PhD Senior Researcher of IDIBAPS and Associated Professor at the University of Barcelona, Spain. He also worked at the Hospital Clinic of Barcelona in the Respiratory Diagnostic Center where he participated in R&D collaborative international projects on integrated care and telemedicine through contribution on reference values and standardization of lung function testing methodology. Dr. Burgos research interests are lung function, eHealth, COPD, spirometry and exercise Physiology. He is a regular member of the ERS-ATS Pulmonary Function Standards Committee and former Chairman of the "Respiratory measurements and technology" Scientific Group of the European Respiratory Society (ERS). Dr. Burgos has published over 90 original manuscripts, editorials, book chapters and reviews with a total of 15000 citations and h index of 31, and he has participated in several European projects. He was awarded in 2016 with the ERS Assembly Lifetime Achievement Award, and European Fellow of European Respiratory Society (FERS) in 2018, award that recognizes lifetime excellence and contributions to research, education and clinical leadership in respiratory medicine.

DLCO: adjust for lung volume, standardised reporting and interpretation BL Graham, V Brusasco, **F Burgos**, BG Cooper, R Jensen, A Kendrick, ... European Respiratory Journal 50 (2), 1701144 1 2017

Automated spirometry quality assurance: supervised learning from multiple experts F Velickovski, L Ceccaroni, R Marti, **F Burgos**, C Gistau, X Alsina-Restoy, ... IEEE journal of biomedical and health informatics 22 (1), 276-284 2 2017

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Protocol for regional implementation of collaborative lung function testing C Vargas, **F Burgos**, I Cano, I Blanco, P Caminal, J Escarrabill, C Gallego, ... NPJ primary care respiratory medicine 26, 16024 6 2016

Algorithm for Automatic Forced Spirometry Quality Assessment: Technological Developments PC Umberto Melia, **Felip Burgos**, Montserrat Vallverdú, Filip Velickovski ...

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Graham Hall MD, PhD Head of Children's Lung Health and Deputy Director at Telethon Kids Institute, Australia. Served as Deputy Editor of Respirology, and is Director of the Australian Council for Clinical Physiologists. He is a member of ATS/ERS Task Forces for Infant and Pre-school Lung Function Testing, Standards for the Forced Oscillation Technique, Updated Technical Standards for Spirometry, and Interpretation of Pulmonary Function tests. He is Co-Chair of the ERS Task Force on Lung Volumes Global Lung Initiative, and the ERS Clinical Research Collaboration – Global Lung Function Initiative Network. Has national and international competitive peer-reviewed funding for multiple studies on physiologic predictors of longitudinal lung health in children with various respiratory diseases. He has over 174 career peer reviewed publications, reviews, editorials, book chapters and position statements including many in multiple breath washout and other aspects of respiratory physiology.

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Jana Kivastik, MD, PhD Associate Professor, Department of Physiology, University of Tartu, Estonia. Her university position includes teaching human physiology and biophysics to students from medical and biological faculties, and also giving lectures to physicians and nurses. Expertise in the recording and interpretation of lung function data. Publications mainly about spirometry and interrupter resistance measurements in children. She has been involved in the ERS task force for the development of a Standardised European Spirometry Driving Licence, and in Spirometry Part 3 Interpretation working group. Faculty member for skills workshops during ERS congresses: Spirometry knowledge and basic skills (2013, 2014) and Clinical interpretation of spirometry results (2018, 2019). ERS expert to evaluate spirometry courses in Norway (2017-2018) and Croatia (2018-2019).

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Francisco García-Río, MD, PhD, FERS Full Professor of Medicine, School of Medicine. Autonoma University of Madrid; Spain. Head of Pneumology Section, Hospital Universitario La Paz, Madrid, Spain. Research lines: lung function, COPD and sleep breathing disorders. 270 publications in PubMed. In lung function tests, main contributions have been the generation of reference values for elderly Europeans subjects (PMIDs:15358698,19745204,22194584), the validation of noninvasive indices of respiratory muscles fatigue in neuromuscular patients (PMIDs:16508243, 12807898), the contribution of bronchial reactivity analysis to assessment of bronchial hyperresponsiveness (PMIDs:20805173, 15002754) and new procedures to operability evaluation (PMID:30195604). Moreover, I have participated in several guidelines about evaluation of respiratory patients in air travel, spirometry and bronchial challenge. Coauthor of 2 SEPAR guidelines (bronchial challenge in asthma; home oxygen therapy). Editor in Chief. Archivos de Bronconeumología. 2008-2014.

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Kathryn Ramsey, PhD. Postdoctoral Research Fellow, Paediatric Respiratory Medicine, University Children's Hospital Bern, Switzerland. She is the current chair of ERS Infant and Preschool Working Group for Infant and Preschool Lung Function. After completing a PhD in the field of Respiratory Medicine at the University of Western Australia, Kathryn has performed seven years of postdoctoral research training at leading international centres including the Telethon Kids Institute, Australia, University of North Carolina at Chapel Hill, USA, and Bern University Children's Hospital, Switzerland. The focus of her research is in respiratory physiology, pathophysiology, and clinical lung function testing. She was a working group member for the ATS Technical Standards Document for Preschool Multiple Breath Washout. She has published key papers into the methodology and clinical utility of multiple breath washout and other lung function techniques including spirometry and the forced oscillation technique. She has received national and international grant funding in the field of paediatric lung function.

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SECTION IV - TIMETABLE

A. TENTATIVE TIMETABLE FOR COMPLETION OF THE PROJECT PLEASE INCLUDE A PROJECT COMPLETION DATE FOR EACH FUNCTION OR ACTIVITY.

Function/Activity	Proposed Dates	Location	# of Participants	Function Completion Date (MM/DD/YYYY)	
identification of gaps and deficiencies in 2005 standards	01/02/2020 to 03/11/2020	via email	17	03/11/2020	
literature review	03/12/2020 to 05/11/2020	via email and conf call	17	05/11/2020	

document development	05/16/2020 to 11/15/2020	via email, conf calls	17	11/15/2020
ATS face-to-face to synthesize review and begin document development	05/16/2020	ATS conference, Philadelphia	17	05/16/2020
review and incorporate patient data	11/16/2020 to 12/30/2020	via email and conf calls	17	12/30/2020
revise document	se document 01/04/2021- via email and 03/01/2021 conf calls		17	03/01/2021
submit document to ATS and ERS	03/01/2021	via email	2	03/01/2021
respond to reviewers' comments	06/01/2021- 06/30/2021	via email and conf calls	17	06/30/2021
submit revised version	06/30/2021	via email	2	06/30/2021

* B. Expected Project Completion Date: 06/30/2021

SECTION V - PROJECT OUTCOMES

All products or works, whether in writing or in another form, that are created partly or completely with the assistance of funding provided by the American Thoracic Society will be the intellectual property of the ATS exclusively, unless otherwise stipulated in writing by the ATS. The disposition of these products or works will be at the sole discretion of the ATS. Recipients agree, as a condition of receipt of ATS funding, that ATS owns the copyright and all other rights to these products or works.

SECTION VI - ATS/ERS Joint Meeting Budget

For Joint Task Forces, after approval by the ERS and the other society, a written agreement will be signed by all parties and should include details on how the expenses will be shared and how and where the reports of the Task Force will be published. If a Task Force is approved, the Science Council can request that the budget is amended and/or reduced. The Task Force Chairs are responsible for ensuring the approved budget is not over-spent. The ERS can rightfully refuse to reimburse travel, accommodation or catering costs if this would be the case. **THE BUDGET REQUESTED TO ERS CONCERNS THE** <u>FULL DURATION OF THE PROJECT</u>

Task Force Meetings Budget:

By using standard costs for each Application, the ERS Science Council can compare all applications and make recommendations on the number of meetings and participants. For the preparation of the budget, please use the following figures **per participant**:

- Travel : €450 per participant for travels within Europe / €1000 per participant for overseas travels
- Accommodation : €150 / night / participant

- Meals: €50 / working day / participant
- Meeting room : €100 / working day / participant

<u>Please note that any residual funds can not be used for purposes other than the meetings planned in the application</u>. Airline tickets <u>must</u> be booked through HRG (ERS Official Travel Partner).

Meetings arranged at the ERS or ATS Congress <u>can not</u> be covered by the Task Force funds except for the expenses of any individuals who are not ERS members and who would not otherwise be expected to attend the Congress.

Meeting 1 budget

* Location: ATS Conference

Funds requested for ATS representatives

(Year 1 Only- Please note that ATS Funds Projects on an annual basis. If more than one ATS meeting is required in the first year please list other ATS meetings under other and provide justification.)

* Round Trip Coach Airfare-Domestic (\$575 per person) Number of Persons?	3	\$1725
* Round Trip Coach Airfare-International (\$2000 per person) Number of Persons?	empty	\$0
 Hotel and per diem (Full Day Meeting at ATS Conference Fri & Sat Only) (\$425 per person) Number of Persons? 	9	\$3825
* Breakfast Meeting at ATS Conference (\$75.00 Per Person) Number of Persons?	9	\$675
* Lunch Meeting at ATS Conference (\$75.00 Per Person) Number of Persons?	9	\$675
Total Budget ATS Meeting 1:		\$6900

Funds requested for ERS Representatives

(Life of the Project – Please note that ERS funds projects one time, so please add all ERS meetings needed for the life of the project) It is assumed that ERS Task Force members will attend both the ATS and ERS Conferences, therefore only non-pulmonologist qualify for ERS travel. Please enter "0" if does not apply.

# of pulmonologist	0	Participants for travels within Europe	* €450/participant	N/A
travet.				
# of pulmonologist	0	Participants for overseas travels	* £1000/participant	Ν/Δ
travel:	0	Farticipants for overseas travels	£1000/participant	N/ <i>T</i>

# of non- pulmonologist travel:	0	Participants for t	ravels wit	hin Europe	* €450/participant	€0
# of non- pulmonologist travel:	5	Participants for overseas travels * €1000/			*€1000/participant	€ 5000
# of hotel nights:	5	Participants	1	nights	* €150/night	€ 750
# of catering:	5	Participants 1 days *€50/day			€ 250	
Total Representative Budget ERS Meeting 1:					€ 6000	

Patient Involvement

Total number of patients:			0	* patient	€0	
Travel:	0	Patients that need travel cost			* €450/patient	€0
Hotel:	0	Patients that need hotel 0 nights night stay		* €150/day	€0	
Food:	0	Patients that need catering	0	days	* €50/day	€0
Total Patients Involvement Budget ERS Meeting 1:					€0	

Meeting 2 budget ☑ Not Applicable

Meeting 3 budget ☑ Not Applicable

Meeting 4 budget ☑ Not Applicable

Additional Budget Cost

ATS/ERS Conference Calls (# of people x # minutes x 0.10)

* # of people 17

* # of minutes 60

* # of calls 15

ATS/ERS Medical Librarian - This item requires approval for CPG's Only 5000.00

* Publication Costs (\$475.00 Per Page)

- Policy Statement 8 Pages Max
- Conference Proceedings & Workshops 8 Pages Max
- Technology Reviews & Standards 8 Pages Max
- Guidelines & Recommendations 15 Pages Max

Number of Pages? -- empty --

* ATS/ERS Other (in dollar, please specify in justifcation below) -- empty --

Please justify:

-- empty --

Staff/Administrative support (non-ERS):

For methodology, if required, you can budget the number of hours that will be needed for the methodological work. The amount indicated here, if approved by the Science Council, can only compensate the work of the person(s) identified in section III B (Proposed members(s) who will perform the methodological tasks).

✓ Not Applicable

SECTION VII

Collaboration: There will be opportunities for other organizations to co-sponsor the document. The ATS/ERS prefers that the project not be discussed with potential co-sponsoring organizations until the project has been approved because premature discussions may jeopardize a final agreement. All negotiations for collaboration will be handled by ATS/ERS staff following project approval.

SECTION VIII - SUPPORTING DOCUMENTS OR REFERENCES

ATS and ERS require references for both chairs justifying their experties in the field.

Documents (please merge all files into one file should not exceed 10 pages)
 [Chair_References_Combined.pdf]

SECTION IX - Conflict of Interest Management

ATS members and others participating in official ATS projects have diverse experiences and relationships that positively contribute to project development. Disclosure and consideration of potential "conflicts of interest" (COI) -- relationships and personal interests that could be perceived as unduly influencing a participant's generation or assessment of evidence, and thereby potentially misinforming healthcare decision makers -- is essential to assure that official ATS projects always reflect the best available evidence and scientific rigor. Therefore, for all proposed projects:

- All project applicants, who are also generally envisioned as the project chair or co-chair(s), must have completed the online 2019
 ATS COI Questionnaire by time of consideration of this application, and in doing so must have fully disclosed all relationships and
 personal interests that are relevant to the project's subject matter. These include but are not limited to all direct financial relationships
 with companies that have business interests related to project subject matter. Please note:
 - ^o Most project applicants have already completed the online COI questionnaire due to involvement in the 2019 ATS International Conference or another 2019 official activity. If so, you simply need to return there (<u>https://thoracic.coiriskmanager.com</u>) to review your disclosure to make sure that it includes everything relevant to this project, and update it if needed. Use the ATS-issued COI website Log-in ID that was previously issued to you, and your self-determined password, or click on the "Forgot Log-in ID" link on the website.
 - If you haven't yet completed the 2019 COI questionnaire, please contact John Harmon at ATS at <u>coioffice@thoracic.org</u> or 212-315-8611 to be reminded of your Login ID if a previous ATS COI website user, or to be registered for the site if a first-time user.
- 2. **COI disclosures are not yet required from other proposed project participants.** Project applications require the names and contact information for the other ATS members or outside experts that you envision as members of your project's planning committee, writing committee, or panel, but these proposed participants are not approved for participation until each has completed ATS COI review, which occurs once the application has been approved-in-concept. At that time (if approved in concept) you and they will be contacted by ATS and instructed to complete or update the ATS COI questionnaire to disclose any COI relevant to project subject matter.
- 3. All projects intended to result in an ATS clinical practice guideline (CPG) must meet additional COI conditions outlined in the Policy for Management of Financial Conflicts of Interest in the Development of ATS Clinical Practice Guidelines. These include specific COI standards for CPG project chairs or co-chairs, and (once the project is approved in concept) ATS review and classification of all proposed panelists as either having no relevant COI, manageable COI, or disqualifying COI.

Contact John Harmon, ATS manager for documents and COI management, at <u>jharmon@thoracic.org</u> or 212-315-8611 if questions about projectrelated COI disclosure and management. Shane McDermott, ATS senior director for ethics and COI, and Kevin Wilson, MD, ATS Documents Editor can assist John where needed.

SECTION X - ERS CONFLICT OF INTEREST (COI) AND CONFIDENTIALITY MANAGEMENT

- 1. Task Force's details
- * Full title: Updated Technical Standards for the Measurement of Lung Volumes
- * Chairs' name: Nirav Bhakta and Aisling McGowan
- 2. Personal Information:
- * Title and name and surname: Dr. Nirav Bhakta; Ms. Aisling McGowan
- * Short statement of my expertise in the topic of the Task Force:

Dr. Bhakta has served as the Director of Education of the Adult Pulmonary Function Lab at the University of California San Francisco Medical Center since 2016. He has demonstrated the ability to lead a multidisciplinary team of physicians, technicians, clerical staff and IT professionals in the development of new reports, improved application of prediction equations, and an automated script to improve physician interpretation. He has succeeded in numerous efforts to improve patient safety, reduce unnecessary testing, and improve the readability and quality of PFT reports. He is co-auhtoring two upcoming book chapters on pulmonary function testing in the 7th edition of Murry and Nadel's Textbook of Respiratory Medicine, one of the world's major textbook on respiratory medicine. He has co-authored two articles on new spirometry indices in COPD. He has had national and international collaborations that have led to publications on mechanisms and phenotyping of airway inflammation in asthma. Dr. Bhakta directs a weekly pulmonary physiology series for first-year pulmonary fellows, leads educational sessions for the technicans in the lab, and led the development of a new curriculum for fellows in the lab including an in depth module on lung volumes covering the clinical rationale for measurement, the physiologic basis of the techiques, technical procedures, and guidance on interpretation. He has been a member of the ATS Proficiency Standards for Pulmonary Function Laboratories Committee since 2019. He has a BS (electrical engineering), MD, and PhD (molecular and cellular physiology). Although Dr. Bhakta is junior compared to many past chairs for similar documents, senior members of the writing committee, such as Dr. Kaminksy, Dr. McCormack and Dr. Coates, will be closely involved and provide leadership support on the ATS side.

Ms. Mcgowan is experienced in Respiratory Physiology and Medical physics. She is the manager of Lung function and Sleep diagnostics at Connolly Hospital. She has been involved in research for 30 years and is an academic Lecturer at Technological University Dublin (TUDublin) and RCSI Dublin. She is passionate about delivery of high quality service. She was on the ERS Spirometry education committee member for 5 years, was the driving force behind the bodybox-workshops at ERS congress in 2018, and is currently chair of ERS Group 9.1 (lung function technologists and scientists). She is an ERS spirometry interpretation skills workshop faculty member. She developed and coordinated recent ERS skills workshops at Congress (Body plethysmpography (2018) and Diffusing capacity (2019)). Ms. McGowan is a Committee member of The Irish Institute of Clinical Measurement Science and the Irish Sleep society. Her current research collaboration as a PhD candidate is with Heart and lung Institute /Imperial college London on lung physiology and airway microbiome.

3. General Disclosure of Conflicts of Interests

* I understand that the intent of this disclosure is not to prevent a Task Force member or chair with a significant financial or other relationship from participating in Task Force, but rather to provide other members with information on which they can make their own judgments. It remains for the other Task Force member and chairs to determine whether my interests or relationships may influence my participation in the project. The ERS does not view the existence of these interests or commitments as necessarily implying bias or decreasing the value of the Task Force member/chair's participation.

Yes, I have the following, real or perceived conflicts of interest that relate to this Task Force. I understand that I have to disclose them to the other Task Force members during the first meeting or teleconference.

If Yes, please list below:

As noted in COI forms attached for everyone, five members (neither of the above chairs are in this group of five) have reported conflicts of interest: 1) related to teaching, consultant or advisory roles for pulmonary function equipment manufacturers (MedGraphics and Vitalograph), 2) having equipment loaned from pulmonary function equipment manufacturers (NDD), or 3) a pharmaceutical company (one member). Per the guidance on the COI form—"I understand that I have to disclose them to the other Task Force members during the first meeting or teleconference."—we will require the members to disclose these verbally on the first teleconference as well as at every face-to-face meeting.

4. Confidentiality Agreement

* The ERS requests that all information related to the conent and development of a Task Force is kept strictly confidential until completion of the reviewing of its Final Document. Task Force Chairs and Members are requested to complete the Confidentiality Agreement within four weeks after acceptance of the project by the ERS Sciense Concil and Executive Committee. The Confidentiality Agreement remains effective until completion of the Final Document's reviewing. A notification is sent by the ERS Office to the Task Force Chairs once the Confidentiality Agreement no longer applies.

I agree and understand that I am not allowed to disclosed any infomation I obtaion as Task Force member to any third party not directly involved

5. Tobacco Industry-related Conflicts of Interests

- ERS does not accept faculty who are receiving funding from the tobacco industry.
- In the case of disclosure of a conflict of interest any time after 1/1/2000 by the person concerned, there is a 5-year ban from the date of disclosure before that person is allowed to participate actively in an ERS activity.
- Where a conflict of interest is discovered and not disclosed, there is a ban for life from participating in any ERS activity. The same ban applies to any undisclosed other real or perceived, direct or indirect links with the tobacco industry, such as the holding of shares, speaking at or attending meetings organised by the tobacco industry.
- Where any person is found to be maintaining a relationship with, or receiving funding from, the tobacco industry after 1/1/2013 there will be a ban for life from involvement in any ERS activity.

* Please select what applies to you:

I declare that I have had NO relationship of any kind with the tobacco industry (since 1/1/2000), nor will have a link to the tobacco industry before the event to which I have been invited by the ERS to participate in.

ERS CONFLICT OF INTEREST SUBMISSION

ERS requests that 50% of the taskforce project participants submit the above conflict of interest form with submission. Please find ERS COI form on ATS project application website and have each project participant fill out https://www.thoracic.org/members/assemblies/about/assembly-project-application-resource-center.php and submit below.

* Submission for project participants: (please merge all files into one file) [COI_Combined_RevisedWithSkloot.pdf]

SECTION XI - Chair Acknowledgement

Submission of application constitutes Electronic signature. Electronic Signatures are considered binding.

SECTION XII - Revising Application After Reviewer Feedback

Please do not complete until Planning Committee reviews are received.

Choose one of the following:

I have revised application based on reviewer feedback

* Revision - Tell us what revisions have been made and how reviews from planning committees were addressesd

Feedback from Miriam Rodriguez: Please remove publications costs if approved you will not publish in the first year. You can ask for publications costs in year 2.

Response: Thank you for catching this. We have removed publication costs from the budget and will request funds for publications and other activities in the second year.

Feedback from Thomy Tonia: Comments from the ERS Methodologist: My only comment is about the medical librarian: it is good that you budget for the services of a medical librarian, as this is essential to make sure that the literature searches are of good quality. I do not understand, however, why you mention that you will take the advise of the librarian but it will not be him/her who will conduct the searches but the Chairs. Why?

Response: We have revised the proposal to more clearly explain our use of the medical librarian. We are using an approach that has worked in former projects. The librarian will build the search strategy by organizing searches by topic, using standardized keywords and cross-referencing, and will also pull the full-text of papers which is important given that not all members have access to all journals at their local institutions. However, the committee members will execute the search and review the titles/abstracts because their clinical and scientific expertise is necessary to decide what is relevant from the output. Here is an excerpt from a meeting of the Interpretation Standards Technical Statement Update committee at ATS in May 2019 related to the medical librarian (Kelley):*The Task Force has been approved to have a medical librarian help with our literature searches. Kelley has our initial search terms and will work to focus and refine these. It was decided that the search strategies for working groups 3 and 4, and 5 and 6 could be combined into two searches as there was a lot of overlap in search terms. Working group 1 will* Feedback from Valerie Vaccaro: Thank you very much for your ERS/ATS task force application. As per usual procedure, an administrative check has been made by the ERS Office. I only have some comments on the budget requested to the ERS:According to the ERS rules, for meetings at the ERS and ATS Congresses, funding can be requested for panellists not working in the respiratory field, who will travel to the Congress only to attend the task force meeting, but not the rest of the event. It usually concerns only 1 or 2 task force members. For these people, you may request funds:for travel (600€ for flights within EU; 1000€ for overseas flights), for accommodation (1 or 2 nights; 150€ per night), for catering ("# of working days" in the application form; 50€ per day). In order to fit the rules, I encourage you to reduce the number of travel and accommodation night requested to a maximum of 4-5 members (you currently requested travel support for 5 people and accommodation for 8). It is anticipated that most of the members on ERS side who are not physicians. Although it will be asking a lot for them to pay for travel to the ATS, we want to abide by the rules. Furthermore, some members may not attend so it will likely work out fine. We have reduced the budget by requesting travel and accommodation funds for only 5 ERS members.

Finally, kindly note that the fund for the third meeting can be entered in the box "Meeting 3" instead than under "other ERS/ATS costs".

Response: In the revised application, upon reconsideration of the timeline given other feedback, we no longer have a third meeting.

Feedback from Connie Hsia (Feedback from Planning Committee, RSF Assembly): There was lively discussion with a mix of opinions. All agree that the proposal is well conceived and important to the mission of the RSF Assembly and the ATS community. Good balance of expertise among members. An update is considered timely — particularly the inclusion of newer techniques and this proposal being part of an essential part of the broader update of the 2005 ATS/ERS pulmonary function standards. Gaps in the 2005 document have been identified. The proposed committee members are accomplished and the co-chairs, although relatively junior, have experience in the field and strong support from senior members. There is good representation of international members and allied health professionals. A strong positive is that patient experiences will be taken into account. **Thank you for the support and positive feedback.**

Additional comments below are abstracted for consideration in the revision: It would help to state what major changes or advances in lung volume measurement have taken place that will actually affect clinical practice.

Response: As the proposal is for a technical standards document, we did not want to expand the scope into clinical use and interpretation. However, we agree that we can better motivate the need for an update by highlighting how specific technical advances may affect clinical practice. We have revised the application to highlight how 1) new knowledge on the equivalence between

choices of TLC computation will give more flexibility to technologists to obtain lung volumes in challenging populations such as those with airflow obstruction or obesity; 2) better guidance on proper technique in children will lead to improved results; and 3) guidance on repeatability will help interpret the bronchodilator response in lung volumes for which there is growing clinical interest in asthma and COPD.

In the goals and objectives of the proposal and the updated report, the authors could include a brief statement on new basic research on why lung volume is unique, different, and mechanistically valuable to the determination of lung function (what this measurement can provide that other in vivo metrics cannot). This goes beyond new methods and new target populations. A brief "basic science" overview should add immense value to an updated report.

Response: We appreciate the opportunity to comment on why lung volumes are important, especially as their value has been debated (e.g. PRO: Ruppel GL, "What is the clinical value of lung volumes?", 2012 *Respiratory Carevs* CON: Enright P "Spirometer + Body Box = VW Beetle + Mercedes?", 2011 *Respiratory Care*). We acknowledge that this is not a clinical review, but a technical statement, and therefore have revised the proposal as suggested with a brief paragraph pointing out the most relevant new basic work. This work includes the importance of lung volumes in understanding the effect of obesity on airflow obstruction and response to bronchodilator, the value of lung volumes in identifying people at risk for COPD but without obstruction on spirometry by the usual metrics, and the effect of hyperinflation on FEV1 in asthma.

While it is stated that a formal systematic review is not planned, the methodology for weighting and integrating the evidence and/or differing expert opinions was not clear. How will literature will be graded for selection and inclusion in the update? Perhaps a trained methodologist is needed. What role will a medical librarian play given that the participants will perform the literature searches? Response: As this is a technical statement rather than a clinical guideline, a trained methodologist is not needed. In this ATS Committee's previous correspondence with Kevin Wilson (ATS Chief, Documents & Patient Education), he wrote "A methodologist is only necessary for guidelines. Thus, I don't think you will need one, unless I am misunderstanding the document type that best meets your goals...it seems to be that a technical statement is the most appropriate document type because it will contain "how to" content. Guidelines are intended to make recommendations about who to treat, which treatment to use, who to test, or which diagnostic test to use. I don't know any methodologists who are comfortable with the type of systematic review that would be conducted for a technical standard (systematic reviews are neither required nor expected for technical statements) and this work is outside the scope of the guideline methodology training program..." As described in response to feedback above, the librarian will optimize the searches, but a small number of working groups composed of subsets

of the members, will use their clinical and scientific expertise to determine the relevance and utility of individual results. These results will be tabulated on a spreadsheet to share with the entire committee. The application has been revised to clarify this.

Some questioned the relevance of CT to the update of technical standards for pulmonary function testing, because imaging modalities are not generally performed in the point-of-care assessment of lung volumes. Others thought that lung volume measurement will change radically because of low dose high speed CT and automated algorithms, and current guidelines do not recognize this development. It will be useful to clearly state your argument for the inclusion of CT.

Response: Thank you for sharing this discussion. We agree that CT imaging is not a standard PFT, but a small section on imaging was included in the 2005 standards. Therefore, because the proposal is for an update to that document, we want to provide an update on the science in this area. Specifically, we have revised the application to call out the studies that have reported improved methods of CT quantification of lung volumes, as well as the value of CT lung volumes in studies on COPD, IPF, and chest trauma.

Also unclear is how patient survey will be designed, implemented, and how the data/feedback would be used. State when patient survey and their input will be available.

Response: We described our approach to the survey in section II-I and added this text for more detail in the revised application: "As we did for the spirometry document, the survey will be designed by the committee after a number of recursive reviews, implemented by sending it out by email through the European Lung Foundation, with data analyzed by a statistician from the ELF and the results used by the committee to create a section in the document on patient feedback about their experience with the test." The availability of the data was described in the timeline, which we have modified based on other reviewer feedback. In support of the likelihood of success with this approach, for the spirometry standards update we ended up with 1760 completed surveys from 52 countries. Given the need to also get input from the patient community served by the ATS, we have also now engaged with the ATS Patient and Family Education Committee to facilitate input from that group.

For pediatric plethysmography standards, the Assembly on Pediatrics should be consulted and included in the review of the document. We think this is very appropriate. I am writing to get the Assembly on Pediatric's support for the proposal.

Response: We agree that issues specific to measurement of lung volumes in children have been under-addressed, and included this in the initial proposal. We have four pediatric pulmonologists and/or physiologists as part of our 17 members (9 ATS, 8 ERS): Graham Hall, Allan Coates, Jane Kirby, and Kathryn Ramsey. Based on this feedback, we reached out to Paul Moore, Chair of the Assembly on Pediatrics and his response, was "Thanks for your email, and I'm happy to confirm the support and anticipated review of the Peds Assembly. I've cc'ed Erick Forno (Peds Planning Committee Chair) on this email, and I'm grateful for the contributions of Graham, Allan, Jane, and Kathryn." Erick Forno responded with "we are happy to support the project and eventually help review the document."

Timeline is vague and needs more detail to increase confidence that objectives can be met. More details about the schedule, agenda, and organization of the two face-to-face meetings and the monthly teleconferences. Specify how the working groups will guide the organization of the meetings and the preparation of the document.

Response: The timeline has been revised to reflect the process more clearly. The application has also been revised to include more detail on the meetings and working groups. The early teleconferences will review the results of gaps identification and literature searches from the smaller working groups, formed by the chairs. The working groups will triage the articles (relevant, somewhat relevant and not relevant) as soon as the searches are finalized. The primary goal of the first face-to-face meeting at ATS 2020 is to develop a strategy for document development, delegating tasks to working groups. Subsequent teleconferences will allow for collective input on the progress and open questions that individual working groups and sections of the document face.

Only 33% of members are women. It would be ideal to increase female representation.

Response: Thank you for this comment. We agree we should aim for a more equal percentage. In response to this feedback, we invited three women. Two declined due to other obligations. Fortunately, we have a yes from Dr. Gwen Skloot from Mount Sinai, an expert in pulmonary function testing and physiology. We also recognize that our ability to significantly change the percentage is somewhat limited now as we should not increase the committee size by too many members due to difficulty coordinating such a large group and the budget implications, and that it is unfair to ask some of the men on the committee to leave.

Consider expanding the group to also include expertise from the Asia Pacific Society of Respirology to ensure coverage of diverse demographic patient groups.

Response: This is a great suggestion. Given our concern about the budget implications of adding more members and the next steps of considering societies from other continents, we made an inquiry to Kevin Wilson (ATS Chief, Documents & Patient Education). He responded: "Is there anything special about the Asian ethnicity that would warrant their representation? If not, then I would either a) leave your panel as is or b) add APSR, ALAT, and TSANZ representatives to cover an additional three continents. That said, you don't need to decide now. The ATS policy is that collaboration with other societies (other than with ERS through an ATS/ERS application) requires approval by the Documents Committee after a project has been approved." There are no specific issues related to Asian ethnicity in terms of making lung volume measurements (interpretation and choice of reference of values is outside the scope of our document), but we will consider based upon gaps identified and the results of literature searches whether these collaborations are needed.

It is unclear whether the writing committee is exclusively composed by the co-chairs.

Response: We have revised the proposal to clarify the writing. We will break up into smaller groups that will each contribute, with chairs guiding the overall direction and writing.

It is not clear why so many face-to-face meetings are needed. Format and goals for the ATS and ERS meetings are not clear. The two meetings are only 3.5 months apart. There is little justification for the "optional live meeting ATS in 2021".Budget is high.

Response: In the revised proposal, we have given additional detail on goals of the first face-toface meeting at ATS. Therefore, after careful consideration of the fairness of travel between ATS and ERS members, we have removed the meeting at ERS. We agree that the 3.5 month interval between ATS and ERS in 2020 is short. We have also removed the optional live meeting at ATS 2021, and will only request that in the second year if necessary. Based on prior experience of committee members on projects such as this one, a second face-to-face meeting is necessary sometimes. These changes have brought the budget down.

Management/resolution of COI should be discussed.

Response: We have followed ATS guidelines on this. Five members (neither of the above chairs are in this group of five) have reported conflicts of interest: 1) related to teaching, consultant or advisory roles for pulmonary function equipment manufacturers (MedGraphics and Vitalograph), 2) having equipment loaned from pulmonary function equipment manufacturers (NDD), or 3) a pharmaceutical company (one member). Per the guidance on the COI form—"I understand that I have to disclose them to the other Task Force members during the first meeting or teleconference."—we will require the members to disclose these verbally on the first teleconference as well as at every face-to-face meeting. Also, we have now clicked "Yes" in section X-3 (previously we thought this referred to the chairs only), and there added the above COI management text to the proposal.

DDIC:Given the scope of the document, the timeline may be ambitious- for example document preparation is 3-4 months. Timeline is a little ambiguous- gaps in literature will be identified at the same time as literature review is being performed. More details on who will do screening of abstracts and full texts needs to be provided- for example the co-chairs will do it or it will be delegated among more members.

Response: We have revised the timeline to make it clearer that we are giving ourselves six months (May to November 2020) for development of the first draft of the document. We have also removed the overlap in identification of gaps and literature review. As noted in the responses above, we have also revised the proposal to provide more details on how the searches and screening of abstracts and full text will be delegated by the chairs to smaller working groups. The working groups will be defined in part by topics that follow the outline of the previous document and will include method-independent topics (e.g. computations, predicted values including GLI, repeatability, pediatrics), body plethysmography, multiple-breath techniques, and imaging modalities. Each working group may be assigned more than one topic.

Budget seems excessive- for non-clinical practice guideline documents, ATS will cover only one face to face meeting besides teleconference and publication costs.

Response: We have revised the proposal as noted above to remove the third face-to-face meeting. This change will reduce the budget.

In addition, librarian costs are generally not covered for non-clinical practice guideline documents. Response: As noted above, based on feedback on prior now-funded proposals from the ATS Proficiency Standards Committee, our experience which has found the skills of a medical librarian valuable to achieve the aims, and guidance from Kevin Wilson (ATS Chief, Documents & Patient Education), we think a medical librarian is necessary and should be covered.

* Can we share your application with ATS members if it is deemed a model application by the Program Review Subcommittee (PRS)? Yes

ATS/ERS GRAND TOTAL BUDGET SUMMARY CHART

	Neutral	ATS	ERS
Meeting 1 budget		\$6900	€ 6000
Meeting 2 budget		\$	€
Meeting 3 budget		\$	€
Meeting 4 budget		\$	€
ATS Publication Costs (\$475.00 Per Page)			
 Policy Statement – 8 Pages Max 			
Conference Proceedings & Workshops – 8 Pages Max		Ş0	N/A
 Technology Reviews & Standards 8 Pages Max 			
 Guidelines & Recommendations – 15 Pages Max 			
Medical Librarian – This item requires approval and justifications from document		\$5000	Ν/Δ
development staff (up to \$5000)	Y	\$3000	
Staff/Administrative Methodological Support (non-ERS)		N/A	€0
Staff/Administrative Support (non-ERS)		N/A	€0
ERS Technical needs		N/A	€0
ATS/ERS Conference Calls	61520		
(# of people x # minutes x 0.10)	\$1530		
Other ATS/ERS Cost	\$0		i.
Grand Total Budget:	\$1530	\$11900	€ 6000